

ניהול מערכות מידע תעשייתיות

קבלת החלטות בהקמת מערכת
מידע תעשייתית

Criteria of Decision Making
Process with Industrials
Information Systems

MES מערכות

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Manufacturing execution systems (MES) are computerized systems used in manufacturing, to track and document the transformation of raw materials to finished goods. MES can provide the right information at the right time and show the manufacturing decision maker "how the current conditions on the plant floor can be optimized to improve production output."^[1] MES work in real time to enable the control of multiple elements of the production process (e.g. inputs, personnel, machines and support services).

MES may operate across multiple function areas, for example: management of product definitions across the product life-cycle, resource scheduling, order execution and dispatch, production analysis and downtime management for Overall Equipment Effectiveness (OEE), Product Quality, or materials track and trace. MES creates the "as-built" record, capturing the data, processes and outcomes of the manufacturing process. This can be especially important in regulated industries, such as food and beverage or pharmaceutical, where documentation and proof of processes, events and actions may be required.

The idea of MES might be seen as an intermediate step between, on the one hand, an Enterprise Resource Planning (ERP) system, and a Supervisory Control and Data Acquisition (SCADA) or process control system on the other; although historically, exact boundaries have fluctuated. Industry groups such as MESA International-- Manufacturing Enterprise Solutions Association were created in the early 1990's in order to address the complexity, and advice on execution, of MES Systems.

Benefits

"Manufacturing Execution Systems [help] create flawless manufacturing processes and provide real-time feedback of requirement changes,"^[2] and provide information at a single source.^[3] Other benefits from successful MES implementation might include:

1. Reduced waste, re-work and scrap, including quicker setup times
2. More accurate capture of cost-information (e.g. labor, scrap, downtime, and tooling)
3. Increased uptime
4. Incorporate Paperless Workflow Activities
5. Reduced inventory, through the eradication of just-in-case inventory^[4]

MES

A wide variety of systems arose using collected data for a dedicated purpose. Further development of these systems during the 1990s introduced overlap in functionality. Then the Manufacturing Enterprise Solutions Association (MESA) introduced some structure by defining 11 functions that set the scope of MES. In 2000, the ANSI/ISA-95 standard merged this model with the Purdue Reference Model (PRM).^[5]

A functional hierarchy was defined in which MES were situated at Level 3 between ERP at Level 4 and process control at Levels 0, 1, 2. With the publication of the third part of the standard in 2005, activities in Level 3 were divided over four main operations: production, quality, logistics and maintenance.

Between 2005 and 2013, additional or revised parts of the ANSI/ISA-95 standard defined the architecture of an MES into more detail, covering how to internally distribute functionality and what information to exchange internally as well as externally. ^[citation needed]

Functional areas

Over the years, international standards and models have refined the scope of such systems in terms of activities^[citation needed]. These typically include:

- Management of product definitions. This may include storage, version control and exchange with other systems of master data like product production rules, bill of material, bill of resources, process set points and recipe data all focused on defining how to make a product. Management of product definitions can be part of Product lifecycle management.
- Management of resources. This may include registration, exchange and analysis of resource information, aiming to prepare and execute production orders with resources of the right capabilities and availability.
- Scheduling (production processes). These activities determine the production schedule as a collection of work orders to meet the production requirements, typically received from Enterprise resource planning or specialized Advanced planning and scheduling systems, making optimal use of local resources.
- Dispatching production orders. Depending on the type of production processes this may include further distribution of batches, runs and work orders, issuing these to work centers and adjustment to unanticipated conditions.
- Execution of production orders. Although actual execution is done by Process control systems, an MES may perform checks on resources and inform other systems about the progress of production processes.
- Collection of production data. This includes collection, storage and exchange of process data, equipment status, material lot information and production logs in either a data historian or relational database.
- Production performance analysis. Create useful information out of the raw collected data about the current status of production, like Work In Progress (WIP) overviews, and the production performance of the past period like the Overall Equipment Effectiveness or any other Performance indicator.
- Production Track & Trace. Registration and retrieval of related information in order to present a complete history of lots, orders or equipment (particularly important in health related productions, e.g. pharmaceuticals).
- The Digitizing of the complete data from the log books into the web/tablet interface with the edit lock feature and also pulling the data from the SCADA into the common databank.
- The Audit Interface which helps in the evaluation of the utility performance like the direct / indirect efficiency of the boiler in the runtime, cooling tower effectiveness in the runtime which is possible only if we are able integrate the complete data from the log books and the SCADA System.

Relationship with other Enterprise systems

MES integrates with ISA-95 (previous Purdue Reference Model, “95”) with multiple relationships.

Relationship with other Level 3 systems

The collection of systems acting on the ISA-95 Level 3 can be called Manufacturing Operations Management Systems (MOMS). Apart from an MES these are typically Laboratory Information Management System (LIMS), Warehouse Management System (WMS) and computerized maintenance management system (CMMS). From the MES point of view possible information flows are:

- To LIMS: quality test requests, sample lots, statistical process data
- From LIMS: quality test results, product certificates, testing progress
- To WMS: material resource requests, material definitions, product deliveries
- From WMS: material availability, staged material lots, product shipments
- To CMMS: equipment running data, equipment assignments, maintenance requests
- From CMMS: maintenance progress, equipment capabilities, maintenance schedule

Relationship with Level 4 systems

Examples of systems acting on ISA-95 Level 4 are Product Lifecycle Management (PLM), Enterprise Resource Planning (ERP), Customer Relationship Management (CRM), Human Resource Management (HRM), Process Development Execution System (PDES). From the MES point of view possible information flows are:

- To PLM: production test results
- From PLM: product definitions, bill of operations (routings), electronic work instructions, equipment settings
- To ERP: production performance results, produced and consumed material
- From ERP: production planning, order requirements
- To CRM: product tracking and tracing information
- From CRM: product complaints
- To HRM: personnel performance
- From HRM: personnel skills, personnel availability
- To PDES: production test and execution results
- From PDES: manufacturing flow definitions, Design of Experiments (DoE) definitions

In many cases, Middleware Enterprise Application Integration (EAI) systems are being used to exchange transaction messages between MES and Level 4 systems. A common data definition, B2MML, has been defined within the ISA-95 standard to link MES systems to these Level 4 systems.

Relationship with Level 0, 1, 2 systems

Systems acting on ISA-95 Level 2 are Supervisory Control And Data Acquisition (SCADA), Programmable Logic Controllers (PLC), Distributed Control Systems

(DCS) and Batch Automation Systems. Information flows between MES and these process control systems are roughly similar:

- To PLCs: work instructions, recipes, set points
- From PLCs: process values, alarms, adjusted set points, production results

Most MES systems include connectivity as part of their product offering. Direct communication of plant floor equipment data is established by connecting to the Programmable Logic Controllers (PLC). Often, plant floor data is first collected and diagnosed for real-time control in a Distributed Control System (DCS) or Supervisory Control and Data Acquisition (SCADA) system. In this case, the MES systems connect to these Level 2 systems for exchanging plant floor data.

The industry standard for plant floor connectivity is OLE for Process Control (OPC).

Manufacturing

Manufacturing is the production of merchandise for use or sale using labour and machines, tools, chemical and biological processing, or formulation. The term may refer to a range of human activity, from handicraft to high tech, but is most commonly applied to industrial production, in which raw materials are transformed into finished goods on a large scale. Such finished goods may be used for manufacturing other, more complex products, such as aircraft, household appliances or automobiles, or sold to wholesalers, who in turn sell them to retailers, who then sell them to end users and consumers.

Manufacturing takes turns under all types of economic systems. In a free market economy, manufacturing is usually directed toward the mass production of products for sale to consumers at a profit. In a collectivist economy, manufacturing is more frequently directed by the state to supply a centrally planned economy. In mixed market economies, manufacturing occurs under some degree of government regulation.

Modern manufacturing includes all intermediate processes required for the production and integration of a product's components. Some industries, such as semiconductor and steel manufacturers use the term *fabrication* instead.

The manufacturing sector is closely connected with engineering and industrial design. Examples of major manufacturers in North America include General Motors Corporation, General Electric, Procter & Gamble, General Dynamics, Boeing, Pfizer, and Precision Castparts. Examples in Europe include Volkswagen Group, Siemens, and Michelin. Examples in Asia include Sony, Huawei, Lenovo, Toyota, Samsung, and Bridgestone.

History and development

- In its earliest form, manufacturing was usually carried out by a single skilled artisan with assistants. Training was by apprenticeship. In much of the pre-

industrial world, the guild system protected the privileges and trade secrets of urban artisans.

- Before the Industrial Revolution, most manufacturing occurred in rural areas, where household-based manufacturing served as a supplemental subsistence strategy to agriculture (and continues to do so in places). Entrepreneurs organized a number of manufacturing households into a single enterprise through the putting-out system.
- Toll manufacturing is an arrangement whereby a first firm with specialized equipment processes raw materials or semi-finished goods for a second firm.

Manufacturing systems: changes in methods of manufacturing

- Craft or guild system
- Agile manufacturing
- American system of manufacturing
- English system of manufacturing
- Fabrication
- Flexible manufacturing
- Just-in-time manufacturing
- Lean manufacturing
- Mass customization (2000s) - 3D printing, design-your-own web sites for sneakers, clothing
- Mass production
- Ownership
- Packaging and labeling
- Prefabrication
- Putting-out system
- Rapid manufacturing
- Reconfigurable manufacturing system
- Soviet collectivism in manufacturing

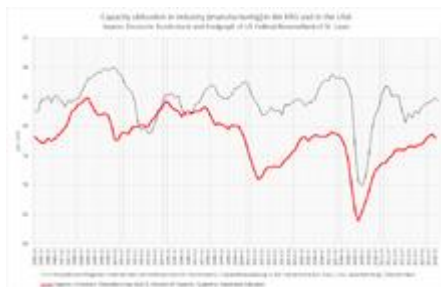
Economics of manufacturing

According to some economists, manufacturing is a wealth-producing sector of an economy, whereas a service sector tends to be wealth-consuming.^{[1][2]} Emerging technologies have provided some new growth in advanced manufacturing employment opportunities in the Manufacturing Belt in the United States. Manufacturing provides important material support for national infrastructure and for national defense.

On the other hand, most manufacturing may involve significant social and environmental costs. The clean-up costs of hazardous waste, for example, may outweigh the benefits of a product that creates it. Hazardous materials may expose workers to health risks. These costs are now well known and there is effort to address them by improving efficiency, reducing waste, using industrial symbiosis, and eliminating harmful chemicals.^[3] The increased use of technologies such as 3D printing also offer the potential to reduce the environmental impact of producing finished goods through distributed manufacturing.^[4]

The negative costs of manufacturing can also be addressed legally. Developed countries regulate manufacturing activity with labor laws and environmental laws. Across the globe, manufacturers can be subject to regulations and pollution taxes to offset the environmental costs of manufacturing activities. Labor unions and craft guilds have played a historic role in the negotiation of worker rights and wages. Environment laws and labor protections that are available in developed nations may not be available in the third world. Tort law and product liability impose additional costs on manufacturing. These are significant dynamics in the ongoing process, occurring over the last few decades, of manufacture-based industries relocating operations to "developing-world" economies where the costs of production are significantly lower than in "developed-world" economies.

Manufacturing and investment



Capacity utilization in manufacturing in the FRG and in the USA

Surveys and analyses of trends and issues in manufacturing and investment around the world focus on such things as:

- the nature and sources of the considerable variations that occur cross-nationally in levels of manufacturing and wider industrial-economic growth;
- competitiveness; and
- attractiveness to foreign direct.

In addition to general overviews, researchers have examined the features and factors affecting particular key aspects of manufacturing development. They have compared production and investment in a range of Western and non-Western countries and presented case studies of growth and performance in important individual industries and market-economic sectors.^{[5][6]}

On June 26, 2009, Jeff Immelt, the CEO of General Electric, called for the United States to increase its manufacturing base employment to 20% of the workforce, commenting that the U.S. has outsourced too much in some areas and can no longer rely on the financial sector and consumer spending to drive demand.^[7] Further, while U.S. manufacturing performs well compared to the rest of the U.S. economy, research shows that it performs poorly compared to manufacturing in other high-wage countries.^[8] A total of 3.2 million – one in six U.S. manufacturing jobs – have disappeared between 2000 and 2007.^[9] In the UK, EEF the manufacturers' organization has led calls for the UK economy to be rebalanced to rely less on financial services and has actively promoted the manufacturing agenda.

Countries by manufacturing output using the most recent known data

Data is provided by [World bank](#).^{[10][11]} It shows the total value of manufacturing in US dollars for its noted year.

Rank	Country/Region	(Millions of \$US)	Year
	<u>World</u>	11,917,240	2013
1	 <u>China</u>	2,922,520	2013
	 <u>European Union</u>	2,312,723	2013
2	 <u>United States</u>	1,943,810	2013
	 <u>Eurozone</u>	1,793,895	2013
3	 <u>Japan</u>	904,590	2013
4	 <u>Germany</u>	771,183	2014
5	 <u>South Korea</u>	389,581	2014
6	 <u>India</u>	325,246	2014
7	 <u>Italy</u>	299,017	2014
8	 <u>France</u>	283,663	2014
9	 <u>Russia</u>	267,591	2013
10	 <u>United Kingdom</u>	246,900	2014
11	 <u>Brazil</u>	218,802	2014
12	 <u>Mexico</u>	216,066	2014
13	 <u>Indonesia</u>	186,743	2014
14	 <u>Spain</u>	168,995	2014
15	 <u>Canada</u>	162,074	2014
16	 <u>Turkey</u>	126,344	2014
17	 <u>Switzerland</u>	123,855	2013
18	 <u>Thailand</u>	121,677	2014
19	 <u>Netherlands</u>	96,953	2014
20	 <u>Australia</u>	92,768	2014

Product lifecycle



A generic lifecycle of products

In industry, **product lifecycle management (PLM)** is the process of managing the entire lifecycle of a product from inception, through engineering design and manufacture, to service and disposal of manufactured products.^{[1][2]} PLM integrates people, data, processes and business systems and provides a product information backbone for companies and their extended enterprise.^[3]

History

The inspiration for the burgeoning business process now known as PLM came from American Motors Corporation (AMC).^[4] The automaker was looking for a way to speed up its product development process to compete better against its larger competitors in 1985, according to François Castaing, Vice President for Product Engineering and Development.^[5] After introducing its compact Jeep Cherokee (XJ), the vehicle that launched the modern sport utility vehicle (SUV) market, AMC began development of a new model, that later came out as the Jeep Grand Cherokee. The first part in its quest for faster product development was computer-aided design (CAD) software system that make engineers more productive.^[5] The second part in this effort was the new communication system that allowed conflicts to be resolved faster, as well as reducing costly engineering changes because all drawings and documents were in a central database.^[5] The product data management was so effective that after AMC was purchased by Chrysler, the system was expanded throughout the enterprise connecting everyone involved in designing and building products.^[5] While an early adopter of PLM technology, Chrysler was able to become the auto industry's lowest-cost producer, recording development costs that were half of the industry average by the mid-1990s.^[5]

1982 - 1983 Rockwell Int'l developed initial concepts of PDM and PLM for the B-1B bomber program. A system called Engineering Data System (EDS) was augmented to interface with Computervision and CADAM systems to track part configurations and lifecycle of components and assemblies. A white paper on this topic was presented during those years at a Computervision User's Group meeting in San Diego. Shortly after Computervision released its system implementing only the PDM aspects as the lifecycle model was specific to Rockwell and Aerospace needs.

PLM systems help organizations in coping with the increasing complexity and engineering challenges of developing new products for the global competitive markets.^[6]

Product lifecycle management (PLM) should be distinguished from 'product life-cycle management (marketing)' (PLCM). PLM describes the engineering aspect of a product, from managing descriptions and properties of a product through its development and useful life; whereas, PLCM refers to the commercial management of life of a product in the business market with respect to costs and sales measures.

Product lifecycle management can be considered one of the four cornerstones of a manufacturing corporation's information technology structure.^[7] All companies need to manage communications and information with their customers (CRM-customer relationship management), their suppliers and fulfillment (SCM-supply chain), their resources within the enterprise (ERP-enterprise resource planning) and their product planning and development (PLM).

One form of PLM is called people-centric PLM. While traditional PLM tools have been deployed only on release or during the release phase, people-centric PLM targets the design phase.

As of 2009, ICT development (EU-funded PROMISE project 2004–2008) has allowed PLM to extend beyond traditional PLM and integrate sensor data and real time 'lifecycle event data' into PLM, as well as allowing this information to be made available to different players in the total lifecycle of an individual product (closing the information loop). This has resulted in the extension of PLM into closed-loop lifecycle management (CL₂M).

Benefits

Documented benefits of product lifecycle management include:

- Reduced time to market
- Increase full price sales
- Improved product quality and reliability
- Reduced prototyping costs
- More accurate and timely request for quote generation
- Ability to quickly identify potential sales opportunities and revenue contributions
- Savings through the re-use of original data
- A framework for product optimization
- Reduced waste
- Savings through the complete integration of engineering workflows
- Documentation that can assist in proving compliance for RoHS or Title 21 CFR Part 11
- Ability to provide contract manufacturers with access to a centralized product record
- Seasonal fluctuation management
- Improved forecasting to reduce material costs

- Maximize supply chain collaboration

Areas of PLM

Within PLM there are five primary areas;

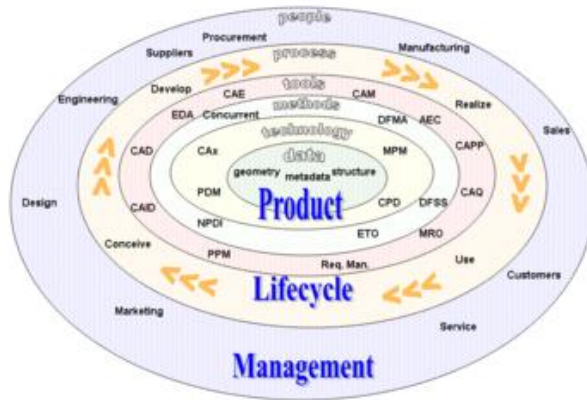
1. Systems engineering (SE)
2. Product and portfolio m² (PPM)
3. Product design (CAx)
4. Manufacturing process management (MPM)
5. Product data management (PDM)

Note: While application software is not required for PLM processes, the business complexity and rate of change requires organizations execute as rapidly as possible.

Systems engineering is focused on meeting all requirements, primary meeting customer needs, and coordinating the systems design process by involving all relevant disciplines. An important aspect for life cycle management is a subset within Systems Engineering called Reliability Engineering. Product and portfolio management is focused on managing resource allocation, tracking progress vs. plan for new product development projects that are in process (or in a holding status). Portfolio management is a tool that assists management in tracking progress on new products and making trade-off decisions when allocating scarce resources. Product design is the process of creating a new product to be sold by a business to its customers. Manufacturing process management is a collection of technologies and methods used to define how products are to be manufactured. Product data management is focused on capturing and maintaining information on products and/or services through their development and useful life. Change management is an important part of PDM/PLM.

Introduction to development process

The core of PLM (product lifecycle management) is in the creation and central management of all product data and the technology used to access this information and knowledge. PLM as a discipline emerged from tools such as CAD, CAM and PDM, but can be viewed as the integration of these tools with methods, people and the processes through all stages of a product's life.^[10] It is not just about software technology but is also a business strategy.^[11]



Product lifecycle management

For simplicity the stages described are shown in a traditional sequential engineering workflow. The exact order of event and tasks will vary according to the product and industry in question but the main processes are:^[12]

- Conceive
 - Specification
 - Concept design
- Design
 - Detailed design
 - Validation and analysis (simulation)
 - Tool design
- Realise
 - Plan manufacturing
 - Manufacture
 - Build/Assemble
 - Test (quality check)
- Service
 - Sell and deliver
 - Use
 - Maintain and support
 - Dispose

The major key point events are:

- Order
- Idea
- Kickoff
- Design freeze
- Launch

The reality is however more complex, people and departments cannot perform their tasks in isolation and one activity cannot simply finish and the next activity start. Design is an iterative process, often designs need to be modified due to manufacturing constraints or conflicting requirements. Where a customer order fits into the time line

depends on the industry type and whether the products are for example, built to order, engineered to order, or assembled to order.

Phases of product lifecycle and corresponding technologies

Many software solutions have been developed to organize and integrate the different phases of a product's lifecycle. PLM should not be seen as a single software product but a collection of software tools and working methods integrated together to address either single stages of the lifecycle or connect different tasks or manage the whole process. Some software providers cover the whole PLM range while others single niche application. Some applications can span many fields of PLM with different modules within the same data model. An overview of the fields within PLM is covered here. It should be noted however that the simple classifications do not always fit exactly, many areas overlap and many software products cover more than one area or do not fit easily into one category. It should also not be forgotten that one of the main goals of PLM is to collect knowledge that can be reused for other projects and to coordinate simultaneous concurrent development of many products. It is about business processes, people and methods as much as software application solutions. Although PLM is mainly associated with engineering tasks it also involves marketing activities such as product portfolio management (PPM), particularly with regards to new product development (NPD). There are several life-cycle models in industry to consider, but most are rather similar. What follows below is one possible life-cycle model; while it emphasizes hardware-oriented products, similar phases would describe any form of product or service, including non-technical or software-based products:^[13]

Phase 1: Conceive

Imagine, specify, plan, and innovate

The first stage is the definition of the product requirements based on customer, company, market and regulatory bodies' viewpoints. From this specification, the product's major technical parameters can be defined. In parallel, the initial concept design work is performed defining the aesthetics of the product together with its main functional aspects. Many different media are used for these processes, from pencil and paper to clay models to 3D CAID computer-aided industrial design software.

In some concepts, the investment of resources into research or analysis-of-options may be included in the conception phase – e.g. bringing the technology to a level of maturity sufficient to move to the next phase. However, life-cycle engineering is iterative. It is always possible that something doesn't work well in any phase enough to back up into a prior phase – perhaps all the way back to conception or research. There are many examples to draw from.

Phase 2: Design

Describe, define, develop, test, analyze and validate

This is where the detailed design and development of the product's form starts, progressing to prototype testing, through pilot release to full product launch. It can also involve redesign and ramp for improvement to existing products as well as planned obsolescence.^[14] The main tool used for design and development is CAD. This can be simple 2D drawing / drafting or 3D parametric feature based solid/surface modeling. Such software includes technology such as Hybrid Modeling, Reverse Engineering, KBE (knowledge-based engineering), NDT (Nondestructive testing), and Assembly construction.

This step covers many engineering disciplines including: mechanical, electrical, electronic, software (embedded), and domain-specific, such as architectural, aerospace, automotive, Along with the actual creation of geometry there is the analysis of the components and product assemblies. Simulation, validation and optimization tasks are carried out using CAE (computer-aided engineering) software either integrated in the CAD package or stand-alone. These are used to perform tasks such as:- Stress analysis, FEA (finite element analysis); kinematics; computational fluid dynamics (CFD); and mechanical event simulation (MES). CAQ (computer-aided quality) is used for tasks such as Dimensional tolerance (engineering) analysis. Another task performed at this stage is the sourcing of bought out components, possibly with the aid of procurement systems.

Phase 3: Realize

Manufacture, make, build, procure, produce, sell and deliver

Once the design of the product's components is complete the method of manufacturing is defined. This includes CAD tasks such as tool design; creation of CNC Machining instructions for the product's parts as well as tools to manufacture those parts, using integrated or separate CAM computer-aided manufacturing software. This will also involve analysis tools for process simulation for operations such as casting, molding, and die press forming. Once the manufacturing method has been identified CPM comes into play. This involves CAPE (computer-aided production engineering) or CAP/CAPP – (production planning) tools for carrying out factory, plant and facility layout and production simulation. For example: press-line simulation; and industrial ergonomics; as well as tool selection management. Once components are manufactured their geometrical form and size can be checked against the original CAD data with the use of computer-aided inspection equipment and software. Parallel to the engineering tasks, sales product configuration and marketing documentation work take place. This could include transferring engineering data (geometry and part list data) to a web based sales configurator and other desktop publishing systems.

Phase 4: Service

Use, operate, maintain, support, sustain, phase-out, retire, recycle and disposal]

The final phase of the lifecycle involves managing of in service information. Providing customers and service engineers with support information for repair and maintenance, as well as waste management/recycling information. This involves

using tools such as Maintenance, Repair and Operations Management (MRO) software.

There is an end-of-life to every product. Whether it be disposal or destruction of material objects or information, this needs to be considered since it may not be free from ramifications.

All phases: product lifecycle

Communicate, manage and collaborate

None of the above phases can be seen in isolation. In reality a project does not run sequentially or in isolation of other product development projects. Information is flowing between different people and systems. A major part of PLM is the co-ordination and management of product definition data. This includes managing engineering changes and release status of components; configuration product variations; document management; planning project resources and timescale and risk assessment.

For these tasks graphical, text and metadata such as product bills of materials (BOMs) needs to be managed. At the engineering departments level this is the domain of PDM – (product data management) software, at the corporate level EDM (enterprise data management) software, these two definitions tend to blur however but it is typical to see two or more data management systems within an organization. These systems are also linked to other corporate systems such as SCM, CRM, and ERP. Associated with these system are project management Systems for project/program planning.

This central role is covered by numerous collaborative product development tools which run throughout the whole lifecycle and across organizations. This requires many technology tools in the areas of conferencing, data sharing and data translation. The field being product visualization which includes technologies such as DMU (digital mock-up), immersive virtual digital prototyping (virtual reality), and photo-realistic imaging.

User skills

The broad array of solutions that make up the tools used within a PLM solution-set (e.g., CAD, CAM, CAx...) were initially used by dedicated practitioners who invested time and effort to gain the required skills. Designers and engineers worked wonders with CAD systems, manufacturing engineers became highly skilled CAM users while analysts, administrators and managers fully mastered their support technologies. However, achieving the full advantages of PLM requires the participation of many people of various skills from throughout an extended enterprise, each requiring the ability to access and operate on the inputs and output of other participants.

Despite the increased ease of use of PLM tools, cross-training all personnel on the entire PLM tool-set has not proven to be practical. Now, however, advances are being made to address ease of use for all participants within the PLM arena. One such advance is the availability of "role" specific user interfaces. Through tailorable user

interfaces (UIs), the commands that are presented to users are appropriate to their function and expertise.

These techniques include:-

- Concurrent engineering workflow
- Industrial design
- Bottom–up design
- Top–down design
- Front-loading design workflow
- Design in context
- Modular design
- NPD new product development
- DFSS design for Six Sigma
- DFMA design for manufacture / assembly
- Digital simulation engineering
- Requirement-driven design
- Specification-managed validation
- Configuration management

Concurrent engineering workflow

Concurrent engineering (British English: **simultaneous engineering**) is a workflow that, instead of working sequentially through stages, carries out a number of tasks in parallel. For example: starting tool design as soon as the detailed design has started, and before the detailed designs of the product are finished; or starting on detail design solid models before the concept design surfaces models are complete. Although this does not necessarily reduce the amount of manpower required for a project, as more changes are required due to the incomplete and changing information, it does drastically reduce lead times and thus time to market.

Feature-based CAD systems have for many years allowed the simultaneous work on 3D solid model and the 2D drawing by means of two separate files, with the drawing looking at the data in the model; when the model changes the drawing will associatively update. Some CAD packages also allow associative copying of geometry between files. This allows, for example, the copying of a part design into the files used by the tooling designer. The manufacturing engineer can then start work on tools before the final design freeze; when a design changes size or shape the tool geometry will then update. Concurrent engineering also has the added benefit of providing better and more immediate communication between departments, reducing the chance of costly, late design changes. It adopts a problem prevention method as compared to the problem solving and re-designing method of traditional sequential engineering.

Bottom–up design

Bottom–up design (CAD-centric) occurs where the definition of 3D models of a product starts with the construction of individual components. These are then virtually brought together in sub-assemblies of more than one level until the full product is digitally defined. This is sometimes known as the review structure showing what the

product will look like. The BOM contains all of the physical (solid) components; it may (but not also) contain other items required for the final product BOM such as paint, glue, oil and other materials commonly described as 'bulk items'. Bulk items typically have mass and quantities but are not usually modelled with geometry.

Bottom-up design tends to focus on the capabilities of available real-world physical technology, implementing those solutions which this technology is most suited to. When these bottom-up solutions have real-world value, bottom-up design can be much more efficient than top-down design. The risk of bottom-up design is that it very efficiently provides solutions to low-value problems. The focus of bottom-up design is "what can we most efficiently do with this technology?" rather than the focus of top-down which is "What is the most valuable thing to do?"

Top-down design

Top-down design is focused on high-level functional requirements, with relatively less focus on existing implementation technology. A top level spec is decomposed into lower and lower level structures and specifications, until the physical implementation layer is reached. The risk of a top-down design is that it will not take advantage of the most efficient applications of current physical technology, especially with respect to hardware implementation. Top-down design sometimes results in excessive layers of lower-level abstraction and inefficient performance when the Top-down model has followed an abstraction path which does not efficiently fit available physical-level technology. The positive value of top-down design is that it preserves a focus on the optimum solution requirements.

A part-centric top-down design may eliminate some of the risks of top-down design. This starts with a layout model, often a simple 2D sketch defining basic sizes and some major defining parameters. Industrial design brings creative ideas to product development. Geometry from this is associatively copied down to the next level, which represents different subsystems of the product. The geometry in the subsystems is then used to define more detail in levels below. Depending on the complexity of the product, a number of levels of this assembly are created until the basic definition of components can be identified, such as position and principal dimensions. This information is then associatively copied to component files. In these files the components are detailed; this is where the classic bottom-up assembly starts.

The top-down assembly is sometime known as a control structure. If a single file is used to define the layout and parameters for the review structure it is often known as a skeleton file.

Defense engineering traditionally develops the product structure from the top down. The system engineering process ^[15] prescribes a functional decomposition of requirements and then physical allocation of product structure to the functions. This top down approach would normally have lower levels of the product structure developed from CAD data as a bottom-up structure or design.

Both-ends-against-the-middle design

Both-ends-against-the-middle (BEATM) design is a design process that endeavors to combine the best features of top-down design, and bottom-up design into one process. A BEATM design process flow may begin with an emergent technology which suggests solutions which may have value, or it may begin with a top-down view of an important problem which needs a solution. In either case the key attribute of BEATM design methodology is to immediately focus at both ends of the design process flow: a top-down view of the solution requirements, and a bottom-up view of the available technology which may offer promise of an efficient solution. The BEATM design process proceeds from both ends in search of an optimum merging somewhere between the top-down requirements, and bottom-up efficient implementation. In this fashion, BEATM has been shown to genuinely offer the best of both methodologies. Indeed some of the best success stories from either top-down or bottom-up have been successful because of an intuitive, yet unconscious use of the BEATM methodology. When employed consciously, BEATM offers even more powerful advantages.

Front loading design and workflow

Front loading is taking top-down design to the next stage. The complete control structure and review structure, as well as downstream data such as drawings, tooling development and CAM models, are constructed before the product has been defined or a project kick-off has been authorized. These assemblies of files constitute a template from which a family of products can be constructed. When the decision has been made to go with a new product, the parameters of the product are entered into the template model and all the associated data is updated. Obviously predefined associative models will not be able to predict all possibilities and will require additional work. The main principle is that a lot of the experimental/investigative work has already been completed. A lot of knowledge is built into these templates to be reused on new products. This does require additional resources "up front" but can drastically reduce the time between project kick-off and launch. Such methods do however require organizational changes, as considerable engineering efforts are moved into "offline" development departments. It can be seen as an analogy to creating a concept car to test new technology for future products, but in this case the work is directly used for the next product generation.

Design in context

Individual components cannot be constructed in isolation. CAD and CaiD models of components are designed within the context of part or all of the product being developed. This is achieved using assembly modelling techniques. Other components' geometry can be seen and referenced within the CAD tool being used. The other components within the sub-assembly may or may not have been constructed in the same system, their geometry being translated from other collaborative product development (CPD) formats. Some assembly checking such as DMU is also carried out using product visualization software.

Product and process lifecycle management (PPLM)

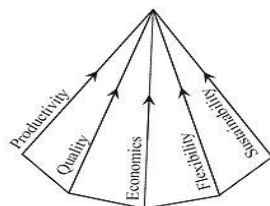
Product and process lifecycle management (**PPLM**) is an alternate genre of PLM in which the process by which the product is made is just as important as the product itself. Typically, this is the life sciences and advanced specialty chemicals markets. The process behind the manufacture of a given compound is a key element of the regulatory filing for a new drug application. As such, PPLM seeks to manage information around the development of the process in a similar fashion that baseline PLM talks about managing information around development of the product.

One variant of PPLM implementations are Process Development Execution Systems (PDES). They typically implement the whole development cycle of high-tech manufacturing technology developments, from initial conception, through development and into manufacture. PDES integrate people with different backgrounds from potentially different legal entities, data, information and knowledge and business processes.

Market size

Total spending on PLM software and services was estimated in 2006 to be above \$30 billion a year.^{[16][17]} Market growth estimates are in the area of 10%.

Pyramid of Production Systems



Pyramid of Production Systems

According to Malakooti (2013),^[18] there are five long-term objectives that should be considered in production systems:

- cost which can be measured in terms of monetary units and usually consists of fixed and variable cost.
- Productivity which can be measured in terms of the number of products produced during a period of time.
- Quality which can be measured, for example, in terms of customers' satisfaction.
- Flexibility, for example, ability of the system to produce variety of products.
- Ecological Soundness which can be measured in terms of biological and environmental impacts of the production system.

The relation between these five objects can be presented as pyramid which its tip is associated with the highest productivity, the highest quality, the most economical, the most flexibility, and the most sustainability. The points inside of this pyramid are associated with different combinations of five criteria. The tip of the pyramid is the ideal point but it is infeasible and the base of pyramid consists of the worst points.

Overall equipment effectiveness (OEE) is a hierarchy of metrics developed by Seiichi Nakajima^[1] in the 1960s to evaluate how effectively a manufacturing operation is utilized. It is based on the Harrington Emerson way of thinking regarding labor efficiency.^[citation needed] The results are stated in a generic form which allows comparison between manufacturing units in differing industries. It is not however an absolute measure and is best used to identify scope for process performance improvement, and how to get the improvement.^[2] If for example the cycle time is reduced, the OEE will increase i.e. more product is produced for less resource. Another example is if one enterprise serves a high volume, low variety market, and another enterprise serves a low volume, high variety market. More changeovers (set-ups) will lower the OEE in comparison, but if the product is sold at a premium, there could be more margin with a lower OEE.

OEE measurement is also commonly used as a key performance indicator (KPI) in conjunction with lean manufacturing efforts to provide an indicator of success. OEE can be illustrated by a brief discussion of the six metrics that comprise the system. The hierarchy consists of two top-level measures and four underlying measures.

Top-level metrics

Overall equipment effectiveness (OEE) and **total effective equipment performance** (TEEP) are two closely related metrics that report the overall utilization of facilities, time and material for manufacturing operations. These top view metrics directly indicate the gap between actual and ideal performance.

- Overall equipment effectiveness quantifies how well a manufacturing unit performs relative to its designed capacity, during the periods when it is scheduled to run.
- Total effective equipment performance (TEEP) measures OEE against calendar hours, i.e.: 24 hours per day, 365 days per year.

Underlying metrics

In addition to the above measures, there are four underlying metrics that provide understanding as to why and where the OEE and TEEP gaps exist.

The measurements are described below:

- **Loading:** The portion of the TEEP Metric that represents the percentage of total calendar time that is actually scheduled for operation.
- **Availability:** The portion of the OEE Metric that represents the percentage of scheduled time that the operation is available to operate. Often referred to as Uptime.
- **Performance:** The portion of the OEE Metric that represents the speed at which the Work Center runs as a percentage of its designed speed.
- **Quality:** The portion of the OEE Metric that represents the Good Units produced as a percentage of the Total Units Started. Commonly referred to as First Pass Yield FPY.

Calculations for OEE and TEEP

What follows is a detailed presentation of each of the six OEE / TEEP Metrics and examples of how to perform calculations. The calculations are not particularly complicated, but care must be taken as to standards that are used as the basis. Additionally, these calculations are valid at the work center or part number level but become more complicated if rolling up to aggregate levels.^[3]

Overall equipment effectiveness

OEE breaks the performance of a manufacturing unit into three separate but measurable components: Availability, Performance, and Quality. Each component points to an aspect of the process that can be targeted for improvement. OEE may be applied to any individual Work Center, or rolled up to Department or Plant levels. This tool also allows for drilling down for very specific analysis, such as a particular Part Number, Shift, or any of several other parameters. It is unlikely that any manufacturing process can run at 100% OEE. Many manufacturers benchmark their industry to set a challenging target; 85% is not uncommon.

- OEE is calculated with the formula (Availability)*(Performance)*(Quality)
- Using the examples given below:
- (Availability= 86.6%)*(Performance=93%)*(Quality=91.3%)= (OEE=73.6%)

Alternatively, and often easier, OEE is calculated by dividing the minimum time needed to produce the parts under optimal conditions by the actual time needed to produce the parts. For example:

- Total Time: 8 hour shift or 28,800 seconds, producing 14,400 parts, or one part every 2 seconds.
- Fastest possible cycle time is 1.5 seconds, hence only 21,600 seconds would have been needed to produce the 14,400 parts. The remaining 7,200 seconds or 2 hours were lost.
- The OEE is now the 21,600 seconds divided by 28,800 seconds (same as maximal 1.5 seconds per part divided by 2 actual seconds per part), or 75%.

Total effective equipment performance

Where OEE measures effectiveness based on scheduled hours, TEEP measures effectiveness against calendar hours, i.e.: 24 hours per day, 365 days per year.

TEEP, therefore, reports the 'bottom line' utilization of assets.

Loading

The Loading portion of the TEEP Metric represents the percentage of time that an operation is scheduled to operate compared to the total Calendar Time that is available. The Loading Metric is a pure measurement of Schedule Effectiveness and is designed to exclude the effects how well that operation may perform.

Calculation: Loading = Scheduled Time / Calendar Time

Example:

A given Work Center is scheduled to run 5 Days per Week, 24 Hours per Day.

For a given week, the Total Calendar Time is 7 Days at 24 Hours.

Loading = (5 days x 24 hours) / (7 days x 24 hours) = 71.4%

Availability

The Availability portion of the OEE Metric represents the percentage of scheduled time that the operation is available to operate. The Availability Metric is a pure measurement of Uptime that is designed to exclude the effects of Quality, Performance, and Scheduled Downtime Events. The losses due to wasted availability are called *availability losses*.^[4]

Example: A given Work Center is scheduled to run for an 8-hour (480 minute) shift with a 30-minute scheduled break and experiences 60 minutes of unplanned (breakdown) time. In this case, the 30 minute break should be considered "scheduled time" although it is planned downtime.

Operating Time = 480 Min Sched – 30 Min Sched Downtime – 60 Min Unsched Downtime = 390 Minutes

Calculation: Availability = operating time / scheduled time

Availability = 390 minutes / 480 minutes = 81.25%

Performance and productivity

Also known as "process rate", the Performance portion of the OEE Metric (also known as process rate) represents the speed at which the Work Center runs as a percentage of its designed speed. The Performance Metric is a pure measurement of speed that is designed to exclude the effects of Quality and Availability. The losses due to wasted performance are also often called *speed losses*. In practice it is often difficult to determine speed losses, and a common approach is to merely assign the remaining unknown losses as speed losses.

Calculation: Performance (Productivity) = (Parts Produced * Ideal Cycle Time) / Operating time ^[5]

Example:

A given Work Center is scheduled to run for an 8-hour (480 minute) shift with a 30-minute scheduled break.

Operating Time = 450 Min Sched – 60 Min Unsched Downtime = 390 Minutes

The Standard Rate for the part being produced is 40 Units/Hour or 1.5 Minutes/Unit

The Work Center produces 242 Total Units during the shift. Note: The basis is Total Units, not Good Units. The Performance metric does not penalize for Quality.

Time to Produce Parts = 242 Units * 1.5 Minutes/Unit = 363 Minutes

Performance (Productivity) = 363 Minutes / 390 Minutes = 93.0%

Quality

The Quality portion of the OEE Metric represents the Good Units produced as a percentage of the Total Units Started. The Quality Metric is a pure measurement of Process Yield that is designed to exclude the effects of Availability and Performance. The losses due to defects and rework are called *quality losses*.

Calculation: Quality = (Units produced - defective units) / (Units produced)

Example:

242 Units are produced. 21 are defective.

(242 units produced - 21 defective units) = 221 units

221 good units / 242 total units produced = 91.32%

"Six Big Losses"

In a 480 minute shift -
 On a machine rated at 100 products output per minute
 Maximum output = 480 mins x 100 units = 48000 units
 Shift info: Output (Good Production) = 32000 units
 Speed = 66 units per minute
 Planned downtime = 82 mins
 Bottleneck loss due to fit/down = 30 mins
 Rejects (in process) = 1255 in 8 hr shift

Output (OEE) = 32000 / 48000 = 66.7%
 480mins x 66.67% = 320 mins, therefore Total Loss = 160 mins

Six Loss Calculations:

Loss Category	Time (mins)	Percentage
Speed loss	6.53	1.36%
Planned downtime	82	17.08%
Breakdown	30	6.25%
Rejects = 1255 / 98 (actual running speed)	12.81	2.67%
Minor stops = 480-320-6.53-82-30-12.81	28.66	5.97%
Total loss	160 mins	33.32%

OEE Calculations (Time in mins):
 Production time = 480 Time less availability loss = 358 Time less performance loss = 333

Availability Loss	Performance Loss	Quality Loss
Planned downtime = 82	Speed loss = 6.53	Rejects on start up = 0
Breakdowns = 30	Minor stops (+5mins) = 28.66	Rejects in process = 12.81
Total = 112	Total = 35.19	Total = 12.81
Availability (368/480) = 77%	Performance (333/368) = 90%	Quality (320/333) = 96%

OEE = 0.77x0.90x0.96 = 66.7%

Example of OEE and Six Loss calculation

To be able to better determine what is contributing to the greatest loss and so what areas should be targeted to improve the performance, these categories (Availability, Performance and Quality) have been subdivided further into what is known as the 'Six Big Losses' to OEE.^[6]

These are categorized as follows:

Availability	Performance	Quality
Planned Downtime	Minor Stops	Production Rejects
Breakdowns	Speed Loss	Rejects on Start up

The reason for identifying the losses in these categories is so that specific countermeasures^[7] can be applied to reduce the loss and improve the overall OEE. The Six Loss categories can be calculated manually, but there are also a plethora of simple calculators online.^{[8][9]}

Heuristic

OEE is useful as a heuristic, but can break down in several circumstances. For example, it may be far more costly to run a facility at certain times. Performance and quality may not be independent of each other or of availability and loading. Experience may develop over time. Since the performance of shop floor managers is at least sometimes compared to the OEE, these numbers are often not reliable, and there are numerous ways to fudge these numbers.^[10]

OEE has properties of a geometric mean. As such it punishes variability among its subcomponents. For example, $20\% * 80\% = 16\%$, whereas $50\% * 50\% = 25\%$. When there are asymmetric costs associated with one or more of the components, then the model may become less appropriate.

Consider a system where the cost of error is exceptionally high. In such a condition, higher quality may be far more important in a proper evaluation of effectiveness than performance or availability. OEE also to some extent assumes a closed system and a potentially static one. If one can bring in additional resources (or lease out unused resources to other projects or business units) then it may be more appropriate for example to use an expected net present value analysis.

Variability in flow also can introduce important costs and risks that may merit further modeling. Sensitivity analysis and measures of change may be helpful.

Further reading

Hansen, Robert C (2005). Overall Equipment Effectiveness (OEE). Industrial Press. ISBN 978-0-8311-3237-8.

- *Koch, Arno (2007). OEE for the Production Team. Makigami. ISBN 978-90-78210-08-5. (English). ISBN 978-90-78210-07-8 (Dutch)., ISBN 978-3-940775-04-7 (German).*
- *Productivity Press Development Team (1999), OEE for Operators: Overall Equipment Effectiveness, Productivity Press, ISBN 978-1-56327-221-9*

Scheduling (production processes)

Scheduling is the process of arranging, controlling and optimizing work and workloads in a production process or manufacturing process. Scheduling is used to allocate plant and machinery resources, plan human resources, plan production processes and purchase materials.

It is an important tool for manufacturing and engineering, where it can have a major impact on the productivity of a process. In manufacturing, the purpose of scheduling is to minimize the production time and costs, by telling a production facility when to make, with which staff, and on which equipment. Production scheduling aims to maximize the efficiency of the operation and reduce costs

Scheduling is the process of arranging, controlling and optimizing work and workloads in a production process. Companies use backward and forward scheduling to allocate plant and machinery resources, plan human resources, plan production processes and purchase materials.

- Forward scheduling is planning the tasks from the date resources become available to determine the shipping date or the due date.
- Backward scheduling is planning the tasks from the due date or required-by date to determine the start date and/or any changes in capacity required.

The benefits of production scheduling include:

- Process change-over reduction
- Inventory reduction, leveling
- Reduced scheduling effort
- Increased production efficiency
- Labor load leveling
- Accurate delivery date quotes
- Real time information

Production scheduling tools greatly outperform older manual scheduling methods. These provide the production scheduler with powerful graphical interfaces which can be used to visually optimize real-time work loads in various stages of production, and pattern recognition allows the software to automatically create scheduling opportunities which might not be apparent without this view into the data. For example, an airline might wish to minimize the number of airport gates required for its aircraft, in order to reduce costs, and scheduling software can allow the planners to see how this can be done, by analyzing time tables, aircraft usage, or the flow of passengers.

Key concepts in scheduling

A key character of scheduling is the productivity, the relation between quantity of inputs and quantity of output. Key concepts here are:

- Inputs : Inputs are plant, labor, materials, tooling, energy and a clean environment.

- Outputs : Outputs are the products produced in factories either for other factories or for the end buyer. The extent to which any one product is produced within any one factory is governed by transaction cost.
- Output within the factory : The output of any one work area within the factory is an input to the next work area in that factory according to the manufacturing process. For example the output of cutting is an input to the bending room.
- Output for the next factory : By way of example, the output of a paper mill is an input to a print factory. The output of a petrochemicals plant is an input to an asphalt plant, a cosmetics factory and a plastics factory.
- Output for the end buyer : Factory output goes to the consumer via a service business such as a retailer or an asphalt paving company.
- Resource allocation : Resource allocation is assigning inputs to produce output. The aim is to maximize output with given inputs or to minimize quantity of inputs to produce required output.

Scheduling Algorithms

Production scheduling can take a significant amount of computing power if there are a large number of tasks. Therefore a range of short-cut algorithms (heuristics) (a.k.a. dispatching rules) are used:

- Stochastic Algorithms : Economic Lot Scheduling Problem and Economic production quantity
- Heuristic Algorithms : Modified due date scheduling heuristic and Shifting bottleneck heuristic

Batch Production Scheduling

Background

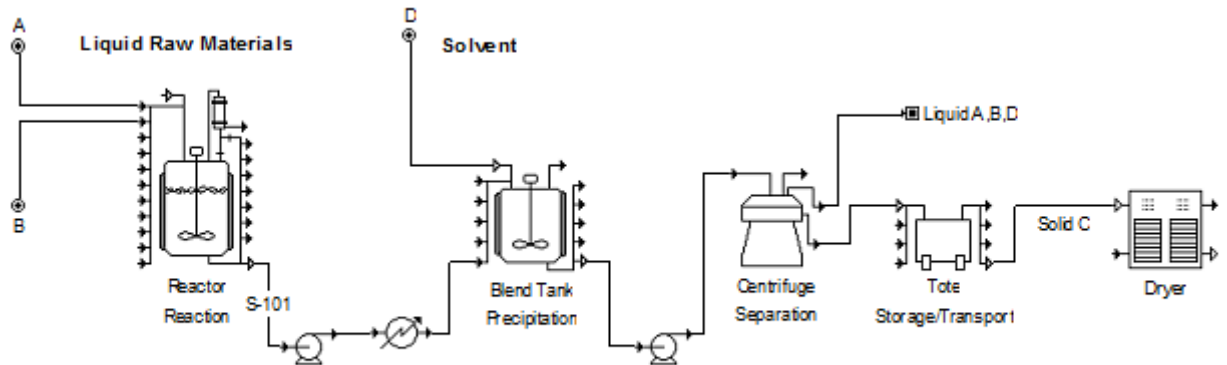
Batch production scheduling is the practice of planning and scheduling of batch manufacturing processes. See Batch production. Although scheduling may apply to traditionally continuous processes such as refining,^{[1][2]} it is especially important for batch processes such as those for pharmaceutical active ingredients, biotechnology processes and many specialty chemical processes.^{[3][4]} Batch production scheduling shares some concepts and techniques with finite capacity scheduling which has been applied to many manufacturing problems.^[5] The specific issues of scheduling batch manufacturing processes have generated considerable industrial and academic interest.

Scheduling in the Batch Processing Environment

A batch process can be described in terms of a recipe which comprises a bill of materials and operating instructions which describe how to make the product.^[6] The ISA S88 batch process control standard^[7] provides a framework for describing a batch process recipe. The standard provides a procedural hierarchy for a recipe. A recipe may be organized into a series of unit-procedures or major steps. Unit-procedures are organized into operations, and operations may be further organized into phases.

The following text-book recipe ^[8] illustrates the organization.

- Charge and Mix materials A and B in a heated reactor, heat to 80C and react 4 hours to form C.
- Transfer to blending tank, add solvent D, Blend 1hour. Solid C precipitates.
- Centrifuge for 2 hours to separate C.
- Dry in a tray dryer for 1 hour.



A simplified S88-style procedural organization of the recipe might appear as follows:

- **Unit Procedure 1: Reaction**
 - Operation 1: Charge A & B (0.5 hours)
 - Operation 2: Blend / Heat (1 hour)
 - Operation 3: Hold at 80C for 4 hours
 - Operation 4: Pump solution through cooler to blend tank (0.5 hours)
 - Operation 5: Clean (1 hour)
- **Unit Procedure 2: Blending Precipitation**
 - Operation 1: Receive solution from reactor
 - Operation 2: Add solvent, D (0.5 hours)
 - Operation 3: Blend for 2 hours
 - Operation 4: Pump to centrifuge for 2 hours
 - Operation 5: Clean up (1 hour)
- **Unit Procedure 3: Centrifugation**
 - Operation 1: Centrifuge solution for 2 hours
 - Operation 2: Clean
- **Unit Procedure 4: Tote**
 - Operation 1: Receive material from centrifuge
 - Operation 2: Load dryer (15 min)
- **Unit Procedure 5: Dry**
 - Operation 1: Load
 - Operation 2: Dry (1 hour)

Note that the organization here is intended to capture the entire process for scheduling. A recipe for process-control purposes may have a more narrow scope.

Most of the constraints and restrictions described by Pinedo^[9] are applicable in batch processing. The various operations in a recipe are subject to timing or precedence constraints that describe when they start and or end with respect to each other. Furthermore, because materials may be perishable or unstable, waiting between

successive operations may be limited or impossible. Operation durations may be fixed or they may depend on the durations of other operations.

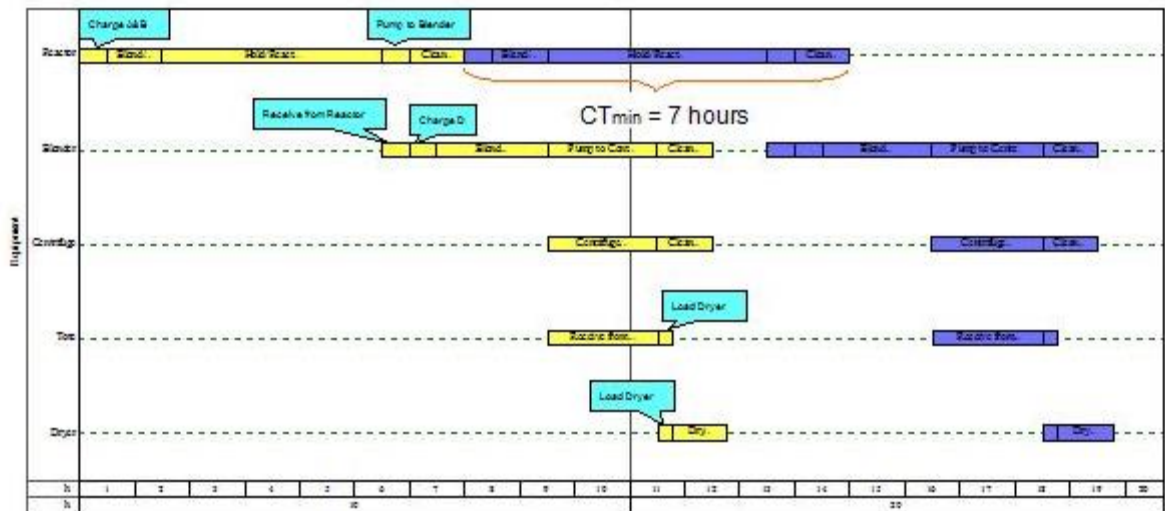
In addition to process equipment, batch process activities may require labor, materials, utilities and extra equipment.

Cycle-Time Analysis

In some simple cases, an analysis of the recipe can reveal the maximum production rate and the rate limiting unit. In the process example above if a number of batches or lots of Product C are to be produced, it is useful to calculate the minimum time between consecutive batch starts (cycle-time). If a batch is allowed to start before the end of the prior batch the minimum cycle-time is given by the following relationship:^[10]

$$CT_{min} = \max_{j=1, M} \{\tau_j\}$$

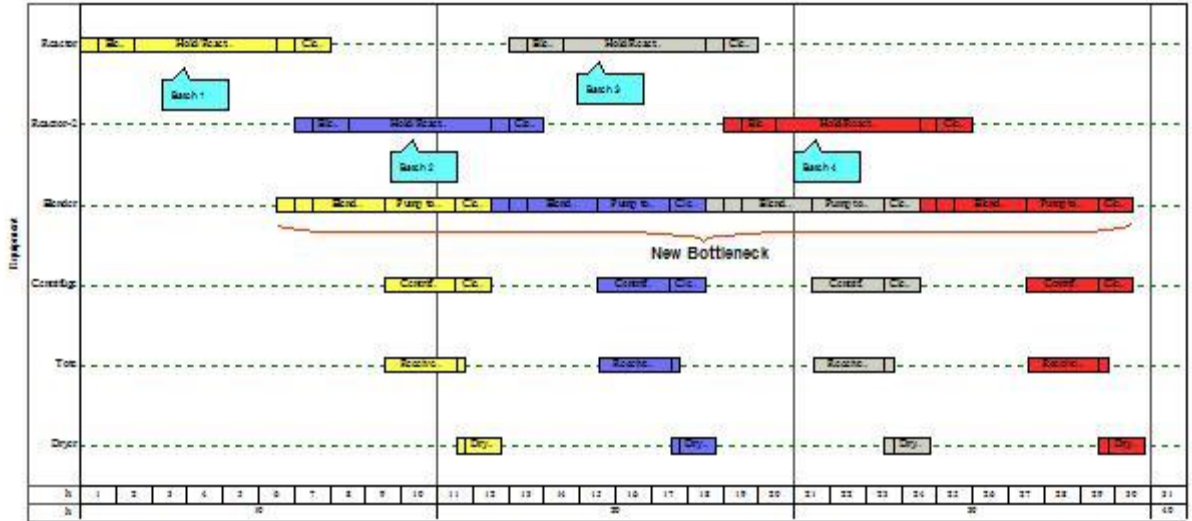
Where CT_{min} is the shortest possible cycle time for a process with M unit-procedures and τ_j is the total duration for the j th unit-procedure. The unit-procedure with the maximum duration is sometimes referred to as the bottleneck. This relationship applies when each unit-procedure has a single dedicated equipment unit.



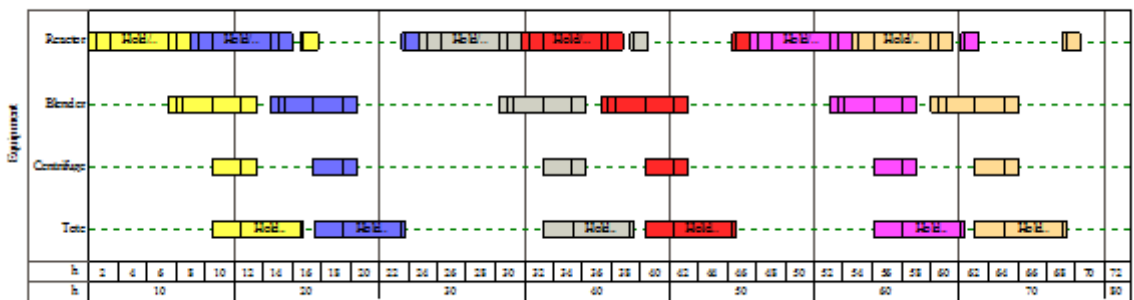
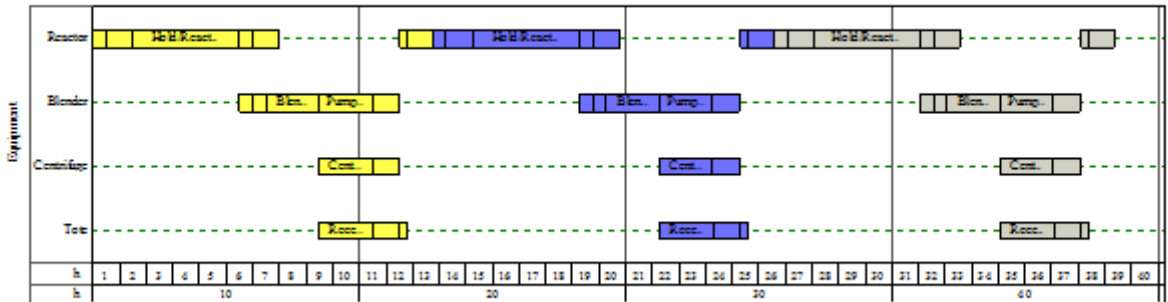
If redundant equipment units are available for at least one unit-procedure, the minimum cycle-time becomes:

$$CT_{min} = \max_{j=1, M} \{\tau_j / N_j\}$$

Where N_j is the number of redundant equipment for unit procedure j .

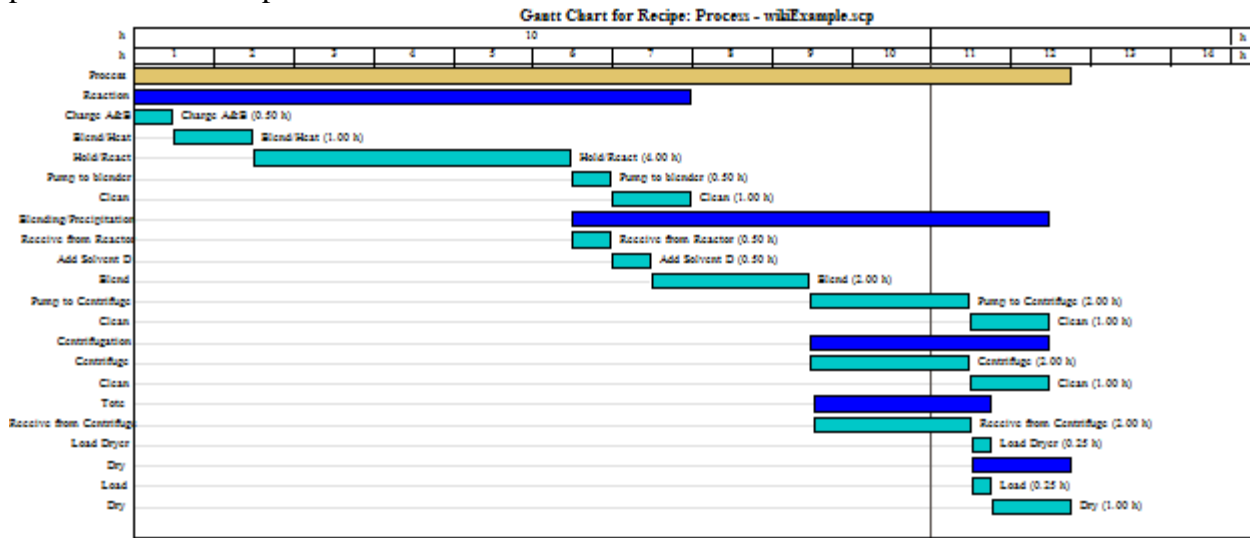


If equipment is reused within a process, the minimum cycle-time becomes more dependent on particular process details. For example, if the drying procedure in the current example is replaced with another reaction in the reactor, the minimum cycle time depends on the operating policy and on the relative durations of other procedures. In the cases below, an increase in the hold time in the tote can decrease the average minimum cycle time.



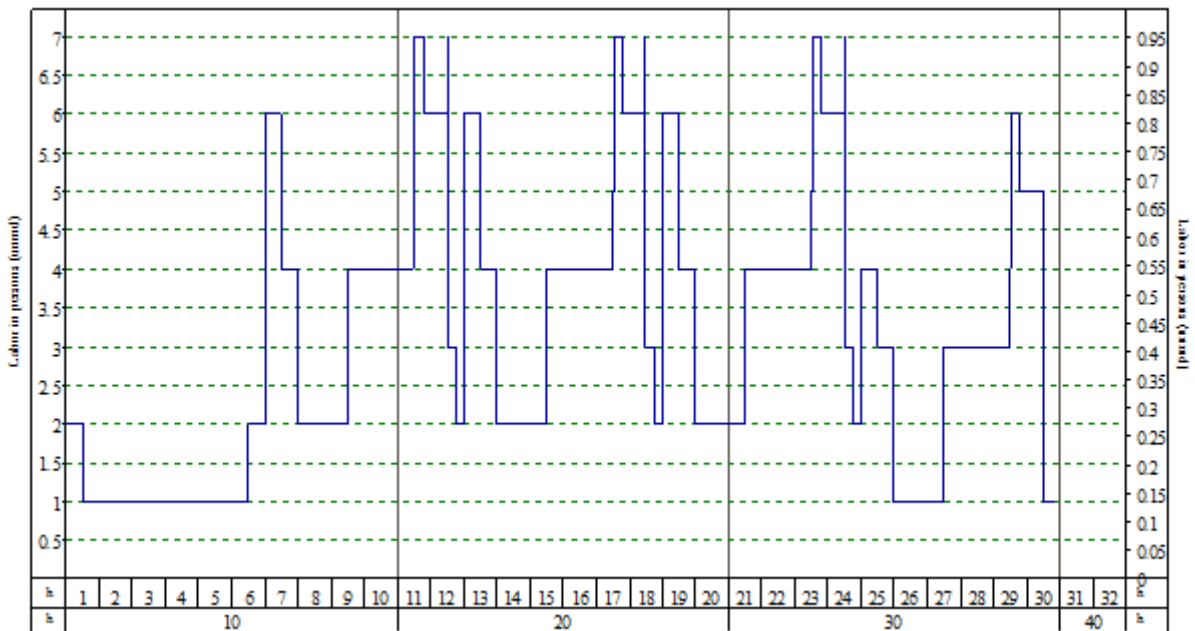
Visualization

Various charts are used to help schedulers visually manage schedules and constraints. The Gantt chart is a display that shows activities on a horizontal bar graph in which the bars represent the time of the activity. Below is an example of a Gantt chart for the process in the example described above.



Another time chart which is also sometimes called a Gantt chart^[11] shows the time during which key resources, e.g. equipment, are occupied. The previous figures show this occupancy-style Gantt chart.

Resources that are consumed on a rate basis, e.g. electrical power, steam or labor, are generally displayed as consumption rate vs time plots.



Algorithmic Methods

When scheduling situations become more complicated, for example when two or more processes share resources, it may be difficult to find the best schedule. A number of common scheduling problems, including variations on the example

described above, fall into a class of problems that become very difficult to solve as their size (number of procedures and operations) grows.^[12]

A wide variety of algorithms and approaches have been applied to batch process scheduling. Early methods, which were implemented in some MRP systems assumed infinite capacity and depended only on the batch time. Such methods did not account for any resources would produce infeasible schedules.^[13]

Mathematical programming methods involve formulating the scheduling problem as an optimization problem where some objective, e.g. total duration, must be minimized (or maximized) subject to a series of constraints which are generally stated as a set of inequalities and equalities. The objective and constraints may involve zero-or-one (integer) variables as well as nonlinear relationships. An appropriate solver is applied for the resulting mixed-integer linear or nonlinear programming (MILP/MINLP) problem. The approach is theoretically guaranteed to find an optimal solution if one exists. The disadvantage is that the solver algorithm may take an unreasonable amount of time. Practitioners may use problem-specific simplifications in the formulation to get faster solutions without eliminating critical components of the scheduling model.^[14]

Constraint programming is a similar approach except that the problem is formulated only as a set of constraints and the goal is to arrive at a feasible solution rapidly. Multiple solutions are possible with this method.^{[15][16]}

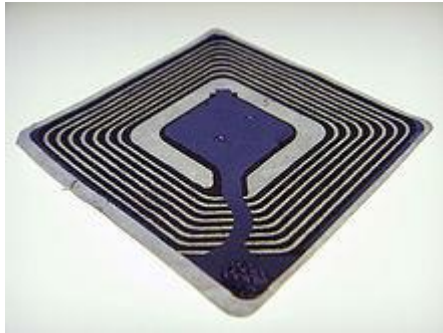
Track and trace

In distribution and logistics of many types of products, track and trace or tracking and tracing, concerns a process of determining the current and past locations (and other information) of a unique item or property.

This concept can be supported by means of reckoning and reporting of the position of vehicles and containers with the property of concern, stored, for example, in a real-time database. This approach leaves the task to compose a coherent depiction of the subsequent status reports.

Another approach is to report the arrival or departure of the object and recording the identification of the object, the location where observed, the time, and the status. This approach leaves the task to verify the reports regarding consistency and completeness. An example of this method might be the package tracking provided by shippers, such as Deutsche Post, United Parcel Service, AirRoad, or FedEx.

Technology



An example of a generic RFID chip.



Some produce traceability makers use matrix barcodes to record data on specific produce.

The international standards organization EPCglobal under GS1 has ratified the EPC network standards (esp. the EPC information services EPCIS standard) which codify the syntax and semantics for supply chain events and the secure method for selectively sharing supply chain events with trading partners. These standards for Tracking and Tracing have been used in successful deployments in many industries and there are now a wide range of products that are certified as being compatible with these standards.

In response to a growing number of recall incidents (food, pharmaceutical, toys, etc.), a wave of software, hardware, consulting and systems vendors have emerged over the last few years to offer a range of traceability solutions and tools for industry. Radio-frequency identification and barcodes are two common technology methods used to deliver traceability.

RFID is synonymous with track-and-trace solutions, and has a critical role to play in supply chains. RFID is a code-carrying technology, and can be used in place of a barcode to enable non-line of sight-reading. Deployment of RFID was earlier inhibited by cost limitations but the usage is now increasing.

Barcoding is a common and cost-effective method used to implement traceability at both the item and case-level. Variable data in a barcode or a numeric or alphanumeric code format can be applied to the packaging or label. The secure data can be used as a pointer to traceability information and can also correlate with production data such as time to market and product quality.^[1]

Packaging converters have a choice of three different classes of technology to print barcodes:

- Inkjet (dot on demand or continuous) systems are capable of printing high resolution (300 dpi or higher for dot on demand) images at press speed (up to 1000fpm). These solutions can be deployed either on-press or off-line.
- Laser marking can be employed to ablate a coating or to cause a color change in certain materials. The advantage of laser is fine detail and high speed for character printing, and no consumables. Not all substrates accept a laser mark, and certain colors (e.g. red) are not suitable for barcode reading.
- Thermal transfer and direct thermal. For lower speed off-press applications, thermal transfer and direct thermal printers are ideal for printing variable data on labels.

Consumers can access web sites to trace the origins of their purchased products or to find the status of shipments. Consumers can type a code found on an item into a search box at the tracing website and view information. This can also be done via a smartphone taking a picture of a 2D barcode and thereby opening up a website that verifies the product (i.e. product authentication).

Enterprise resource planning

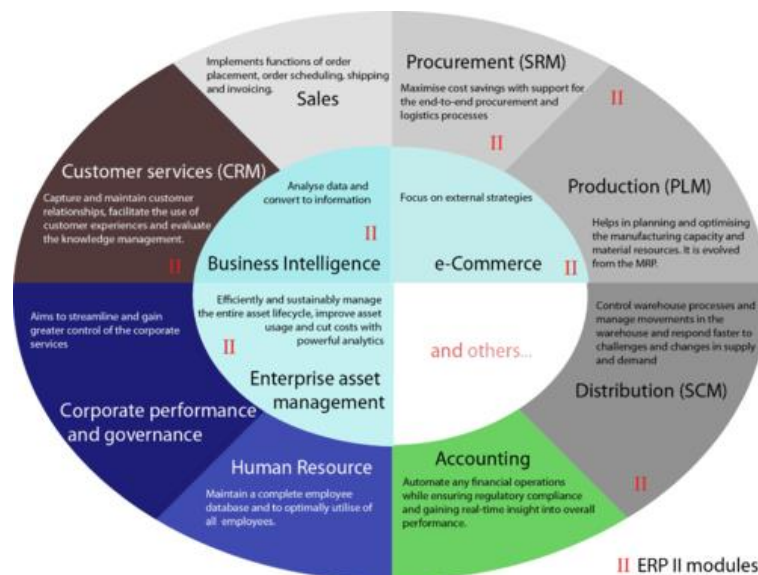


Diagram showing some typical ERP modules

Enterprise resource planning (ERP) is business-management software—typically a suite of integrated applications—that an organization can use to collect, store, manage and interpret data from many business activities, including:

- product planning, cost
- manufacturing or service delivery
- marketing and sales
- inventory management
- shipping and payment

ERP provides an integrated view of core business processes, often in real-time, using common databases maintained by a database management system. ERP systems track business resources—cash, raw materials, production capacity—and the status of business commitments: orders, purchase orders, and payroll. The applications that make up the system share data across various departments (manufacturing, purchasing, sales, accounting, etc.) that provide the data.^[1] ERP facilitates information flow between all business functions, and manages connections to outside stakeholders.^[2]

Enterprise system software is a multibillion-dollar industry that produces components that support a variety of business functions. IT investments have become the largest category of capital expenditure in United States-based businesses over the past^[which?] decade. Though early ERP systems focused on large enterprises, smaller enterprises increasingly use ERP systems.^{[3][need quotation to verify]}

The ERP system is considered a vital organizational tool^[by whom?] because it integrates varied organizational systems and facilitates error-free transactions and production. However, developing an ERP system differs from traditional system development.^[4] ERP systems run on a variety of computer hardware and network configurations, typically using a database as an information repository.^[5]

The Gartner Group first used the acronym ERP in the 1990s,^{[6][third-party source needed]} where it was seen^[by whom?] to extend the capabilities of material requirements planning (MRP), and the later manufacturing resource planning (MRP II),^{[7][8]} as well as computer-integrated manufacturing.^[citation needed] Without replacing these terms, ERP came to represent a larger whole that reflected the evolution of application integration beyond manufacturing.^[9]

Not all ERP packages developed from a manufacturing core; ERP vendors variously began assembling their packages with accounting, maintenance, and human-resource components.^[citation needed] By the mid-1990s ERP systems addressed all core enterprise functions.^[citation needed] Governments and non-profit organizations also began^[when?] to use ERP systems.^[10]

Expansion

ERP systems experienced rapid growth in the 1990s. Because of the year 2000 problem and introduction of the euro disrupted legacy systems, many companies took the opportunity to replace their old systems with ERP.^[11]

ERP systems initially focused on automating back office functions that did not directly affect customers and the public. Front office functions, such as customer relationship management (CRM), dealt directly with customers, or e-business systems such as e-commerce, e-government, e-telecom, and e-finance—or supplier relationship management (SRM) became integrated later, when the Internet simplified communicating with external parties.^[citation needed]

"ERP II" was coined in 2000 in an article by Gartner Publications entitled *ERP Is Dead—Long Live ERP II*.^[12] It describes web-based software that provides real-time

access to ERP systems to employees and partners (such as suppliers and customers). The ERP II role expands traditional ERP resource optimization and transaction processing. Rather than just manage buying, selling, etc.—ERP II leverages information in the resources under its management to help the enterprise collaborate with other enterprises.^[13] ERP II is more flexible than the first generation ERP. Rather than confine ERP system capabilities within the organization, it goes beyond the corporate walls to interact with other systems. *Enterprise application suite* is an alternate name for such systems.

Developers now make more effort to integrate mobile devices with the ERP system. ERP vendors are extending ERP to these devices, along with other business applications. Technical stakes of modern ERP concern integration—hardware, applications, networking, supply chains. ERP now covers more functions and roles—including decision making, stakeholders' relationships, standardization, transparency, globalization, etc.^[14]

Characteristics

ERP (Enterprise Resource Planning) systems typically include the following characteristics:

- An integrated system that operates in (or near) real time without relying on periodic updates^[citation needed]
- A common database that supports all applications
- A consistent look and feel across modules
- Installation of the system with elaborate application/data integration by the Information Technology (IT) department, provided the implementation is not done in small steps^[15]

Functional areas of ERP

An ERP system covers the following common functional areas. In many ERP systems these are called and grouped together as *ERP modules*:

- Financial accounting: General ledger, fixed asset, payables including vouchering, matching and payment, receivables cash application and collections, cash management, financial consolidation
- Management accounting: Budgeting, costing, cost management, activity based costing
- Human resources: Recruiting, training, rostering, payroll, benefits, 401K, diversity management, retirement, separation
- Manufacturing: Engineering, bill of materials, work orders, scheduling, capacity, workflow management, quality control, manufacturing process, manufacturing projects, manufacturing flow, product life cycle management
- Order Processing: Order to cash, order entry, credit checking, pricing, available to promise, inventory, shipping, sales analysis and reporting, sales commissioning.

- Supply chain management: Supply chain planning, supplier scheduling, product configurator, order to cash, purchasing, inventory, claim processing, warehousing (receiving, putaway, picking and packing).
- Project management: Project planning, resource planning, project costing, work breakdown structure, billing, time and expense, performance units, activity management
- Customer relationship management: Sales and marketing, commissions, service, customer contact, call center support — CRM systems are not always considered part of ERP systems but rather Business Support systems (BSS).
- Data services : Various "self-service" interfaces for customers, suppliers and/or employees

Best practices

Most ERP systems incorporate *best practices*. This means the software reflects the vendor's interpretation of the most effective way to perform each business process. Systems vary in how conveniently the customer can modify these practices.^[16] Companies that implemented industry best practices reduced time-consuming project tasks such as configuration, documentation, testing, and training. In addition, best practices reduced risk by 71% compared to other software implementations.^[17]

Use of best practices eases compliance with requirements such as IFRS, Sarbanes-Oxley, or Basel II. They can also help comply with de facto industry standards, such as electronic funds transfer. This is because the procedure can be readily codified within the ERP software, and replicated with confidence across multiple businesses who share that business requirement.^[citation needed]

Connectivity to plant floor information

ERP systems connect to real-time data and transaction data in a variety of ways. These systems are typically configured by systems integrators, who bring unique knowledge on process, equipment, and vendor solutions.

Direct integration—ERP systems have connectivity (communications to plant floor equipment) as part of their product offering. This requires that the vendors offer specific support for the plant floor equipment their customers operate. ERP vendors must be experts in their own products and connectivity to other vendor products, including those of their competitors.

Database integration—ERP systems connect to plant floor data sources through staging tables in a database. Plant floor systems deposit the necessary information into the database. The ERP system reads the information in the table. The benefit of staging is that ERP vendors do not need to master the complexities of equipment integration. Connectivity becomes the responsibility of the systems integrator.

Enterprise appliance transaction modules (EATM)—These devices communicate directly with plant floor equipment and with the ERP system via methods supported by the ERP system. EATM can employ a staging table, web services, or system-

specific program interfaces (APIs). An EATM offers the benefit of being an off-the-shelf solution.

Custom-integration solutions—Many system integrators offer custom solutions. These systems tend to have the highest level of initial integration cost, and can have a higher long term maintenance and reliability costs. Long term costs can be minimized through careful system testing and thorough documentation. Custom-integrated solutions typically run on workstation or server-class computers.

Implementation

ERP's scope usually implies significant changes to staff work processes and practices.^[18] Generally, three types of services are available to help implement such changes—consulting, customization, and support.^[18] Implementation time depends on business size, number of modules, customization, the scope of process changes, and the readiness of the customer to take ownership for the project. Modular ERP systems can be implemented in stages. The typical project for a large enterprise takes about 14 months and requires around 150 consultants.^[19] Small projects can require months; multinational and other large implementations can take years.^[citation needed] Customization can substantially increase implementation times.^[19]

Besides that, information processing influences various business functions e.g. some large corporations like Wal-Mart use a just in time inventory system. This reduces inventory storage and increases delivery efficiency, and requires up-to-date-data. Before 2014, Walmart used a system called Inforem developed by IBM to manage replenishment.^[20]

Process preparation

Implementing ERP typically requires changes in existing business processes.^[21] Poor understanding of needed process changes prior to starting implementation is a main reason for project failure.^[22] The difficulties could be related to the system, business process, infrastructure, training, or lack of motivation.

It is therefore crucial that organizations thoroughly analyze business processes before they implement ERP software. Analysis can identify opportunities for process modernization. It also enables an assessment of the alignment of current processes with those provided by the ERP system. Research indicates that risk of business process mismatch is decreased by:

- Linking current processes to the organization's strategy
- Analyzing the effectiveness of each process
- Understanding existing automated solutions^{[23][24]}

ERP implementation is considerably more difficult (and politically charged) in decentralized organizations, because they often have different processes, business rules, data semantics, authorization hierarchies, and decision centers.^[25] This may require migrating some business units before others, delaying implementation to work through the necessary changes for each unit, possibly reducing integration (e.g.,

linking via Master data management) or customizing the system to meet specific needs.^[26]

A potential disadvantage is that adopting "standard" processes can lead to a loss of competitive advantage. While this has happened, losses in one area are often offset by gains in other areas, increasing overall competitive advantage.^{[27][28]}

Configuration

Configuring an ERP system is largely a matter of balancing the way the organization wants the system to work with the way it was designed to work. ERP systems typically include many settings that modify system operations. For example, an organization can select the type of inventory accounting—FIFO or LIFO—to use; whether to recognize revenue by geographical unit, product line, or distribution channel; and whether to pay for shipping costs on customer returns.^[26]

Two tier enterprise resource planning

Two-tier ERP software and hardware lets companies run the equivalent of two ERP systems at once: one at the corporate level and one at the division or subsidiary level. For example, a manufacturing company^[who?] uses an ERP system to manage across the organization. This company uses independent global or regional distribution, production or sales centers, and service providers to support the main company's customers. Each independent center or subsidiary may have its own business models, workflows, and business processes.

Given the realities of globalization, enterprises continuously evaluate how to optimize their regional, divisional, and product or manufacturing strategies to support strategic goals and reduce time-to-market while increasing profitability and delivering value.^[29] With two-tier ERP, the regional distribution, production, or sales centers and service providers continue operating under their own business model—separate from the main company, using their own ERP systems. Since these smaller companies' processes and workflows are not tied to main company's processes and workflows, they can respond to local business requirements in multiple locations.^[30]

Factors that affect enterprises' adoption of two-tier ERP systems include:

- Manufacturing globalization, the economics of sourcing in emerging economies
- Potential for quicker, less costly ERP implementations at subsidiaries, based on selecting software more suited to smaller companies
- Extra effort, (often involving the use of Enterprise application integration^[31]) is required where data must pass between two ERP systems^[32] Two-tier ERP strategies give enterprises agility in responding to market demands and in aligning IT systems at a corporate level while inevitably resulting in more systems as compared to one ERP system used throughout the organization.^[33]

Customization

ERP systems are theoretically based on industry best practices, and their makers intend that organizations deploy them *as is*.^{[34][35]} ERP vendors do offer customers configuration options that let organizations incorporate their own business rules, but often feature gaps remain even after configuration is complete.

ERP customers have several options to reconcile feature gaps, each with their own pros/cons. Technical solutions include rewriting part of the delivered software, writing a homegrown module to work within the ERP system, or interfacing to an external system. These three options constitute varying degrees of system customization—with the first being the most invasive and costly to maintain.^[36] Alternatively, there are non-technical options such as changing business practices or organizational policies to better match the delivered ERP feature set. Key differences between customization and configuration include:

- Customization is always optional, whereas the software must always be configured before use (e.g., setting up cost/profit center structures, organizational trees, purchase approval rules, etc.).
- The software is designed to handle various configurations, and behaves predictably in any allowed configuration.
- The effect of configuration changes on system behavior and performance is predictable and is the responsibility of the ERP vendor. The effect of customization is less predictable. It is the customer's responsibility, and increases testing activities.
- Configuration changes survive upgrades to new software versions. Some customizations (e.g., code that uses pre-defined "hooks" that are called before/after displaying data screens) survive upgrades, though they require retesting. Other customizations (e.g., those involving changes to fundamental data structures) are overwritten during upgrades and must be re-implemented.^[37]

Customization advantages include that it:

- Improves user acceptance^[38]
- Offers the potential to obtain competitive advantage vis-à-vis companies using only standard features

Customization disadvantages include that it:

- Increases time and resources required to implement and maintain^[36]
- Inhibits seamless communication between suppliers and customers who use the same ERP system uncustomized^[citation needed]
- Can create over reliance on customization, undermining the principles of ERP as a standardizing software platform

Extensions

ERP systems can be extended with third-party software.^[39] ERP vendors typically provide access to data and features through published interfaces. Extensions offer features such as:^[citation needed]

- Reporting, and republishing
- Capturing transactional data, e.g., using scanners, tills or RFID
- Access to specialized data and capabilities, such as syndicated marketing data and associated trend analytics
- Advanced planning and scheduling (APS)
- Managing facilities, and transmission in real-time

Data migration

Data migration is the process of moving, copying, and restructuring data from an existing system to the ERP system. Migration is critical to implementation success and requires significant planning. Unfortunately, since migration is one of the final activities before the production phase, it often receives insufficient attention. The following steps can structure migration planning:^[40]

- Identify data to migrate
- Determine migration timing
- Generate data templates^[clarification needed]
- Freeze the toolset
- Decide on migration-related setups^[clarification needed]
- Define data archiving policies and procedures

Comparison to special-purpose applications

Advantages

The fundamental advantage of ERP is that integrated myriad business processes saves time and expense. Management can make decisions faster and with fewer errors. Data becomes visible across the organization. Tasks that benefit from this integration include:^[citation needed]

- Sales forecasting, which allows inventory optimization.
- Chronological history of every transaction through relevant data compilation in every area of operation.
- Order tracking, from acceptance through fulfillment
- Revenue tracking, from invoice through cash receipt
- Matching purchase orders (what was ordered), inventory receipts (what arrived), and costing (what the vendor invoiced)

ERP systems centralize business data, which:

- Eliminates the need to synchronize changes between multiple systems—consolidation of finance, marketing, sales, human resource, and manufacturing applications
- Brings legitimacy and transparency to each bit of statistical data
- Facilitates standard product naming/coding
- Provides a comprehensive enterprise view (no "islands of information"), making real-time information available to management anywhere, any time to make proper decisions

- Protects sensitive data by consolidating multiple security systems into a single structure^[41]

Benefits

ERP can improve quality and efficiency of the business. By keeping a company's internal business processes running smoothly, ERP can lead to better outputs that may benefit the company, such as in customer service and manufacturing.

- ERP supports upper level management by providing information for decision making.
- ERP creates a more agile company that adapts better to change. ERP makes a company more flexible and less rigidly structured so organization components operate more cohesively, enhancing the business—internally and externally.^[42]
- ERP can improve data security. A common control system, such as the kind offered by ERP systems, allows organizations the ability to more easily ensure key company data is not compromised.^[citation needed]
- ERP provides increased opportunities for collaboration. Data takes many forms in the modern enterprise. Documents, files, forms, audio and video, emails. Often, each data medium has its own mechanism for allowing collaboration. ERP provides a collaborative platform that lets employees spend more time collaborating on content rather than mastering the learning curve of communicating in various formats across distributed systems.^[citation needed]

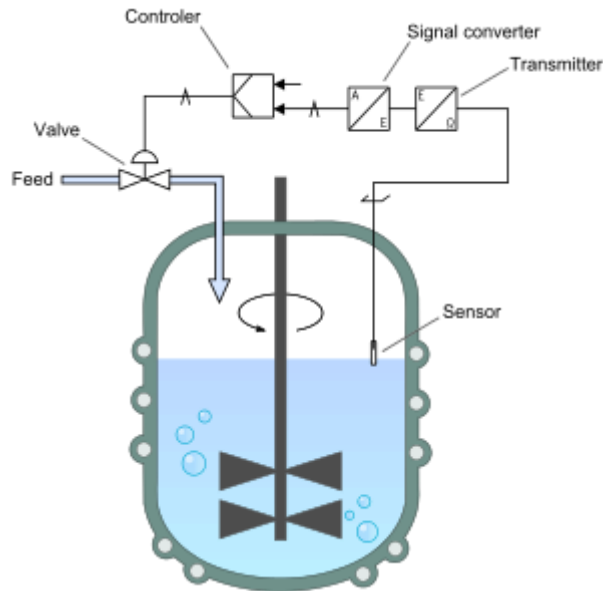
Disadvantages

Customization can be problematic. Compared to the best-of-breed approach, ERP can be seen as meeting an organization's lowest common denominator needs, forcing the organization to find workarounds to meet unique demands.^[43]

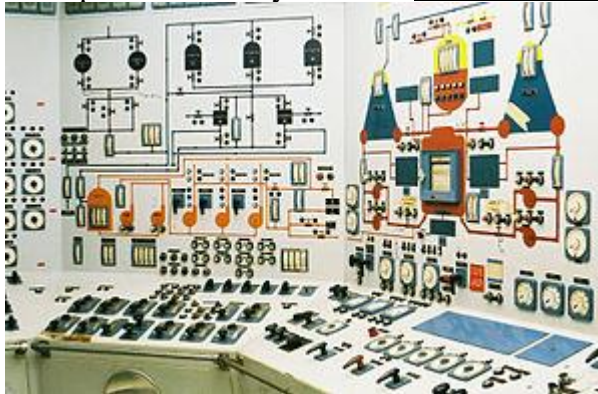
- Re-engineering business processes to fit the ERP system may damage competitiveness or divert focus from other critical activities.
- ERP can cost more than less integrated or less comprehensive solutions.
- High ERP switching costs can increase the ERP vendor's negotiating power, which can increase support, maintenance, and upgrade expenses.
- Overcoming resistance to sharing sensitive information between departments can divert management attention.
- Integration of truly independent businesses can create unnecessary dependencies.
- Extensive training requirements take resources from daily operations.
- Due to ERP's architecture (OLTP, On-Line Transaction Processing) ERP systems are not well suited for production planning and supply chain management (SCM).
- Harmonization of ERP systems can be a mammoth task (especially for big companies) and requires a lot of time, planning, and money.^[44]

Recognized ERP limitations have sparked new trends in ERP application development. Development is taking place in four significant areas: more flexible ERP, Web-enabled ERP, inter-enterprise ERP, and e-business suites.

Process control



Example of control system of a continuous stirred-tank reactor.

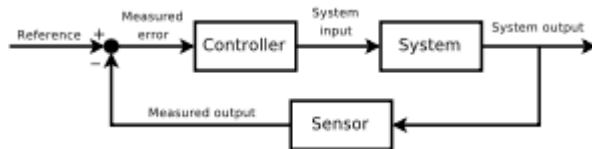


Control panel of a nuclear reactor.

Process control is an engineering discipline that deals with architectures, mechanisms and algorithms for maintaining the output of a specific process within a desired range. For instance, the temperature of a chemical reactor may be controlled to maintain a consistent product output.

Process control is extensively used in industry and enables mass production of consistent products from continuously operated processes such as oil refining, paper manufacturing, chemicals, power plants and many others. Process control enables automation, by which a small staff of operating personnel can operate a complex process from a central control room.

Background



General Example of Feedback loop

Process control may either use feedback or it may be open loop. Control may also be continuous (automobile cruise control) or cause a sequence of discrete events, such as a timer on a lawn sprinkler (on/off) or controls on an elevator (logical sequence).

A thermostat on a heater is an example of control that is on or off. A temperature sensor turns the heat source on if the temperature falls below the set point and turns the heat source off when the set point is reached. There is no measurement of the difference between the set point and the measured temperature (e.g. no error measurement) and no adjustment to the rate at which heat is added other than all or none.

A familiar example of feedback control is cruise control on an automobile. Here speed is the **measured variable**. The operator (driver) adjusts the desired speed **set point** (e.g. 100 km/hr) and the controller monitors the speed sensor and compares the measured speed to the set point. Any deviations, such as changes in grade, drag, wind speed or even using a different grade of fuel (for example an ethanol blend) are corrected by the controller making a compensating adjustment to the fuel valve open position, which is the **manipulated variable**. The controller makes adjustments having information only about the error (magnitude, rate of change or cumulative error) although settings known as *tuning* are used to achieve stable control. The operation of such controllers is the subject of control theory.

A commonly used control device called a programmable logic controller, or a PLC, is used to read a set of digital and analog inputs, apply a set of logic statements, and generate a set of analog and digital outputs.

For example, if an adjustable valve were used to hold level in a tank the logical statements would compare the equivalent pressure at depth setpoint to the pressure reading of a sensor below the normal low liquid level and determine whether more or less valve opening was necessary to keep the level constant. A PLC output would then calculate an incremental amount of change in the valve position. Larger more complex systems can be controlled by a Distributed Control System (DCS) or SCADA system.

Types of processes using process control

Processes can be characterized as one or more of the following forms:

- Discrete – Found in many manufacturing, motion and packaging applications. Robotic assembly, such as that found in automotive production, can be characterized as discrete process control. Most discrete manufacturing involves the production of discrete pieces of product, such as metal stamping.

- Batch – Some applications require that specific quantities of raw materials be combined in specific ways for particular durations to produce an intermediate or end result. One example is the production of adhesives and glues, which normally require the mixing of raw materials in a heated vessel for a period of time to form a quantity of end product. Other important examples are the production of food, beverages and medicine. Batch processes are generally used to produce a relatively low to intermediate quantity of product per year (a few pounds to millions of pounds).
- Continuous – Often, a physical system is represented through variables that are smooth and uninterrupted in time. The control of the water temperature in a heating jacket, for example, is an example of continuous process control. Some important continuous processes are the production of fuels, chemicals and plastics. Continuous processes in manufacturing are used to produce very large quantities of product per year (millions to billions of pounds).

SCADA

SCADA (supervisory control and data acquisition) is a system that operates with coded signals over communication channels so as to provide control of remote equipment (using typically one communication channel per remote station). The control system may be combined with a data acquisition system by adding the use of coded signals over communication channels to acquire information about the status of the remote equipment for display or for recording functions.^[1] It is a type of industrial control system (ICS). Industrial control systems are computer-based systems that monitor and control industrial processes that exist in the physical world. SCADA systems historically distinguish themselves from other ICS systems by being large-scale processes that can include multiple sites, and large distances.^[2] These processes include industrial, infrastructure, and facility-based processes, as described below:

- Industrial processes include those of manufacturing, production, power generation, fabrication, and refining, and may run in continuous, batch, repetitive, or discrete modes.
- Infrastructure processes may be public or private, and include water treatment and distribution, wastewater collection and treatment, oil and gas pipelines, electrical power transmission and distribution, wind farms, civil defense siren systems, and large communication systems.
- Facility processes occur both in public facilities and private ones, including buildings, airports, ships, and space stations. They monitor and control heating, ventilation, and air conditioning systems (HVAC), access, and energy consumption.

Common system components

A SCADA system usually consists of the following subsystems:

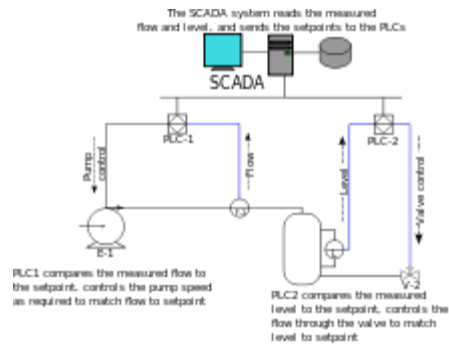
- Remote terminal units (RTUs) connect to sensors in the process and convert sensor signals to digital data. They have telemetry hardware capable of

sending digital data to the supervisory system, as well as receiving digital commands from the supervisory system. RTUs often have embedded control capabilities such as ladder logic in order to accomplish boolean logic operations.

- Programmable logic controller (PLCs) connect to sensors in the process and convert sensor signals to digital data. PLCs have more sophisticated embedded control capabilities (typically one or more IEC 61131-3 programming languages) than RTUs. PLCs do not have telemetry hardware, although this functionality is typically installed alongside them. PLCs are sometimes used in place of RTUs as field devices because they are more economical, versatile, flexible, and configurable.
- A telemetry system is typically used to connect PLCs and RTUs with control centers, data warehouses, and the enterprise. Examples of wired telemetry media used in SCADA systems include leased telephone lines and WAN circuits. Examples of wireless telemetry media used in SCADA systems include satellite (VSAT), licensed and unlicensed radio, cellular and microwave.
- A data acquisition server is a software service which uses industrial protocols to connect software services, via telemetry, with field devices such as RTUs and PLCs. It allows clients to access data from these field devices using standard protocols.
- A human-machine interface or HMI is the apparatus or device which presents processed data to a human operator, and through this, the human operator monitors and interacts with the process. The HMI is a client that requests data from a data acquisition server.
- A Historian is a software service which accumulates time-stamped data, boolean events, and boolean alarms in a database which can be queried or used to populate graphic trends in the HMI. The historian is a client that requests data from a data acquisition server.
- A supervisory (computer) system, gathering (acquiring) data on the process and sending commands (control) to the SCADA system.
- Communication infrastructure connecting the supervisory system to the remote terminal units.
- Various processes and analytical instrumentation.

Systems concepts

The term SCADA (Supervisory Control and Data Acquisition) usually refers to centralized systems which monitor and control entire sites, or complexes of systems spread out over large areas (anything from an industrial plant to a nation). Most control actions are performed automatically by RTUs or by PLCs. Host control functions are usually restricted to basic overriding or *supervisory* level intervention. For example, a PLC may control the flow of cooling water through part of an industrial process, but the SCADA system may allow operators to change the set points for the flow, and enable alarm conditions, such as loss of flow and high temperature, to be displayed and recorded. The feedback control loop passes through the RTU or PLC, while the SCADA system monitors the overall performance of the loop.



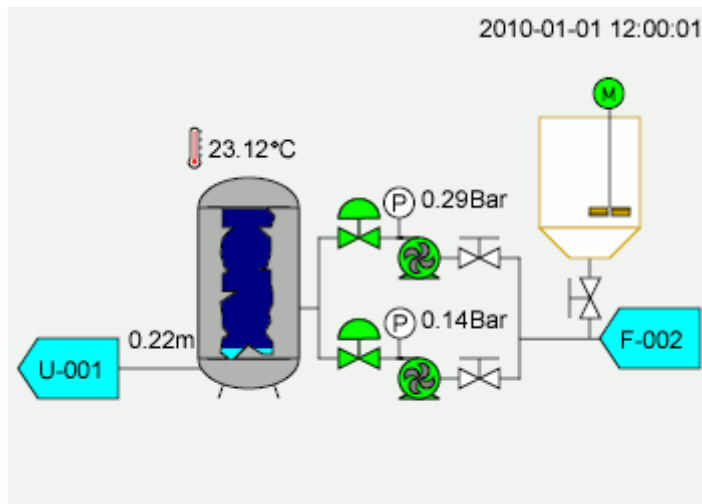
SCADA's schematic overview

Data acquisition begins at the RTU or PLC level and includes meter readings and equipment status reports that are communicated to SCADA as required. Data is then compiled and formatted in such a way that a control room operator using the HMI can make supervisory decisions to adjust or override normal RTU (PLC) controls. Data may also be fed to a Historian, often built on a commodity Database Management System, to allow trending and other analytical auditing.

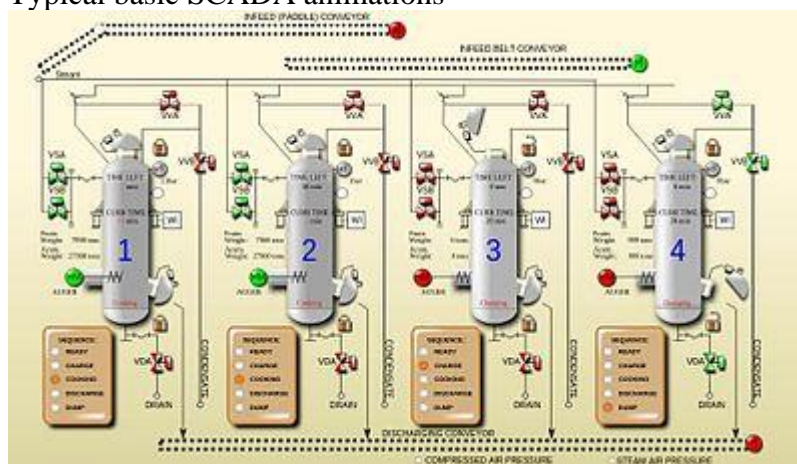
SCADA systems typically implement a distributed database, commonly referred to as a *tag database*, which contains data elements called *tags* or *points*. A point represents a single input or output value monitored or controlled by the system. Points can be either "hard" or "soft". A hard point represents an actual input or output within the system, while a soft point results from logic and math operations applied to other points. (Most implementations conceptually remove the distinction by making every property a "soft" point expression, which may, in the simplest case, equal a single hard point.) Points are normally stored as value-timestamp pairs: a value, and the timestamp when it was recorded or calculated. A series of value-timestamp pairs gives the history of that point. It is also common to store additional metadata with tags, such as the path to a field device or PLC register, design time comments, and alarm information.

SCADA systems are significantly important systems used in national infrastructures such as electric grids, water supplies and pipelines. However, SCADA systems may have security vulnerabilities, so the systems should be evaluated to identify risks and solutions implemented to mitigate those risks.^[3]

Human-machine interface



Typical basic SCADA animations



More complex SCADA animation

A human-machine interface (HMI) is the input-output device through which the human operator controls the process, and which presents process data to a human operator.

HMI(Human Machine interface) is usually linked to the SCADA system's databases and software programs, to provide trending, diagnostic data, and management information such as scheduled maintenance procedures, logistic information, detailed schematics for a particular sensor or machine, and expert-system troubleshooting guides.

The HMI system usually presents the information to the operating personnel graphically, in the form of a mimic diagram. This means that the operator can see a schematic representation of the plant being controlled. For example, a picture of a pump connected to a pipe can show the operator that the pump is running and how much fluid it is pumping through the pipe at the moment. The operator can then switch the pump off. The HMI software will show the flow rate of the fluid in the pipe decrease in real time. Mimic diagrams may consist of line graphics and schematic symbols to represent process elements, or may consist of digital photographs of the process equipment overlain with animated symbols.

The HMI package for the SCADA system typically includes a drawing program that the operators or system maintenance personnel use to change the way these points are represented in the interface. These representations can be as simple as an on-screen traffic light, which represents the state of an actual traffic light in the field, or as complex as a multi-projector display representing the position of all of the elevators in a skyscraper or all of the trains on a railway.

An important part of most SCADA implementations is alarm handling. The system monitors whether certain alarm conditions are satisfied, to determine when an alarm event has occurred. Once an alarm event has been detected, one or more actions are taken (such as the activation of one or more alarm indicators, and perhaps the generation of email or text messages so that management or remote SCADA operators are informed). In many cases, a SCADA operator may have to acknowledge the alarm event; this may deactivate some alarm indicators, whereas other indicators remain active until the alarm conditions are cleared. Alarm conditions can be explicit—for example, an alarm point is a digital status point that has either the value NORMAL or ALARM that is calculated by a formula based on the values in other analogue and digital points—or implicit: the SCADA system might automatically monitor whether the value in an analogue point lies outside high and low- limit values associated with that point. Examples of alarm indicators include a siren, a pop-up box on a screen, or a coloured or flashing area on a screen (that might act in a similar way to the "fuel tank empty" light in a car); in each case, the role of the alarm indicator is to draw the operator's attention to the part of the system 'in alarm' so that appropriate action can be taken. In designing SCADA systems, care must be taken when a cascade of alarm events occurs in a short time, otherwise the underlying cause (which might not be the earliest event detected) may get lost in the noise. Unfortunately, when used as a noun, the word 'alarm' is used rather loosely in the industry; thus, depending on context it might mean an alarm point, an alarm indicator, or an alarm event.

Hardware solutions

SCADA solutions often have Distributed Control System (DCS) components. Use of "smart" RTUs or PLCs, which are capable of autonomously executing simple logic processes without involving the master computer, is increasing. A standardized control programming language, IEC 61131-3 (a suite of 5 programming languages including Function Block, Ladder, Structured Text, Sequence Function Charts and Instruction List), is frequently used to create programs which run on these RTUs and PLCs. Unlike a procedural language such as the C programming language or FORTRAN, IEC 61131-3 has minimal training requirements by virtue of resembling historic physical control arrays. This allows SCADA system engineers to perform both the design and implementation of a program to be executed on an RTU or PLC. A Programmable Automation Controller (PAC) is a compact controller that combines the features and capabilities of a PC-based control system with that of a typical PLC. PACs are deployed in SCADA systems to provide RTU and PLC functions. In many electrical substation SCADA applications, "distributed RTUs" use information processors or station computers to communicate with digital protective relays, PACs, and other devices for I/O, and communicate with the SCADA master in lieu of a traditional RTU.

Since about 1998, virtually all major PLC manufacturers have offered integrated HMI/SCADA systems, many of them using open and non-proprietary communications protocols. Numerous specialized third-party HMI/SCADA packages, offering built-in compatibility with most major PLCs, have also entered the market, allowing mechanical engineers, electrical engineers and technicians to configure HMIs themselves, without the need for a custom-made program written by a software programmer. The Remote Terminal Unit (RTU) connects to physical equipment. Typically, an RTU converts the electrical signals from the equipment to digital values such as the open/closed status from a switch or a valve, or measurements such as pressure, flow, voltage or current. By converting and sending these electrical signals out to equipment the RTU can control equipment, such as opening or closing a switch or a valve, or setting the speed of a pump.

Supervisory station

The term *supervisory station* refers to the servers and software responsible for communicating with the field equipment (RTUs, PLCs, SENSORS etc.), and then to the HMI software running on workstations in the control room, or elsewhere. In smaller SCADA systems, the master station may be composed of a single PC. In larger SCADA systems, the master station may include multiple servers, distributed software applications, and disaster recovery sites. To increase the integrity of the system the multiple servers will often be configured in a dual-redundant or hot-standby formation providing continuous control and monitoring in the event of a server malfunction or breakdown.

Operational philosophy

For some installations, the costs that would result from the control system failing are extremely high. Hardware for some SCADA systems is ruggedized to withstand temperature, vibration, and voltage extremes. In the most critical installations, reliability is enhanced by having redundant hardware and communications channels, up to the point of having multiple fully equipped control centres. A failing part can be quickly identified and its functionality automatically taken over by backup hardware. A failed part can often be replaced without interrupting the process. The reliability of such systems can be calculated statistically and is stated as the mean time to failure, which is a variant of Mean Time Between Failures (MTBF). The calculated mean time to failure of such high reliability systems can be on the order of centuries.

Communication infrastructure and methods

SCADA systems have traditionally used combinations of radio and direct wired connections, although SONET/SDH is also frequently used for large systems such as railways and power stations. The remote management or monitoring function of a SCADA system is often referred to as telemetry. Some users want SCADA data to travel over their pre-established corporate networks or to share the network with other applications. The legacy of the early low-bandwidth protocols remains, though.

SCADA protocols are designed to be very compact. Many are designed to send information only when the master station polls the RTU. Typical legacy SCADA protocols include Modbus RTU, RP-570, Profibus and Conitel. These communication

protocols are all SCADA-vendor specific but are widely adopted and used. Standard protocols are IEC 60870-5-101 or 104, IEC 61850 and DNP3. These communication protocols are standardized and recognized by all major SCADA vendors. Many of these protocols now contain extensions to operate over TCP/IP. Although the use of conventional networking specifications, such as TCP/IP, blurs the line between traditional and industrial networking, they each fulfill fundamentally differing requirements.^[4]

With increasing security demands (such as North American Electric Reliability Corporation (NERC) and Critical Infrastructure Protection (CIP) in the US), there is increasing use of satellite-based communication. This has the key advantages that the infrastructure can be self-contained (not using circuits from the public telephone system), can have built-in encryption, and can be engineered to the availability and reliability required by the SCADA system operator. Earlier experiences using consumer-grade VSAT were poor. Modern carrier-class systems provide the quality of service required for SCADA.^[5]

RTUs and other automatic controller devices were developed before the advent of industry wide standards for interoperability. The result is that developers and their management created a multitude of control protocols. Among the larger vendors, there was also the incentive to create their own protocol to "lock in" their customer base. A list of automation protocols is compiled here.

Recently, OLE for process control (OPC) has become a widely accepted solution for intercommunicating different hardware and software, allowing communication even between devices originally not intended to be part of an industrial network.

SCADA architectures

The United States Army's Training Manual 5-601 covers "SCADA Systems for C4ISR Facilities".

SCADA systems have evolved through four generations as follows:^{[6][7][8][9]}

First generation: "Monolithic"

Early SCADA system computing was done by large minicomputers. Common network services did not exist at the time SCADA was developed. Thus SCADA systems were independent systems with no connectivity to other systems. The communication protocols used were strictly proprietary at that time. The first-generation SCADA system redundancy was achieved using a back-up mainframe system connected to all the Remote Terminal Unit sites and was used in the event of failure of the primary mainframe system. Some first generation SCADA systems were developed as "turn key" operations that ran on minicomputers such as the PDP-11 series made by the Digital Equipment Corporation.

Second generation: "Distributed"

SCADA information and command processing was distributed across multiple stations which were connected through a LAN. Information was shared in near real time. Each station was responsible for a particular task thus making the size and cost of each station less than the one used in First Generation. The network protocols used were still not standardized. Since the protocols were proprietary, very few people beyond the developers knew enough to determine how secure a SCADA installation was. Security of the SCADA installation was usually overlooked.*

Third generation: "Networked"

Similar to a distributed architecture, any complex SCADA can be reduced to simplest components and connected through communication protocols. In the case of a networked design, the system may be spread across more than one LAN network called a process control network (PCN) and separated geographically. Several distributed architecture SCADAs running in parallel, with a single supervisor and historian, could be considered a network architecture. This allows for a more cost effective solution in very large scale systems.

Fourth generation: "Internet of Things"

With the commercial availability of cloud computing, SCADA systems have increasingly adopted Internet of Things technology to significantly reduce infrastructure costs and increase ease of maintenance and integration. As a result, SCADA systems can now report state in near real-time and use the horizontal scale available in cloud environments to implement more complex control algorithms than are practically feasible to implement on traditional programmable logic controllers.^[10] Further, the use of open network protocols such as TLS inherent in the Internet of Things technology, provides a more readily comprehensible and manageable security boundary than the heterogeneous mix of proprietary network protocols typical of many decentralized SCADA implementations. One such example of this technology is an innovative approach to rainwater harvesting through the implementation of real time controls (RTC).

This decentralization of data also requires a different approach to SCADA than traditional PLC based programs. When a SCADA system is used locally, the preferred methodology involves binding the graphics on the user interface to the data stored in specific PLC memory addresses. However, when the data comes from a disparate mix of sensors, controllers and databases (which may be local or at varied connected locations), the typical 1 to 1 mapping becomes problematic. A solution to this is Data Modeling, a concept derived from object oriented programming.^[11]

In a Data Model, a virtual representation of each device is constructed in the SCADA software. These virtual representations ("Models") can contain not just the address mapping of the device represented, but also any other pertinent information (web based info, database entries, media files, etc.) that may be used by other facets of the SCADA/IoT implementation. As the increased complexity of the Internet of Things renders traditional SCADA increasingly "house-bound," and as communication protocols evolve to favor platform-independent, service-oriented architecture (such as OPC UA), it is likely that more SCADA software developers will implement some form of data modeling.

SCADA Vendors

Some examples of SCADA vendors

- Siemens
- Honeywell
- Tecnomatix (USDATA)
- ABB
- Tibbo Systems (AggreGate SCADA/HMI)
- Schneider Electric (Wonderware, Televant Citect)
- Survalent Technology Company (STC)
- Rockwell Automation
- Open Systems International
- Micro-Comm (SCADAVIEW CSX)
- Emerson Process Management
- Endress & Hauser
- ReLab Software
- HAWK SCADA (www.HawkRemote.com)

Security issues

SCADA systems that tie together decentralized facilities such as power, oil, and gas pipelines and water distribution and wastewater collection systems were designed to be open, robust, and easily operated and repaired, but not necessarily secure.^[12] The move from proprietary technologies to more standardized and open solutions together with the increased number of connections between SCADA systems, office networks, and the Internet has made them more vulnerable to types of network attacks that are relatively common in computer security. For example, United States Computer Emergency Readiness Team (US-CERT) released a vulnerability advisory^[13] that allowed unauthenticated users to download sensitive configuration information including password hashes on an Inductive Automation Ignition system utilizing a standard attack type leveraging access to the Tomcat Embedded Web server. Security researcher Jerry Brown submitted a similar advisory regarding a buffer overflow vulnerability^[14] in a Wonderware InBatchClient ActiveX control. Both vendors made updates available prior to public vulnerability release. Mitigation recommendations were standard patching practices and requiring VPN access for secure connectivity. Consequently, the security of some SCADA-based systems has come into question as they are seen as potentially vulnerable to cyber attacks.^{[15][16][17]}

In particular, security researchers are concerned about:

- the lack of concern about security and authentication in the design, deployment and operation of some existing SCADA networks
- the belief that SCADA systems have the benefit of security through obscurity through the use of specialized protocols and proprietary interfaces
- the belief that SCADA networks are secure because they are physically secured
- the belief that SCADA networks are secure because they are disconnected from the Internet.

SCADA systems are used to control and monitor physical processes, examples of which are transmission of electricity, transportation of gas and oil in pipelines, water distribution, traffic lights, and other systems used as the basis of modern society. The security of these SCADA systems is important because compromise or destruction of these systems would impact multiple areas of society far removed from the original compromise. For example, a blackout caused by a compromised electrical SCADA system would cause financial losses to all the customers that received electricity from that source. How security will affect legacy SCADA and new deployments remains to be seen.

There are many threat vectors to a modern SCADA system. One is the threat of unauthorized access to the control software, whether it be human access or changes induced intentionally or accidentally by virus infections and other software threats residing on the control host machine. Another is the threat of packet access to the network segments hosting SCADA devices. In many cases, the control protocol lacks any form of cryptographic security, allowing an attacker to control a SCADA device by sending commands over a network. In many cases SCADA users have assumed that having a VPN offered sufficient protection, unaware that security can be trivially bypassed with physical access to SCADA-related network jacks and switches. Industrial control vendors suggest approaching SCADA security like Information Security with a defense in depth strategy that leverages common IT practices.^[18]

The reliable function of SCADA systems in our modern infrastructure may be crucial to public health and safety. As such, attacks on these systems may directly or indirectly threaten public health and safety. Such an attack has already occurred, carried out on Maroochy Shire Council's sewage control system in Queensland, Australia.^[19] Shortly after a contractor installed a SCADA system in January 2000, system components began to function erratically. Pumps did not run when needed and alarms were not reported. More critically, sewage flooded a nearby park and contaminated an open surface-water drainage ditch and flowed 500 meters to a tidal canal. The SCADA system was directing sewage valves to open when the design protocol should have kept them closed. Initially this was believed to be a system bug. Monitoring of the system logs revealed the malfunctions were the result of cyber attacks. Investigators reported 46 separate instances of malicious outside interference before the culprit was identified. The attacks were made by a disgruntled ex-employee of the company that had installed the SCADA system. The ex-employee was hoping to be hired by the utility full-time to maintain the system.

In April 2008, the Commission to Assess the Threat to the United States from Electromagnetic Pulse (EMP) Attack issued a Critical Infrastructures Report which discussed the extreme vulnerability of SCADA systems to an electromagnetic pulse (EMP) event. After testing and analysis, the Commission concluded: "SCADA systems are vulnerable to EMP insult. The large numbers and widespread reliance on such systems by all of the Nation's critical infrastructures represent a systemic threat to their continued operation following an EMP event. Additionally, the necessity to reboot, repair, or replace large numbers of geographically widely dispersed systems will considerably impede the Nation's recovery from such an assault."^[20]

Many vendors of SCADA and control products have begun to address the risks posed by unauthorized access by developing lines of specialized industrial firewall and VPN

solutions for TCP/IP-based SCADA networks as well as external SCADA monitoring and recording equipment. The International Society of Automation (ISA) started formalizing SCADA security requirements in 2007 with a working group, WG4. WG4 "deals specifically with unique technical requirements, measurements, and other features required to evaluate and assure security resilience and performance of industrial automation and control systems devices".^[21]

The increased interest in SCADA vulnerabilities has resulted in vulnerability researchers discovering vulnerabilities in commercial SCADA software and more general offensive SCADA techniques presented to the general security community.^[22] In electric and gas utility SCADA systems, the vulnerability of the large installed base of wired and wireless serial communications links is addressed in some cases by applying bump-in-the-wire devices that employ authentication and Advanced Encryption Standard encryption rather than replacing all existing nodes.^[23]

In June 2010, anti-virus security company VirusBlokAda reported the first detection of malware that attacks SCADA systems (Siemens' WinCC/PCS 7 systems) running on Windows operating systems. The malware is called Stuxnet and uses four zero-day attacks to install a rootkit which in turn logs into the SCADA's database and steals design and control files.^{[24][25]} The malware is also capable of changing the control system and hiding those changes. The malware was found on 14 systems, the majority of which were located in Iran.^[26]

In October 2013 National Geographic released a docudrama titled, "American Blackout" which dealt with a large-scale cyber attack on SCADA and the United States' electrical grid.

SCADA In the workplace

SCADA can be a great tool while working in an environment where operational duties need to be monitored through electronic communication instead of locally. For example, an operator can position a valve to open or close through SCADA without leaving the control station or the computer. The SCADA system also can switch a pump or motor on or off and has the capability of putting motors on a Hand operating status, Off, or Automatic. Hand refers to operating the equipment locally, while Automatic has the equipment operate according to set points the operator provides on a computer that can communicate with the equipment through SCADA.

Manufacturing Enterprise Solutions Association

Manufacturing Enterprise Solutions Association International (MESA, aka MESA International) ^[1] is a global, nonprofit community of manufacturing companies, information technology hardware and software suppliers, system integrators, consulting service providers, analysts, editors, academics and students. The shared goal of MESA members is to improve business results and production

operations through optimized application and implementation of information technology and best management practices.

MESA member companies and individuals span the full range of manufacturing from discrete to batch to mixed model to process. The association's efforts are focused on helping the manufacturing community to use information technology to provide real-time visibility into the production process.

MESA provides a variety of programs and events that work together to help manufacturers and producers to:

- Better understand what is possible in terms of information technology to improve profitability, business value, agility, and customer satisfaction
- Engage "best practices" to see what other manufacturers have done to achieve measurable success
- Approach investment decisions in technology with more information and confidence
- Learn to improve the deployment of new technology

MESA was initially founded, in 1992, to promote Manufacturing Execution Systems, its acronym and reach was later broadened to include Operations and Maintenance (O&M) and the integration of those systems with plant floor devices and control systems, as well as enterprise systems. In 2012, MESA merged with WBF (World Batch Forum), the standards organization responsible for B2MML and BatchML.

Activities

MESA members participate in and contribute to a number of activities:

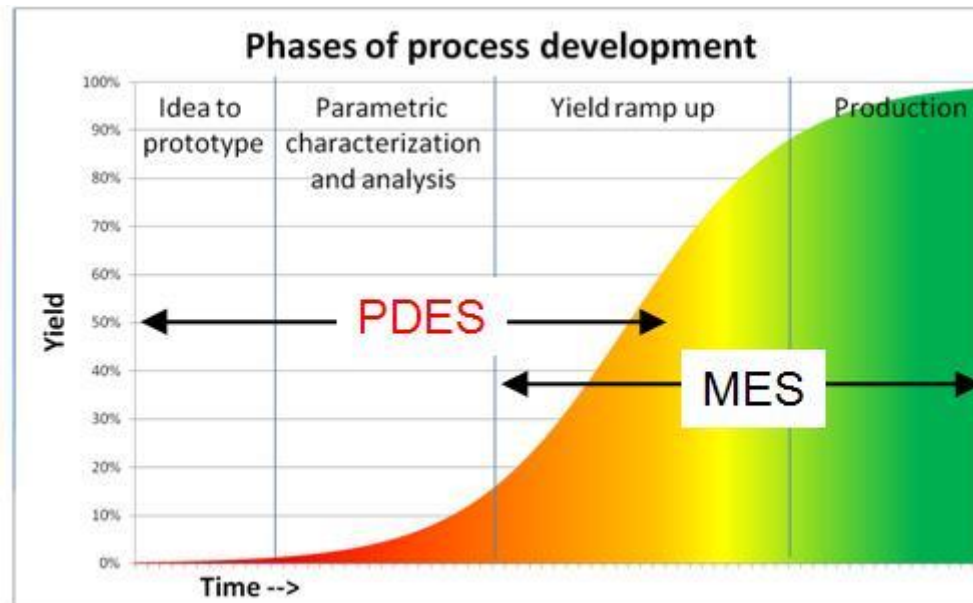
- Education
- Webcasts
- Creation of relevant content for manufacturing/enterprise integration topics (example: MESA model for manufacturing) – also link papers for MESA. Content is peer reviewed, non commercial. As an example, the following figure represents the latest version of the MESA Model (originally developed in 2008):

Process development execution system

Process development execution systems (PDES) are software systems used to guide the development of high-tech manufacturing technologies like semiconductor manufacturing, MEMS manufacturing, photovoltaics manufacturing, biomedical devices or nanoparticle manufacturing. Software systems of this kind have similarities to product lifecycle management (PLM) systems. They guide the development of new or improved technologies from its conception, through development and into manufacturing. Furthermore they borrow on concepts of manufacturing execution systems (MES) systems but tailor them for R&D rather than for production. PDES

integrate people (with different backgrounds from potentially different legal entities), data (from diverse sources), information, knowledge and business processes.

Benefits



Documented benefits of process development execution systems include:

- Reduced time to market
- Reduced amounts of experimentation
- Improved quality / more robust manufacturing process
- Reduced prototyping costs
- Savings through the re-use of original data, information and knowledge
- A framework for product optimization
- Reduced waste
- Savings through the complete integration of engineering workflows
- Ability to provide collaboration partners with access to a centralized development record

Relationships with other level 3 / level 4 systems

A **process development execution system (PDES)** is a system used by companies to perform development activities for high-tech manufacturing processes. Software systems of this kind leverage diverse concepts from other software categories like PLM, manufacturing execution system (MES), ECM but focus on tools to speed up the technology development rather than the production.

A PDES is similar to a manufacturing execution systems (MES) in several ways. The key distinguishing factor of a PDES is that it is tailored for steering the development of a manufacturing process, while MES is tailored for executing the volume production using the developed process. Therefore, the toolset and focus of a PDES is on lower volume but higher flexibility and experimentation freedom. The tools of an

MES are more focused on less variance, higher volumes, tighter control and logistics. Both types of application software increase traceability, productivity, and quality of the delivered result. For PDESs quality refers to the capability of the process to perform without failure under a wide range of conditions, i.e. the robustness of the developed manufacturing process. For MESs quality refers to the quality of the manufactured good/commodity. Additionally both software types share functions including equipment tracking, product genealogy, labour and item tracking, costing, electronic signature capture, defect and resolution monitoring, executive dashboards, and other various reporting solutions.

In contrast to PLM systems, PDES typically address the collaboration and innovation challenges with a bottom-up approach. They start-out with the details of manufacturing technologies (like PPLM), a single manufacturing step with all its physical aware parameterization and integrating steps into sequences, into devices, into systems, etc.

Other rather similar software categories are laboratory information management systems (LIMS) and laboratory information system (LIS). PDESs offer a wider set of functionalities e.g. virtual manufacturing techniques, while they are typically not integrated with the equipment in the laboratory.

PDESs have many parts and can be deployed on various scales – from simple Work in Progress tracking, to a complex solution integrated throughout an enterprise development infrastructure. The latter connects with other enterprise systems like enterprise resource and planning systems (ERPs), manufacturing execution systems (MESs), product lifecycle management (PLM), supervisory, control and data acquisition (SCADA) solutions and scheduling and planning systems (both long-term and short-term tactical).

Example: PDES usage during semiconductor device development

New ideas for manufacturing processes (for new goods/commodities or improved manufacturing) are often based on, or can at least benefit from, previous developments and recipes already in use. The same is true when developing new devices, for example, a MEMS sensor or actuator. A PDES offers an easy way to access these previous developments in a structured manner. Information can be retrieved faster, and previous results can be taken into account more efficiently. A PDES typically offers means to display and search for result data from different viewpoints, and to categorise the data according different aspects. These functionalities are applied to all result data, such as materials, process steps, machines, experiments, documents and pictures. The PDES also provides a way to relate entities belonging to the same or similar context and to explore the resulting information.

In the assembly phase from process steps to process flows, a PDES helps to easily build, store, print, and transfer new process flows. By providing access to previously assembled process flows the designer is able to use those as building blocks or

modules in the newly developed flow. The usage of standard building blocks can dramatically reduce the design time and the probability of errors.

A PDES demonstrates its real benefits in the verification phase. Knowledge (for example in the semiconductor device fabrication – clean before deposition; After polymer spin-on no temperature higher than 100 °C until resist is removed) is provided in a format that can be interpreted by a computer as rules. If a domain expert enters the rules for his/her process steps, all engineers can later use these rules to check newly developed process flows, even if the domain expert is not available. For a PDES, this means it has to be able to

1. manage rules
2. connect rules with Boolean terms (and, or, not) and
3. check process flows using these rules. This rule check verifies the principle manufacturability of a newly designed manufacturing flow.

The processing rule check gives no indication about the functionality or even the structure of the produced good or device. In the area of semiconductor device fabrication, the techniques of semiconductor process simulation / TCAD can provide an idea about the produced structures. To support this 'virtual fabrication', a PDES is able to manage simulation models for process steps. Usually the simulation results are seen as standalone data. To rectify this situation PDESs are able to manage the resulting files in combination with the process flow. This enables the engineer to easily compare the expected results with the simulated outcome. The knowledge gained from the comparison can again be used to improve the simulation model.

After virtual verification the device is produced in an experimental fabrication environment. A PDES allows a transfer of the process flow to the fabrication environment (for example in semiconductor: FAB). This can be done by simply printing out a runcard for the operator or by interfacing to the Manufacturing Execution Systems (MES) of the facility. On the other hand a PDES is able to manage and document last minute changes to the flow like parameter adjustments during the fabrication. During and after processing a lot of measurements are taken. The results of these measurements are often produced in the form of files such as images or simple text files containing rows and columns of data. The PDES is able to manage these files, to link related results together, and to manage different versions of certain files, for example reports. Paired with flexible text, and graphical retrieval and search methods, a PDES provides the mechanism to view and assess the accumulated data, information and knowledge from different perspectives. It provides insight into both the information aspects as well as the time aspects of previous developments.

Development activities within high tech industries are an increasingly collaborative effort. This leads to the need to exchange information between the partners or to transfer process intellectual property from a vendor to a customer. PDESs' support this transfer while being selective to protect the IPR of the company.

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Open Platform Communications (OPC) is a series of standards and specifications for industrial telecommunication. An industrial automation industry task force developed the original standard in 1996 under the name OLE for Process Control (Object Linking and Embedding for Process Control). OPC specifies the communication of real-time plant data between control devices from different manufacturers.

After the initial release in 1996, the OPC Foundation was created to maintain the standard.[1] As OPC has been adopted beyond the field of process control, the OPC Foundation changed the name to Open Platform Communications in 2011.[2] The change in name reflects the applications of OPC technology for applications in building automation, discrete manufacturing, process control and many others. OPC has also grown beyond its original OLE (Object Linking and Embedding) implementation to include other data transportation technologies including Microsoft's .NET Framework, XML, and even the OPC Foundation's binary-encoded TCP format.

The OPC Specification was based on the OLE, COM, and DCOM technologies developed by Microsoft for the Microsoft Windows operating system family. The specification defined a standard set of objects, interfaces and methods for use in process control and manufacturing automation applications to facilitate interoperability. The most common OPC specification is OPC Data Access, which is used to read and write real-time data. When vendors refer to OPC generically, they typically mean OPC Data Access (OPC DA). OPC DA itself has gone through three major revisions since its inception. Versions are backwards compatible, in that a version 3 OPC Server can still be accessed by a version 1 OPC Client, since the specifications add functionality, but still require the older version to be implemented as well. However, a Client could be written that does not support the older functions since everything can be done using the newer ones, so a DA-3-compatible Client will not necessarily work with a DA 1.0 Server.



Programmable logic controller

Siemens Simatic S7-400 system in a rack, left-to-right: power supply unit (PS), CPU, interface module (IM) and communication processor (CP).

A **programmable logic controller, PLC**, or **programmable controller** is a digital computer used for automation of typically industrial electromechanical processes, such as control of machinery on factory assembly lines, amusement rides, or light fixtures. PLCs are used in many machines, in many industries. PLCs are designed for multiple arrangements of digital and analog inputs and outputs, extended temperature ranges, immunity to electrical noise, and resistance to vibration and impact. Programs to control machine operation are typically stored in battery-backed-up or non-volatile memory. A PLC is an example of a "hard" real-time system since output results must be produced in response to input conditions within a limited time, otherwise unintended operation will result.

Before the PLC, control, sequencing, and safety interlock logic for manufacturing automobiles was mainly composed of relays, cam timers, drum sequencers, and dedicated closed-loop controllers. Since these could number in the hundreds or even thousands, the process for updating such facilities for the yearly model change-over was very time consuming and expensive, as electricians needed to individually rewire the relays to change their operational characteristics.

Digital computers, being general-purpose programmable devices, were soon applied to control of industrial processes. Early computers required specialist programmers, and stringent operating environmental control for temperature, cleanliness, and power quality. Using a general-purpose computer for process control required protecting the computer from the plant floor conditions. An industrial control computer would have several attributes: it would tolerate the shop-floor environment, it would support

discrete (bit-form) input and output in an easily extensible manner, it would not require years of training to use, and it would permit its operation to be monitored. The response time of any computer system must be fast enough to be useful for control; the required speed varying according to the nature of the process.^[1] Since many industrial processes have timescales easily addressed by millisecond response times, modern (fast, small, reliable) electronics greatly facilitate building reliable controllers, especially because performance can be traded off for reliability.

In 1968 GM Hydra-Matic (the automatic transmission division of General Motors) issued a request for proposals for an electronic replacement for hard-wired relay systems based on a white paper written by engineer Edward R. Clark. The winning proposal came from Bedford Associates of Bedford, Massachusetts. The first PLC, designated the 084 because it was Bedford Associates' eighty-fourth project, was the result.^[2] Bedford Associates started a new company dedicated to developing, manufacturing, selling, and servicing this new product: Modicon, which stood for **MODular DIGital CONtroller**. One of the people who worked on that project was Dick Morley, who is considered to be the "father" of the PLC.^[3] The Modicon brand was sold in 1977 to Gould Electronics, later acquired by German Company AEG, and then by French Schneider Electric, the current owner.

One of the very first 084 models built is now on display at Modicon's headquarters in North Andover, Massachusetts. It was presented to Modicon by GM, when the unit was retired after nearly twenty years of uninterrupted service. Modicon used the 84 moniker at the end of its product range until the 984 made its appearance.

The automotive industry is still one of the largest users of PLCs.

Development

Early PLCs were designed to replace relay logic systems. These PLCs were programmed in "ladder logic", which strongly resembles a schematic diagram of relay logic. This program notation was chosen to reduce training demands for the existing technicians. Other early PLCs used a form of instruction list programming, based on a stack-based logic solver.

Modern PLCs can be programmed in a variety of ways, from the relay-derived ladder logic to programming languages such as specially adapted dialects of BASIC and C. Another method is state logic, a very high-level programming language designed to program PLCs based on state transition diagrams.

Many early PLCs did not have accompanying programming terminals that were capable of graphical representation of the logic, and so the logic was instead represented as a series of logic expressions in some version of Boolean format, similar to Boolean algebra. As programming terminals evolved, it became more common for ladder logic to be used, for the aforementioned reasons and because it was a familiar format used for electromechanical control panels. Newer formats such as state logic and Function Block (which is similar to the way logic is depicted when using digital integrated logic circuits) exist, but they are still not as popular as ladder logic. A primary reason for this is that PLCs solve the logic in a predictable and repeating

sequence, and ladder logic allows the programmer (the person writing the logic) to see any issues with the timing of the logic sequence more easily than would be possible in other formats.

Programming

Early PLCs, up to the mid-1990s, were programmed using proprietary programming panels or special-purpose programming terminals, which often had dedicated function keys representing the various logical elements of PLC programs.^[2] Some proprietary programming terminals displayed the elements of PLC programs as graphic symbols, but plain ASCII character representations of contacts, coils, and wires were common. Programs were stored on cassette tape cartridges. Facilities for printing and documentation were minimal due to lack of memory capacity. The oldest PLCs used non-volatile magnetic core memory.

More recently, PLCs are programmed using application software on personal computers, which now represent the logic in graphic form instead of character symbols. The computer is connected to the PLC through Ethernet, RS-232, RS-485, or RS-422 cabling. The programming software allows entry and editing of the ladder-style logic. Generally the software provides functions for debugging and troubleshooting the PLC software, for example, by highlighting portions of the logic to show current status during operation or via simulation. The software will upload and download the PLC program, for backup and restoration purposes. In some models of programmable controller, the program is transferred from a personal computer to the PLC through a programming board which writes the program into a removable chip such as an EPROM

Functionality

The functionality of the PLC has evolved over the years to include sequential relay control, motion control, process control, distributed control systems, and networking. The data handling, storage, processing power, and communication capabilities of some modern PLCs are approximately equivalent to desktop computers. PLC-like programming combined with remote I/O hardware, allow a general-purpose desktop computer to overlap some PLCs in certain applications. Desktop computer controllers have not been generally accepted in heavy industry because the desktop computers run on less stable operating systems than do PLCs, and because the desktop computer hardware is typically not designed to the same levels of tolerance to temperature, humidity, vibration, and longevity as the processors used in PLCs. Operating systems such as Windows do not lend themselves to deterministic logic execution, with the result that the controller may not always respond to changes of input status with the consistency in timing expected from PLCs. Desktop logic applications find use in less critical situations, such as laboratory automation and use in small facilities where the application is less demanding and critical, because they are generally much less expensive than PLCs. ^[citation needed]

Programmable logic relay (PLR)

In more recent years, small products called PLRs (programmable logic relays), and also by similar names, have become more common and accepted. These are much like PLCs, and are used in light industry where only a few points of I/O (i.e. a few signals coming in from the real world and a few going out) are needed, and low cost is desired. These small devices are typically made in a common physical size and shape by several manufacturers, and branded by the makers of larger PLCs to fill out their low end product range. Popular names include PICO Controller, NANO PLC, and other names implying very small controllers. Most of these have 8 to 12 discrete inputs, 4 to 8 discrete outputs, and up to 2 analog inputs. Size is usually about 4" wide, 3" high, and 3" deep. Most such devices include a tiny postage-stamp-sized LCD screen for viewing simplified ladder logic (only a very small portion of the program being visible at a given time) and status of I/O points, and typically these screens are accompanied by a 4-way rocker push-button plus four more separate push-buttons, similar to the key buttons on a VCR remote control, and used to navigate and edit the logic. Most have a small plug for connecting via RS-232 or RS-485 to a personal computer so that programmers can use simple Windows applications for programming instead of being forced to use the tiny LCD and push-button set for this purpose. Unlike regular PLCs that are usually modular and greatly expandable, the PLRs are usually not modular or expandable, but their price can be two orders of magnitude less than a PLC, and they still offer robust design and deterministic execution of the logics.

PLC topics

The main difference from other computers is that PLCs are armored for severe conditions (such as dust, moisture, heat, cold), and have the facility for extensive input/output (I/O) arrangements. These connect the PLC to sensors and actuators. PLCs read limit switches, analog process variables (such as temperature and pressure), and the positions of complex positioning systems. Some use machine vision.^[4] On the actuator side, PLCs operate electric motors, pneumatic or hydraulic cylinders, magnetic relays, solenoids, or analog outputs. The input/output arrangements may be built into a simple PLC, or the PLC may have external I/O modules attached to a computer network that plugs into the PLC.

Scan time

A PLC program is generally executed repeatedly as long as the controlled system is running. The status of physical input points is copied to an area of memory accessible to the processor, sometimes called the "I/O Image Table". The program is then run from its first instruction rung down to the last rung. It takes some time for the processor of the PLC to evaluate all the rungs and update the I/O image table with the status of outputs.^[5] This scan time may be a few milliseconds for a small program or on a fast processor, but older PLCs running very large programs could take much longer (say, up to 100 ms) to execute the program. If the scan time were too long, the response of the PLC to process conditions would be too slow to be useful.

As PLCs became more advanced, methods were developed to change the sequence of ladder execution, and subroutines were implemented.^[6] This simplified programming could be used to save scan time for high-speed processes; for example, parts of the

program used only for setting up the machine could be segregated from those parts required to operate at higher speed.

Special-purpose I/O modules may be used where the scan time of the PLC is too long to allow predictable performance. Precision timing modules, or counter modules for use with shaft encoders, are used where the scan time would be too long to reliably count pulses or detect the sense of rotation of an encoder. The relatively slow PLC can still interpret the counted values to control a machine, but the accumulation of pulses is done by a dedicated module that is unaffected by the speed of the program execution.

System scale

A small PLC will have a fixed number of connections built in for inputs and outputs. Typically, expansions are available if the base model has insufficient I/O.

Modular PLCs have a chassis (also called a rack) into which are placed modules with different functions. The processor and selection of I/O modules are customized for the particular application. Several racks can be administered by a single processor, and may have thousands of inputs and outputs. Either a special high speed serial I/O link or comparable communication method is used so that racks can be distributed away from the processor, reducing the wiring costs for large plants. Options are also available to mount I/O points directly to the machine and utilize quick disconnecting cables to sensors and valves, saving time for wiring and replacing components.

User interface

PLCs may need to interact with people for the purpose of configuration, alarm reporting, or everyday control. A human-machine interface (HMI) is employed for this purpose. HMIs are also referred to as man-machine interfaces (MMIs) and graphical user interfaces (GUIs). A simple system may use buttons and lights to interact with the user. Text displays are available as well as graphical touch screens. More complex systems use programming and monitoring software installed on a computer, with the PLC connected via a communication interface.

Communications

PLCs have built-in communications ports, usually 9-pin RS-232, RS-422, rs-485, Ethernet. Various protocols are usually included. Many of these protocols are vendor specific.

Most modern PLCs can communicate over a network to some other system, such as a computer running a SCADA (Supervisory Control And Data Acquisition) system or web browser.

PLCs used in larger I/O systems may have peer-to-peer (P2P) communication between processors. This allows separate parts of a complex process to have individual control while allowing the subsystems to co-ordinate over the

communication link. These communication links are also often used for HMI devices such as keypads or PC-type workstations.

Formerly, some manufacturers offered dedicated communication modules as an add-on function where the processor had no network connection built-in.

Programming

PLC programs are typically written in a special application on a personal computer, then downloaded by a direct-connection cable or over a network to the PLC. The program is stored in the PLC either in battery-backed-up RAM or some other non-volatile flash memory. Often, a single PLC can be programmed to replace thousands of relays.^[7]

Under the IEC 61131-3 standard, PLCs can be programmed using standards-based programming languages. A graphical programming notation called Sequential Function Charts is available on certain programmable controllers. Initially most PLCs utilized Ladder Logic Diagram Programming, a model which emulated electromechanical control panel devices (such as the contact and coils of relays) which PLCs replaced. This model remains common today.

IEC 61131-3 currently defines five programming languages for programmable control systems: function block diagram (FBD), ladder diagram (LD), structured text (ST; similar to the Pascal programming language), instruction list (IL; similar to assembly language), and sequential function chart (SFC).^[8] These techniques emphasize logical organization of operations.^[7]

While the fundamental concepts of PLC programming are common to all manufacturers, differences in I/O addressing, memory organization, and instruction sets mean that PLC programs are never perfectly interchangeable between different makers. Even within the same product line of a single manufacturer, different models may not be directly compatible.

Security

Prior to the discovery of the Stuxnet computer worm in June 2010, security of PLCs received little attention. PLCs generally contain a real-time operating system such as OS-9 or VxWorks, and exploits for these systems exist much as they do for desktop computer operating systems such as Microsoft Windows. PLCs can also be attacked by gaining control of a computer they communicate with.^[9]

Simulation



PLCLogix PLC Simulation Software

In order to properly understand the operation of a PLC, it is necessary to spend considerable time programming, testing, and debugging PLC programs. PLC systems are inherently expensive, and down-time is often very costly. In addition, if a PLC is programmed incorrectly it can result in lost productivity and dangerous conditions. PLC simulation software such as PLCLogix can save time in the design of automated control applications and can also increase the level of safety associated with equipment since various "what if" scenarios can be tried and tested before the system is activated.^[10]

Redundancy

Some special processes need to work permanently with minimum unwanted down time. Therefore, it is necessary to design a system which is fault-tolerant and capable of handling the process with faulty modules. In such cases to increase the system availability in the event of hardware component failure, redundant CPU or I/O modules with the same functionality can be added to hardware configuration for preventing total or partial process shutdown due to hardware failure.

PLC compared with other control systems



Allen-Bradley PLC installed in a control panel

PLCs are well adapted to a range of automation tasks. These are typically industrial processes in manufacturing where the cost of developing and maintaining the automation system is high relative to the total cost of the automation, and where changes to the system would be expected during its operational life. PLCs contain input and output devices compatible with industrial pilot devices and controls; little electrical design is required, and the design problem centers on expressing the desired sequence of operations. PLC applications are typically highly customized systems, so the cost of a packaged PLC is low compared to the cost of a specific custom-built controller design. On the other hand, in the case of mass-produced goods, customized control systems are economical. This is due to the lower cost of the components,

which can be optimally chosen instead of a "generic" solution, and where the non-recurring engineering charges are spread over thousands or millions of units.

For high volume or very simple fixed automation tasks, different techniques are used. For example, a consumer dishwasher would be controlled by an electromechanical cam timer costing only a few dollars in production quantities.

A microcontroller-based design would be appropriate where hundreds or thousands of units will be produced and so the development cost (design of power supplies, input/output hardware, and necessary testing and certification) can be spread over many sales, and where the end-user would not need to alter the control. Automotive applications are an example; millions of units are built each year, and very few end-users alter the programming of these controllers. However, some specialty vehicles such as transit buses economically use PLCs instead of custom-designed controls, because the volumes are low and the development cost would be uneconomical.^[11]

Very complex process control, such as used in the chemical industry, may require algorithms and performance beyond the capability of even high-performance PLCs. Very high-speed or precision controls may also require customized solutions; for example, aircraft flight controls. Single-board computers using semi-customized or fully proprietary hardware may be chosen for very demanding control applications where the high development and maintenance cost can be supported. "Soft PLCs" running on desktop-type computers can interface with industrial I/O hardware while executing programs within a version of commercial operating systems adapted for process control needs.^[11]

Programmable controllers are widely used in motion control, positioning control, and torque control. Some manufacturers produce motion control units to be integrated with PLC so that G-code (involving a CNC machine) can be used to instruct machine movements.^[citation needed]

PLCs may include logic for single-variable feedback analog control loop, a proportional, integral, derivative (PID) controller. A PID loop could be used to control the temperature of a manufacturing process, for example. Historically PLCs were usually configured with only a few analog control loops; where processes required hundreds or thousands of loops, a distributed control system (DCS) would instead be used. As PLCs have become more powerful, the boundary between DCS and PLC applications has become less distinct.

PLCs have similar functionality as remote terminal units (RTU). An RTU, however, usually does not support control algorithms or control loops. As hardware rapidly becomes more powerful and cheaper, RTUs, PLCs, and DCSs are increasingly beginning to overlap in responsibilities, and many vendors sell RTUs with PLC-like features, and vice versa. The industry has standardized on the IEC 61131-3 functional block language for creating programs to run on RTUs and PLCs, although nearly all vendors also offer proprietary alternatives and associated development environments.

In recent years "safety" PLCs have started to become popular, either as standalone models or as functionality and safety-rated hardware added to existing controller architectures (Allen Bradley Guardlogix, Siemens F-series etc.). These differ from

conventional PLC types as being suitable for use in safety-critical applications for which PLCs have traditionally been supplemented with hard-wired safety relays. For example, a safety PLC might be used to control access to a robot cell with trapped-key access, or perhaps to manage the shutdown response to an emergency stop on a conveyor production line. Such PLCs typically have a restricted regular instruction set augmented with safety-specific instructions designed to interface with emergency stops, light screens, and so forth. The flexibility that such systems offer has resulted in rapid growth of demand for these controllers.

Discrete and analog signals

Discrete signals behave as binary switches, yielding simply an On or Off signal (1 or 0, True or False, respectively). Push buttons, limit switches, and photoelectric sensors are examples of devices providing a discrete signal. Discrete signals are sent using either voltage or current, where a specific range is designated as *On* and another as *Off*. For example, a PLC might use 24 V DC I/O, with values above 22 V DC representing *On*, values below 2VDC representing *Off*, and intermediate values undefined. Initially, PLCs had only discrete I/O.

Analog signals are like volume controls, with a range of values between zero and full-scale. These are typically interpreted as integer values (counts) by the PLC, with various ranges of accuracy depending on the device and the number of bits available to store the data. As PLCs typically use 16-bit signed binary processors, the integer values are limited between -32,768 and +32,767. Pressure, temperature, flow, and weight are often represented by analog signals. Analog signals can use voltage or current with a magnitude proportional to the value of the process signal. For example, an analog 0 to 10 V or 4-20 mA input would be converted into an integer value of 0 to 32767.

Current inputs are less sensitive to electrical noise (e.g. from welders or electric motor starts) than voltage inputs.

Example

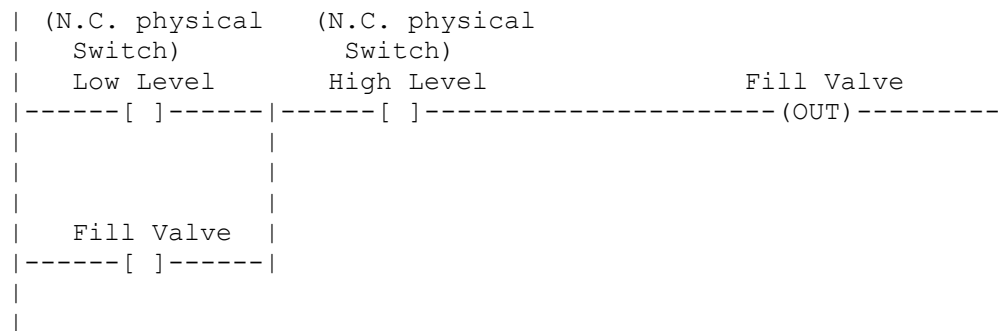
As an example, say a facility needs to store water in a tank. The water is drawn from the tank by another system, as needed, and our example system must manage the water level in the tank by controlling the valve that refills the tank. Shown is a "ladder diagram" which shows the control system. A ladder diagram is a method of drawing control circuits which pre-dates PLCs. The ladder diagram resembles the schematic diagram of a system built with electromechanical relays. Shown are:

- Two inputs (from the low and high level switches) represented by contacts of the float switches
- An output to the fill valve, labelled as the fill valve which it controls
- An "internal" contact, representing the output signal to the fill valve which is created in the program.
- A logical control scheme created by the interconnection of these items in software

In ladder diagram, the contact symbols represent the state of bits in processor memory, which corresponds to the state of physical inputs to the system. If a discrete input is energized, the memory bit is a 1, and a "normally open" contact controlled by that bit will pass a logic "true" signal on to the next element of the ladder. Therefore, the contacts in the PLC program that "read" or look at the physical switch contacts in this case must be "opposite" or open in order to return a TRUE for the closed physical switches. Internal status bits, corresponding to the state of discrete outputs, are also available to the program.

In the example, the physical state of the float switch contacts must be considered when choosing "normally open" or "normally closed" symbols in the ladder diagram. The PLC has two discrete inputs from float switches (Low Level and High Level). Both float switches (normally closed) open their contacts when the water level in the tank is above the physical location of the switch.

When the water level is below both switches, the float switch physical contacts are both closed, and a true (logic 1) value is passed to the Fill Valve output. Water begins to fill the tank. The internal "Fill Valve" contact latches the circuit so that even when the "Low Level" contact opens (as the water passes the lower switch), the fill valve remains on. Since the High Level is also normally closed, water continues to flow as the water level remains between the two switch levels. Once the water level rises enough so that the "High Level" switch is off (opened), the PLC will shut the inlet to stop the water from overflowing; this is an example of seal-in (latching) logic. The output is sealed in until a high level condition breaks the circuit. After that the fill valve remains off until the level drops so low that the Low Level switch is activated, and the process repeats again.



A complete program may contain thousands of rungs, evaluated in sequence. Typically the PLC processor will alternately scan all its inputs and update outputs, then evaluate the ladder logic; input changes during a program scan will not be effective until the next I/O update. A complete program scan may take only a few milliseconds, much faster than changes in the controlled process.

Programmable controllers vary in their capabilities for a "rung" of a ladder diagram. Some only allow a single output bit. There are typically limits to the number of series contacts in line, and the number of branches that can be used. Each element of the rung is evaluated sequentially. If elements change their state during evaluation of a rung, hard-to-diagnose faults can be generated, although sometimes (as above) the technique is useful. Some implementations forced evaluation from left-to-right as

displayed and did not allow reverse flow of a logic signal (in multi-branched rungs) to affect the output.

In addition OPC DA specification, the OPC Foundation also maintains the OPC HDA (Historical Data Access) specification. In contrast to the real time data that is accessible with OPC DA, OPC HDA allows access and retrieval of archived data.

Next, you have the OPC AE specification. This OPC AE (Alarms & Events) is also maintained by the OPC Foundation. The OPC A&E specification defines the exchange of alarm and event type message information, as well as variable states and state management.

OPC was designed to provide a common bridge for Windows-based software applications and process control hardware. Standards define consistent methods of accessing field data from plant floor devices. This method remains the same regardless of the type and source of data. An OPC Server for one hardware device provides the same methods for an OPC Client to access its data as any and every other OPC Server for that same and any other hardware device. The aim was to reduce the amount of duplicated effort required from hardware manufacturers and their software partners, and from the SCADA and other HMI producers in order to interface the two. Once a hardware manufacturer had developed their OPC Server for the new hardware device their work was done to allow any 'top end' to access their device, and once the SCADA producer had developed their OPC Client their work was done to allow access to any hardware, existing or yet to be created, with an OPC compliant server.

OPC servers provide a method for many different software packages (so long as it is an OPC Client) to access data from a process control device, such as a PLC or DCS. Traditionally, any time a package needed access to data from a device, a custom interface, or driver, had to be written. The purpose of OPC is to define a common interface that is written once and then reused by any business, SCADA, HMI, or custom software packages.

There is nothing in the OPC specifications to restrict the server to providing access to a process control device. OPC Servers can be written for anything from getting the internal temperature of a microprocessor to the current temperature in Monument Valley.

Once an OPC Server is written for a particular device, it can be reused by any application that is able to act as an OPC client. OPC servers use Microsoft's OLE technology (also known as the Component Object Model, or COM) to communicate with clients. COM technology permits a standard for real-time information exchange between software applications and process hardware to be defined.

It is important to note that some OPC specifications are published, others are available only to members of the OPC Foundation. So whilst no company "owns" OPC and anyone can develop an OPC server, whether or not they are a member of the OPC Foundation, non-members will not necessarily be using the latest specifications. Anyone can integrate OPC products, and there is no pre-requisite for the system integrator to belong to any organization. It is therefore up to each company that requires OPC products to ensure that their products are certified and that their system integrators have the necessary training.

OPC Unified Architecture

The OPC Unified Architecture (UA) has been specified and is being tested and implemented through its Early Adopters program. It can be implemented with Java, Microsoft .NET, or C,

eliminating the need to use a Microsoft-Windows-based platform of earlier OPC versions. UA combines the functionality of the existing OPC interfaces with new technologies such as XML and Web Services to deliver higher level MES and ERP support.

On September 16, 2010, The OPC Foundation and the MTConnect Institute announced a cooperation to ensure interoperability and consistency between the two standards.[3]

Performance indicator

A **performance indicator** or **key performance indicator (KPI)** is a type of performance measurement.^[1] KPIs evaluate the success of an organization or of a particular activity in which it engages. Often success is simply the repeated, periodic achievement of some levels of operational goal (e.g. zero defects, 10/10 customer satisfaction, etc.), and sometimes success is defined in terms of making progress toward strategic goals.^[2] Accordingly, choosing the right KPIs relies upon a good understanding of what is important to the organization.^[3] 'What is important' often depends on the department measuring the performance - e.g. the KPIs useful to finance will really differ from the KPIs assigned to sales. Since there is a need to understand well what is important, various techniques to assess the present state of the business, and its key activities, are associated with the selection of performance indicators. These assessments often lead to the identification of potential improvements, so performance indicators are routinely associated with 'performance improvement' initiatives. A very common way to choose KPIs is to apply a management framework such as the balanced scorecard.

Categorization of indicators

There are four types of performance measures, which fall into two groups:

- **Result Indicators (RIs) / Key Result Indicators (KRIs):** they reflect the fact that many measures are a summation of more than one team's input. These measures are useful in looking at the combined teamwork but do not help management fix a problem as it is difficult to pinpoint which teams were responsible for the performance or nonperformance.
- **Performance Indicators (PIs) / Key Performance Indicators (KPIs):** they are measures that can be tied to a team or a cluster of teams working closely together for a common purpose. Good or bad performance is now the responsibility of one team: these measures thus give clarity and ownership. ^[4]

KPIs represent a set of measures focusing on those aspects of organizational performance that are the most critical for the current and future success of the organization. KPIs are rarely new to the organization. Either they have not been recognized or they were gathering dust somewhere unknown to the current management team.^[5]

Case Study: How an airline was turned around by one KPI

KPI story is about a senior official, who set about turning around British Airways (BA) in the 1980s, reportedly by concentrating on one KPI. The senior official employed some consultants to investigate and report on the key measures he should concentrate on to turn around the ailing airline. They identified one critical success factor (CSF), the timely arrival and departure of airplanes. (Finding CSFs and narrowing them down to no more than five to eight is a vital step in any KPI exercise, and one seldom performed.) While everybody in the airline industry knows the importance of timely planes, the consultants nevertheless pointed out that this is where the KPIs lay and proposed that he focus on a late plane KPI. The senior official arranged to be notified whenever a BA plane was delayed over a certain time and the BA managers at the relevant airport knew that if a plane was delayed beyond a certain threshold, they would receive a personal call from the senior official based around Blanchard's one-minute manager reprimand. Whatever the excuse is, quite frankly, was not good enough. The senior BA official would point out that the manager had over six hours of advance notice that the plane was already late and needed to use this window of opportunity to take actions that would bring the plane back on time. Prior to the "personal call policy," the airport manager (and many other airline employees) had the "not our fault" syndrome. A late plane created by another BA team was "their problem, not ours." But after receiving the personal call from the senior official, the airport manager undertook many proactive steps to recapture lost time, no matter who had created the delay. Actions included:

- Doubling up the cleaning crew, even though there was an additional external cost to this;
- Communicating to the refueling team which planes were a priority;
- Providing the external caterers with late plane updates so they could better manage re-equipping the late plane;
- Asking staff on the check-in counters to watch for at-risk customers and escort them to the gate;
- Not allowing the business-class passengers to check in late, as was previously allowed;
- Possibly asking traffic control for a favor or two.

It was not long before BA planes had a reputation for leaving on time. The late planes KPI was linked to many other critical success factors for the airline including the 'delivery in full and on time' critical success factor, the 'timely arrival and departure of airplanes'; the 'increase repeat business from key customers' critical success factor, etc. The late planes KPI affected many aspects of the business. Late planes:

1. Increased costs, including additional airport surcharges and the cost of accommodating passengers overnight as a result of planes being curfewed due to late-night noise restrictions.
2. Increased customer dissatisfaction and alienated people meeting passengers at their destination (possible future customers).
3. Increased ozone depletion (environmental impact) because additional fuel was used in order to make up time during the flight.

4. Hurt staff development as they learned to replicate the bad habits that created late planes.
5. Adversely affected supplier relationships and servicing schedules, resulting in poor service quality.
6. Increased employee dissatisfaction, as they were constantly dealing with crises and with frustrated customers.^{[6][7]}

The seven characteristics of effective KPIs

Following extensive analysis and discussions with over 3,000 participants in KPI workshops, covering most organization types in both public and private sectors, facilitator David Parmenter defined seven characteristics of effective KPIs:^[8]

<i>Non-Financial</i>	They are non-financial measures (not expressed in dollars, yen, pounds, Euro, etc.)
<i>Timely</i>	They are measured frequently (e.g., 24/7, daily or weekly)
<i>CEO focus</i>	They are acted upon by the CEO and senior management team
<i>Simple</i>	All staff understand the measure and what corrective action is required
<i>Team-based</i>	Responsibility can be assigned to a team or a cluster of teams who work closely together
<i>Significant impact</i>	They affect more than one of the organization's top Critical Success Factors and more than one balanced scorecard perspective
<i>Limited dark side</i>	They encourage appropriate action - i.e., they have been tested to ensure they have a positive impact on performance (whereas poorly thought through measures can lead to dysfunctional behaviour)

Identifying indicators of organization

Performance indicators differ from business drivers and aims (or goals). A school might consider the failure rate of its students as a key performance indicator which might help the school understand its position in the educational community, whereas a business might consider the percentage of income from returning customers as a potential KPI.

The key stages in identifying KPIs are:

- Having a pre-defined business process (BP).
- Having requirements for the BPs.
- Having a quantitative/qualitative measurement of the results and comparison with set goals.
- Investigating variances and tweaking processes or resources to achieve short-term goals.

Key performance indicators (KPIs) are ways to periodically assess the performances of organizations, business units, and their division, departments and employees. Accordingly, KPIs are most commonly defined in a way that is understandable, meaningful, and measurable. They are rarely defined in such a way such that their

fulfillment would be hampered by factors seen as non-controllable by the organizations or individuals responsible. Such KPIs are usually ignored by organizations.^[citation needed]

A KPI can follow the SMART criteria. This means the measure has a **S**pecific purpose for the business, it is **M**easurable to really get a value of the KPI, the defined norms have to be **A**chievable, the improvement of a KPI has to be **R**elevant to the success of the organization, and finally it must be **T**ime phased, which means the value or outcomes are shown for a predefined and relevant period.^[citation needed]

In order to be evaluated, KPIs are linked to target values, so that the value of the measure can be assessed as meeting expectations or not.

Unintended consequences – the dark side of performance measures

Every performance measure has a dark side, an unintended negative consequence. The importance of understanding this dark side and the careful selection of measures should never be underestimated. David Parmenter has stated that well over half the measures in an organization may be encouraging unintended behavior. The frequency with which measures are set to fail by at best naïve or at worst corrupt management is breathtaking.^[9]

As Dean Spitzer says “People will do what management inspects, not necessarily what management expects”

How performance measures can go wrong can be illustrated by two examples:

1. Late train measure backfires

A classic example is provided by a city train service that had an on-time measure with some draconian penalties targeted at the train drivers. The drivers who were behind schedule learned simply to stop at the top end of each station, triggering the green light at the other end of the platform, and then continue the journey without the delay of letting passengers on or off. After a few stations, a driver was back on time, but the customers, both on the train and on the platform, were not so happy. Management needed to realize that late trains are not caused by train drivers, just as late planes are not caused by pilots. Lesson: Management should have been focusing on controllable events that led to late trains, such as the timeliness of investigating signal faults reported by drivers or preventative maintenance on critical equipment that is running behind schedule.^[10]

2. Timeliness of treatment measure fails in accident and emergency department

Managers at a hospital in the United Kingdom were concerned about the time it was taking to treat patients in the accident and emergency department. They decided to measure the time from patient registration to being seen by a house doctor. Staff realized that they could not stop patients registering with minor sports injuries but

they could delay the registration of patients in ambulances as they were receiving good care from the paramedics. The nursing staff thus began asking the paramedics to leave their patients in the ambulance until a house doctor was ready to see them, thus improving the "average" time it took to treat patients. Each day there would be a parking lot full of ambulances and some even circling the hospital awaiting a parking spot. Lesson: Management should have been focusing on the timeliness of treatment of critical patients. Thus, they only needed to measure the time from registration to consultation of these critical patients. Nurses would have treated patients in ambulances as a priority, the very thing they were doing before the measures came into being.^[11]

There needs to be a new approach to measurement — one that is done by trained staff, an approach that is consultative, promotes partnership between staff and management, and finally achieves alignment with the organization's critical success factors and strategic direction.

Dean Spitzer, an expert on performance measurement, has suggested the appointment of a chief measurement officer who would be part psychologist, part teacher, part salesman and part project manager. The chief measurement officer would be responsible for setting all performance measures, assessing of the potential 'dark side' of a given measure, abandoning broken measures and leading all balanced scorecard initiatives.^{[12][13]}

KPI examples

Some examples are:

1. New customers acquisition.
2. Demographic analysis of individuals (potential customers) applying to become customers, and the levels of approval, rejections, and pending numbers
3. Status of existing customers
4. Customer attrition
5. Turnover (i.e., revenue) generated by segments of the customer population
6. Outstanding balances held by segments of customers and terms of payment
7. Collection of bad debts within customer relationships
8. Profitability of customers by demographic segments and segmentation of customers by profitability

Many of these customer KPIs are developed and managed with customer relationship management software.

Faster availability of data is a competitive issue for most organizations. For example, businesses which have higher operational/credit risk (involving for example credit cards or wealth management) may want weekly or even daily availability of KPI analysis, facilitated by appropriate IT systems and tools.

Manufacturing

Overall equipment effectiveness, is a set of broadly accepted non-financial metrics which reflect manufacturing success.

- **OEE** = Availability x Performance x Quality
- **Availability** = Run Time / Total Time

By Definition: Percentage of the actual amount of production time the machine is running to the production time the machine is available.

- **Performance** = Total Count / Target Counter

By Definition: Percentage of total parts produced on the machine to the production rate of machine.

- **Quality** = Good Count / Total Count

By Definition: Percentage of good parts out of the total parts produced on the machine.

- **Cycle Time** – Cycle time is the total time from the beginning to the end of your process, as defined by you and your customer. Cycle time includes process time, during which a unit is acted upon to bring it closer to an output, and delay time, during which a unit of work is spent waiting to take the next action.
- **Cycle Time Ratio (CTR)** – $CTR = \text{Standard Cycle Time} / \text{Real Cycle Time}$
- Utilization
- Rejection rate

Supply chain management

Businesses can utilize KPIs to establish and monitor progress toward a variety of goals, including lean manufacturing objectives, minority business enterprise and diversity spending, environmental "green" initiatives, cost avoidance programs and low-cost country sourcing targets.

Any business, regardless of size, can better manage supplier performance with the help of KPIs robust capabilities, which include:

- Automated entry and approval functions
- On-demand, real-time scorecard measures
- Rework on procured inventory
- Single data repository to eliminate inefficiencies and maintain consistency
- Advanced workflow approval process to ensure consistent procedures
- Flexible data-input modes and real-time graphical performance displays
- Customized cost savings documentation
- Simplified setup procedures to eliminate dependence upon IT resources

Main SCM KPIs will detail the following processes:

- Sales forecasts

- Inventory
- Procurement and suppliers
- Warehousing
- Transportation
- Reverse logistics

Suppliers can implement KPIs to gain an advantage over the competition. Suppliers have instant access to a user-friendly portal for submitting standardized cost savings templates. Suppliers and their customers exchange vital supply chain performance data while gaining visibility to the exact status of cost improvement projects and cost savings documentation.

Government

The provincial government of Ontario, Canada has been using KPIs since 1998 to measure the performance of higher education institutions in the province. All post secondary schools collect and report performance data in five areas – graduate satisfaction, student satisfaction, employer satisfaction, employment rate, and graduation rate.^[14]

Human Resource Management

Employee turnover

- Employee performance indicators
- Cross functional team analysis

Further performance indicators

Duration of a stockout situation

- Customer order waiting time

Problems

In practice, overseeing key performance indicators can prove expensive or difficult for organizations. Some indicators such as staff morale may be impossible to quantify. As such dubious KPIs can be adopted that can be used as a rough guide rather than a precise benchmark.^[citation needed]

Key performance indicators can also lead to perverse incentives and unintended consequences as a result of employees working to the specific measurements at the expense of the actual quality or value of their work.^{[15][16]} For example, measuring the productivity of a software development team in terms of source lines of code encourages copy and paste code and over-engineered design, leading to bloated code bases that are particularly difficult to maintain, understand and modify.

Oftentimes where there is a lack of understanding of how to develop good measures companies will resort to using percentages to quantify their measure. This is wrong and shows that the company did not do enough research on the measure.^[citation needed]

Overall equipment effectiveness

Overall equipment effectiveness (OEE) is a hierarchy of metrics developed by Seiichi Nakajima^[1] in the 1960s to evaluate how effectively a manufacturing operation is utilized. It is based on the Harrington Emerson way of thinking regarding labor efficiency.^[citation needed] The results are stated in a generic form which allows comparison between manufacturing units in differing industries. It is not however an absolute measure and is best used to identify scope for process performance improvement, and how to get the improvement.^[2] If for example the cycle time is reduced, the OEE will increase i.e. more product is produced for less resource. Another example is if one enterprise serves a high volume, low variety market, and another enterprise serves a low volume, high variety market. More changeovers (set-ups) will lower the OEE in comparison, but if the product is sold at a premium, there could be more margin with a lower OEE.

OEE measurement is also commonly used as a key performance indicator (KPI) in conjunction with lean manufacturing efforts to provide an indicator of success. OEE can be illustrated by a brief discussion of the six metrics that comprise the system. The hierarchy consists of two top-level measures and four underlying measures.

Top-level metrics

Overall equipment effectiveness (OEE) and **total effective equipment performance** (TEEP) are two closely related metrics that report the overall utilization of facilities, time and material for manufacturing operations. These top view metrics directly indicate the gap between actual and ideal performance.

- Overall equipment effectiveness quantifies how well a manufacturing unit performs relative to its designed capacity, during the periods when it is scheduled to run.
- Total effective equipment performance (TEEP) measures OEE against calendar hours, i.e.: 24 hours per day, 365 days per year.

Underlying metrics

In addition to the above measures, there are four underlying metrics that provide understanding as to why and where the OEE and TEEP gaps exist.

The measurements are described below:

- **Loading:** The portion of the TEEP Metric that represents the percentage of total calendar time that is actually scheduled for operation.

- **Availability**: The portion of the OEE Metric that represents the percentage of scheduled time that the operation is available to operate. Often referred to as Uptime.
- **Performance**: The portion of the OEE Metric that represents the speed at which the Work Center runs as a percentage of its designed speed.
- **Quality**: The portion of the OEE Metric that represents the Good Units produced as a percentage of the Total Units Started. Commonly referred to as First Pass Yield FPY.

Calculations for OEE and TEEP

What follows is a detailed presentation of each of the six OEE / TEEP Metrics and examples of how to perform calculations. The calculations are not particularly complicated, but care must be taken as to standards that are used as the basis. Additionally, these calculations are valid at the work center or part number level but become more complicated if rolling up to aggregate levels.^[1]

Overall equipment effectiveness

OEE breaks the performance of a manufacturing unit into three separate but measurable components: Availability, Performance, and Quality. Each component points to an aspect of the process that can be targeted for improvement. OEE may be applied to any individual Work Center, or rolled up to Department or Plant levels. This tool also allows for drilling down for very specific analysis, such as a particular Part Number, Shift, or any of several other parameters. It is unlikely that any manufacturing process can run at 100% OEE. Many manufacturers benchmark their industry to set a challenging target; 85% is not uncommon.

- OEE is calculated with the formula $(\text{Availability}) * (\text{Performance}) * (\text{Quality})$
- Using the examples given below:
- $(\text{Availability}=86.6\%) * (\text{Performance}=93\%) * (\text{Quality}=91.3\%) = (\text{OEE}=73.6\%)$

Alternatively, and often easier, OEE is calculated by dividing the minimum time needed to produce the parts under optimal conditions by the actual time needed to produce the parts. For example:

- Total Time: 8 hour shift or 28,800 seconds, producing 14,400 parts, or one part every 2 seconds.
- Fastest possible cycle time is 1.5 seconds, hence only 21,600 seconds would have been needed to produce the 14,400 parts. The remaining 7,200 seconds or 2 hours were lost.
- The OEE is now the 21,600 seconds divided by 28,800 seconds (same as maximal 1.5 seconds per part divided by 2 actual seconds per part), or 75%.

Total effective equipment performance

Where OEE measures effectiveness based on scheduled hours, TEEP measures effectiveness against calendar hours, i.e.: 24 hours per day, 365 days per year.

TEEP, therefore, reports the 'bottom line' utilization of assets.

Loading

The Loading portion of the TEEP Metric represents the percentage of time that an operation is scheduled to operate compared to the total Calendar Time that is available. The Loading Metric is a pure measurement of Schedule Effectiveness and is designed to exclude the effects how well that operation may perform.

Calculation: Loading = Scheduled Time / Calendar Time

Example:

A given Work Center is scheduled to run 5 Days per Week, 24 Hours per Day.

For a given week, the Total Calendar Time is 7 Days at 24 Hours.

Loading = (5 days x 24 hours) / (7 days x 24 hours) = 71.4%

Availability

The Availability portion of the OEE Metric represents the percentage of scheduled time that the operation is available to operate. The Availability Metric is a pure measurement of Uptime that is designed to exclude the effects of Quality, Performance, and Scheduled Downtime Events. The losses due to wasted availability are called *availability losses*.^[4]

Example: A given Work Center is scheduled to run for an 8-hour (480 minute) shift with a 30-minute scheduled break and experiences 60 minutes of unplanned (breakdown) time. In this case, the 30 minute break should be considered "scheduled time" although it is planned downtime.

Operating Time = 480 Min Sched – 30 Min Sched Downtime – 60 Min Unsched
Downtime = 390 Minutes

Calculation: Availability = operating time / scheduled time

Availability = 390 minutes / 480 minutes = 81.25%

Performance and productivity

Also known as "process rate", the Performance portion of the OEE Metric (also known as process rate) represents the speed at which the Work Center runs as a percentage of its designed speed. The Performance Metric is a pure measurement of speed that is designed to exclude the effects of Quality and Availability. The losses due to wasted performance are also often called *speed losses*. In practice it is often difficult to determine speed losses, and a common approach is to merely assign the remaining unknown losses as speed losses.

Calculation: Performance (Productivity) = (Parts Produced * Ideal Cycle Time) / Operating time ^[5]

Example:

A given Work Center is scheduled to run for an 8-hour (480 minute) shift with a 30-minute scheduled break.

Operating Time = 450 Min Sched – 60 Min Unsched Downtime = 390 Minutes

The Standard Rate for the part being produced is 40 Units/Hour or 1.5 Minutes/Unit

The Work Center produces 242 Total Units during the shift. Note: The basis is Total Units, not Good Units. The Performance metric does not penalize for Quality.

Time to Produce Parts = 242 Units * 1.5 Minutes/Unit = 363 Minutes

Performance (Productivity) = 363 Minutes / 390 Minutes = 93.0%

Quality

The Quality portion of the OEE Metric represents the Good Units produced as a percentage of the Total Units Started. The Quality Metric is a pure measurement of Process Yield that is designed to exclude the effects of Availability and Performance. The losses due to defects and rework are called *quality losses*.

Calculation: Quality = (Units produced - defective units) / (Units produced)

Example:

242 Units are produced. 21 are defective.

(242 units produced - 21 defective units) = 221 units

221 good units / 242 total units produced = 91.32%

"Six Big Losses"

To be able to better determine what is contributing to the greatest loss and so what areas should be targeted to improve the performance, these categories (Availability, Performance and Quality) have been subdivided further into what is known as the 'Six Big Losses' to OEE.^[6]

These are categorized as follows:

Availability	Performance	Quality
Planned Downtime	Minor Stops	Production Rejects
Breakdowns	Speed Loss	Rejects on Start up

The reason for identifying the losses in these categories is so that specific countermeasures^[7] can be applied to reduce the loss and improve the overall OEE. The Six Loss categories can be calculated manually, but there are also a plethora of simple calculators online.^{[8][9]}

Heuristic

OEE is useful as a heuristic, but can break down in several circumstances. For example, it may be far more costly to run a facility at certain times. Performance and quality may not be independent of each other or of availability and loading. Experience may develop over time. Since the performance of shop floor managers is at least sometimes compared to the OEE, these numbers are often not reliable, and there are numerous ways to fudge these numbers.^[10]

OEE has properties of a geometric mean. As such it punishes variability among its subcomponents. For example, $20\% * 80\% = 16\%$, whereas $50\% * 50\% = 25\%$. When there are asymmetric costs associated with one or more of the components, then the model may become less appropriate.

Consider a system where the cost of error is exceptionally high. In such a condition, higher quality may be far more important in a proper evaluation of effectiveness than performance or availability. OEE also to some extent assumes a closed system and a potentially static one. If one can bring in additional resources (or lease out unused resources to other projects or business units) then it may be more appropriate for example to use an expected net present value analysis.

Variability in flow also can introduce important costs and risks that may merit further modeling. Sensitivity analysis and measures of change may be helpful.

Pharmaceutical drug- Case study

A **pharmaceutical drug** (also referred to as a **pharmaceutical**, **pharmaceutical preparation**, **pharmaceutical product**, **medicinal product**, **medicine**, **medication**, **medicament**, or simply a **drug**) is a drug used to diagnose, cure, treat, or prevent disease.^{[1][2][3]} Drug therapy (pharmacotherapy) is an important part of the medical field and relies on the science of pharmacology for continual advancement and on pharmacy for appropriate management.

Drugs are classified in various ways. One of the key divisions is by level of control, which distinguishes prescription drugs (those that a pharmacist dispenses only on the order of a physician, physician assistant, or qualified nurse) from over-the-counter drugs (those that consumers can order for themselves). Another key distinction is between traditional small molecule drugs, usually derived from chemical synthesis, and biopharmaceuticals, which include recombinant proteins, vaccines, blood products used therapeutically (such as IVIG), gene therapy, and cell therapy (for instance, stem cell therapies). Other ways to classify medicines are by mode of action, route of administration, biological system affected, or therapeutic effects. An elaborate and widely used classification system is the Anatomical Therapeutic

Chemical Classification System (ATC system). The World Health Organization keeps a list of essential medicines.

Drug discovery and drug development are complex and expensive endeavors undertaken by pharmaceutical companies, academic scientists, and governments. Governments generally regulate what drugs can be marketed, how drugs are marketed, and in some jurisdictions, drug pricing. Controversies have arisen over drug pricing and disposal of used drugs.

Definition

In Europe, the term is "medicinal product", and it is defined by EU law as: "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."^{[4]:36}

In the US, a "drug" is:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)^[5]

Classification

Pharmaceutical or a drug is classified on the basis of their origin.

1. Drug from natural origin: Herbal or plant or mineral origin, some drug substances are of marine origin.
2. Drug from chemical as well as natural origin: Derived from partial herbal and partial chemical synthesis Chemical, example steroidal drugs
3. Drug derived from chemical synthesis.
4. Drug derived from animal origin: For example, hormones, and enzymes.
5. Drug derived from microbial origin: Antibiotics
6. Drug derived by biotechnology genetic-engineering, hybridoma technique for example
7. Drug derived from radioactive substances.

One of the key classifications is between traditional small molecule drugs, usually derived from chemical synthesis, and biologic medical products, which include recombinant proteins, vaccines, blood products used therapeutically (such as IVIG), gene therapy, and cell therapy (for instance, stem cell therapies).

Pharmaceutical or drug or medicines are classified in various other groups besides their origin on the basis of pharmacological properties like mode of action and their pharmacological action or activity,^[6] such as by chemical properties, mode or route of administration, biological system affected, or therapeutic effects. An elaborate and widely used classification system is the Anatomical Therapeutic Chemical Classification System (ATC system). The World Health Organization keeps a list of essential medicines.

A sampling of classes of medicine includes:

1. Antipyretics: reducing fever (pyrexia/pyresis)
2. Analgesics: reducing pain (painkillers)
3. Antimalarial drugs: treating malaria
4. Antibiotics: inhibiting germ growth
5. Antiseptics: prevention of germ growth near burns, cuts and wounds
6. Mood stabilizers: lithium and valpromide
7. Hormone replacements: Premarin
8. Oral contraceptives: Enovid, "biphasic" pill, and "triphasic" pill
9. Stimulants: methylphenidate, amphetamine
10. Tranquilizers: meprobamate, chlorpromazine, reserpine, chlordiazepoxide, diazepam, and alprazolam
11. Statins: lovastatin, pravastatin, and simvastatin

Pharmaceuticals may also be described as "specialty", independent of other classifications, which is an ill defined class of drugs that might be difficult to administer, require special handling during administration, require patient monitoring during and immediately after administration, have particular regulatory requirements restricting their use, and are generally expensive relative to other drugs.^[7]

Types of medicines

For the gastrointestinal tract (digestive system)

- Upper digestive tract: antacids, reflux suppressants, antiflatulents, antidopaminergics, proton pump inhibitors (PPIs), H₂-receptor antagonists, cytoprotectants, prostaglandin analogues
- Lower digestive tract: laxatives, antispasmodics, antidiarrhoeals, bile acid sequestrants, opioid

For the cardiovascular system

General: β-receptor blockers ("beta blockers"), calcium channel blockers, diuretics, cardiac glycosides, antiarrhythmics, nitrate, antianginals, vasoconstrictors, vasodilators.

- Affecting blood pressure/(antihypertensive drugs): ACE inhibitors, angiotensin receptor blockers, beta-blockers, α blockers, calcium channel blockers, thiazide diuretics, loop diuretics, aldosterone inhibitors
- Coagulation: anticoagulants, heparin, antiplatelet drugs, fibrinolytics, anti-hemophilic factors, haemostatic drugs
- HMG-CoA reductase inhibitors (statins) for lowering LDL cholesterol inhibitors: hypolipidaemic agents..

Administration

Administration is the process by which a patient takes a medicine. There are three major categories of drug administration; enteral (by mouth), parenteral (into the blood stream), and other (which includes giving a drug through intranasal, topical, inhalation, and rectal means).^[8]

It can be performed in various dosage forms such as pills, tablets, or capsules.

There are many variations in the routes of administration, including intravenous (into the blood through a vein) and oral administration (through the mouth).

They can be administered all at once as a bolus, at frequent intervals or continuously. Frequencies are often abbreviated from Latin, such as *every 8 hours* reading Q8H from *Quaque VIII Hora*.

Drug discovery

In the fields of medicine, biotechnology and pharmacology, drug discovery is the process by which new candidate drugs are discovered.

Historically, drugs were discovered through identifying the active ingredient from traditional remedies or by serendipitous discovery. Later chemical libraries of synthetic small molecules, natural products or extracts were screened in intact cells or whole organisms to identify substances that have a desirable therapeutic effect in a process known as classical pharmacology. Since sequencing of the human genome which allowed rapid cloning and synthesis of large quantities of purified proteins, it has become common practice to use high throughput screening of large compounds libraries against isolated biological targets which are hypothesized to be disease modifying in a process known as reverse pharmacology. Hits from these screens are then tested in cells and then in animals for efficacy. Even more recently, scientists have been able to understand the shape of biological molecules at the atomic level, and to use that knowledge to design (see drug design) drug candidates.

Modern drug discovery involves the identification of screening hits, medicinal chemistry and optimization of those hits to increase the affinity, selectivity (to reduce the potential of side effects), efficacy/potency, metabolic stability (to increase the half-life), and oral bioavailability. Once a compound that fulfills all of these requirements has been identified, it will begin the process of drug development prior to clinical trials. One or more of these steps may, but not necessarily, involve computer-aided drug design.

Despite advances in technology and understanding of biological systems, drug discovery is still a lengthy, "expensive, difficult, and inefficient process" with low rate of new therapeutic discovery.^[9] In 2010, the research and development cost of each new molecular entity (NME) was approximately US\$1.8 billion.^[10] Drug discovery is done by pharmaceutical companies, with research assistance from universities. The "final product" of drug discovery is a patent on the potential drug. The drug requires very expensive Phase I, II and III clinical trials, and most of them fail. Small companies have a critical role, often then selling the rights to larger companies that have the resources to run the clinical trials.

Development

Drug development is a blanket term used to define the process of bringing a new drug to the market once a lead compound has been identified through the process of drug discovery. It includes pre-clinical research (microorganisms/animals) and clinical trials (on humans) and may include the step of obtaining regulatory approval to market the drug.

Regulation

The regulation of drugs varies by jurisdiction. In some countries, such as the United States, they are regulated at the national level by a single agency. In other jurisdictions they are regulated at the state level, or at both state and national levels by various bodies, as is the case in Australia. The role of therapeutic goods regulation is designed mainly to protect the health and safety of the population. Regulation is aimed at ensuring the safety, quality, and efficacy of the therapeutic goods which are covered under the scope of the regulation. In most jurisdictions, therapeutic goods must be registered before they are allowed to be marketed. There is usually some degree of restriction of the availability of certain therapeutic goods depending on their risk to consumers.

Depending upon the jurisdiction, drugs may be divided into over-the-counter drugs (OTC) which may be available without special restrictions, and prescription drugs, which must be prescribed by a licensed medical practitioner. The precise distinction between OTC and prescription depends on the legal jurisdiction. A third category, "behind-the-counter" drugs, is implemented in some jurisdictions. These do not require a prescription, but must be kept in the dispensary, not visible to the public, and only be sold by a pharmacist or pharmacy technician. Doctors may also prescribe prescription drugs for off-label use - purposes which the drugs were not originally approved for by the regulatory agency. The Classification of Pharmaco-Therapeutic Referrals helps guide the referral process between pharmacists and doctors.

The International Narcotics Control Board of the United Nations imposes a world law of prohibition of certain drugs. They publish a lengthy list of chemicals and plants whose trade and consumption (where applicable) is forbidden. OTC drugs are sold without restriction as they are considered safe enough that most people will not hurt themselves accidentally by taking it as instructed. Many countries, such as the United

Kingdom have a third category of "pharmacy medicines", which can only be sold in registered pharmacies by or under the supervision of a pharmacist.

Drug pricing

United Kingdom

In the UK the Pharmaceutical Price Regulation Scheme is intended to ensure that the National Health Service is able to purchase drugs at reasonable prices.^[*citation needed*]

Canada

In Canada, the Patented Medicine Prices Review Board examines drug pricing, compares the proposed Canadian price to that of seven other countries and determines if a price is excessive or not. In these circumstances, drug manufacturers must submit a proposed price to the appropriate regulatory agency.^[*citation needed*]

Brazil

In Brazil, the prices are regulated through a legislation under the name of *Medicamento Genérico* (generic drugs) since 1999.^[*citation needed*]

United States

Main article: Prescription drug prices in the United States

In the United States, drug costs are unregulated, but instead are the result of negotiations between drug companies and insurance companies.^[*citation needed*]

Blockbuster drug

Main article: List of largest selling pharmaceutical products

A blockbuster drug is a drug generating more than \$1 billion of revenue for the pharmaceutical company that sells it each year.^[11] Cimetidine was the first drug ever to reach more than \$1 billion a year in sales, thus making it the first blockbuster drug.^[12]

"In the pharmaceutical industry, a blockbuster drug is one that achieves acceptance by prescribing physicians as a therapeutic standard for, most commonly, a highly prevalent chronic (rather than acute) condition. Patients often take the medicines for long periods."^[13]

Leading blockbuster drugs as of 2011

This section is **outdated**. Please update this article to reflect recent events or newly available information. (*October 2015*)

Drug	Trade name	Type	Indication	Company	Sales^[14] (\$billion/year)*
<u>Atorvastatin</u>	Lipitor	Small molecule	<u>Hypercholesterolemia</u>	<u>Pfizer</u>	12.5
<u>Clopidogrel</u>	Plavix	Small molecule	<u>Atherosclerosis</u>	<u>Bristol-Myers Squibb Sanofi</u>	9.1
<u>Fluticasone/salmeterol</u>	Advair	Small molecule	<u>Asthma</u>	<u>GlaxoSmithKline</u>	8.7
<u>Esomeprazole</u>	Nexium	Small molecule	<u>Gastroesophageal reflux disease</u>	<u>AstraZeneca</u>	8.3
<u>Rosuvastatin</u>	Crestor	Small molecule	<u>Hypercholesterolemia</u>	<u>AstraZeneca</u>	7.4
<u>Quetiapine</u>	Seroquel	Small molecule	<u>Bipolar disorder</u> <u>Schizophrenia</u> <u>Major Depressive Disorder</u>	<u>AstraZeneca</u>	7.2
<u>Adalimumab</u>	Humira	Biologic	<u>Rheumatoid Arthritis</u>	<u>AbbVie</u>	6.6
<u>Etanercept</u>	Enbrel	Biologic	<u>Rheumatoid Arthritis</u>	<u>Amgen Pfizer</u>	6.5
<u>Infliximab</u>	Remicade	Biologic	<u>Crohn's Disease</u> <u>Rheumatoid Arthritis</u>	<u>Johnson & Johnson</u>	6.4
<u>Olanzapine</u>	Zyprexa	Small molecule	<u>Schizophrenia</u>	<u>Eli Lilly and Company</u>	6.2

*Sales are for the 12 months preceding 30 June 2011.

History

Prescription drug history

Antibiotics first arrived on the medical scene in 1932 thanks to Gerhard Domagk;^[15] and coined the "wonder drugs". The introduction of the sulfa drugs led to a decline in the U.S. mortality rate from pneumonia to drop from 0.2% each year to 0.05% by 1939.^[16] Antibiotics inhibit the growth or the metabolic activities of bacteria and other microorganisms by a chemical substance of microbial origin. Penicillin, introduced a few years later, provided a broader spectrum of activity compared to sulfa drugs and reduced side effects. Streptomycin, found in 1942, proved to be the first drug effective against the cause of tuberculosis and also came to be the best known of a long series

of important antibiotics. A second generation of antibiotics was introduced in the 1940s: aureomycin and chloramphenicol. Aureomycin was the best known of the second generation.

Lithium was discovered in the 19th century for nervous disorders and its possible mood-stabilizing or prophylactic effect; it was cheap and easily produced. As lithium fell out of favor in France, valpromide came into play. This antibiotic was the origin of the drug that eventually created the mood stabilizer category. Valpromide had distinct psychotropic effects that were of benefit in both the treatment of acute manic states and in the maintenance treatment of manic depression illness. Psychotropics can either be sedative or stimulant; sedatives aim at damping down the extremes of behavior. Stimulants aim at restoring normality by increasing tone. Soon arose the notion of a tranquilizer which was quite different from any sedative or stimulant. The term tranquilizer took over the notions of sedatives and became the dominant term in the West through the 1980s. In Japan, during this time, the term tranquilizer produced the notion of a psyche-stabilizer and the term mood stabilizer vanished.^[17]

Premarin (conjugated estrogens, introduced in 1942) and Prempro (a combination estrogen-progestin pill, introduced in 1995) dominated the hormone replacement therapy (HRT) during the 1990s. HRT is not a life-saving drug, nor does it cure any disease. HRT has been prescribed to improve one's quality of life. Doctors prescribe estrogen for their older female patients both to treat short-term menopausal symptoms and to prevent long-term diseases. In the 1960s and early 1970s more and more physicians began to prescribe estrogen for their female patients. Between 1991 to 1999, Premarin was listed as the most popular prescription and best-selling drug in America.^[17]

The first oral contraceptive, Enovid, was approved by FDA in 1960. Oral contraceptives inhibit ovulation and so prevent conception. Enovid was known to be much more effective than alternatives including the condom and the diaphragm. As early as 1960, oral contraceptives were available in several different strengths by every manufacturer. In the 1980s and 1990s an increasing number of options arose including, most recently, a new delivery system for the oral contraceptive via a transdermal patch. In 1982, a new version of the Pill was introduced, known as the "biphasic" pill. By 1985, a new triphasic pill was approved. Physicians began to think of the Pill as an excellent means of birth control for young women.^[17]

Stimulants such as Ritalin (methylphenidate) came to be pervasive tools for behavior management and modification in young children. Ritalin was first marketed in 1955 for narcolepsy; its potential users were middle-aged and the elderly. It wasn't until some time in the 1980s along with hyperactivity in children that Ritalin came onto the market. Medical use of methylphenidate is predominately for symptoms of attention deficit/hyperactivity disorder (ADHD). Consumption of methylphenidate in the U.S. out-paced all other countries between 1991 and 1999. Significant growth in consumption was also evident in Canada, New Zealand, Australia, and Norway. Currently, 85% of the world's methylphenidate is consumed in America.^[17]

The first minor tranquilizer was Meprobamate. Only fourteen months after it was made available, meprobamate had become the country's largest-selling prescription drug. By 1957, meprobamate had become the fastest-growing drug in history. The

popularity of meprobamate paved the way for Librium and Valium, two minor tranquilizers that belonged to a new chemical class of drugs called the benzodiazepines. These were drugs that worked chiefly as anti-anxiety agents and muscle relaxants. The first benzodiazepine was Librium. Three months after it was approved, Librium had become the most prescribed tranquilizer in the nation. Three years later, Valium hit the shelves and was ten times more effective as a muscle relaxant and anti-convulsant. Valium was the most versatile of the minor tranquilizers. Later came the widespread adoption of major tranquilizers such as chlorpromazine and the drug reserpine. In 1970 sales began to decline for Valium and Librium, but sales of new and improved tranquilizers, such as Xanax, introduced in 1981 for the newly created diagnosis of panic disorder, soared.^[17]

Mevacor (lovastatin) is the first and most influential statin in the American market. The 1991 launch of Pravachol (pravastatin), the second available in the United States, and the release of Zocor (simvastatin) made Mevacor no longer the only statin on the market. In 1998, Viagra was released as a treatment for erectile dysfunction.^[17]

Ancient pharmacology

Using plants and plant substances to treat all kinds of diseases and medical conditions is believed to date back to prehistoric medicine.

The Kahun Gynaecological Papyrus, the oldest known medical text of any kind, dates to about 1800 BC and represents the first documented use of any kind of drug.^{[18][19]} It and other medical papyri describe Ancient Egyptian medical practices, such as using honey to treat infections and the legs of bee-eaters to treat neck pains.

Ancient Babylonian medicine demonstrate the use of prescriptions in the first half of the 2nd millennium BC. Medicinal creams and pills were employed as treatments.^[20]

On the Indian subcontinent, the Atharvaveda, a sacred text of Hinduism whose core dates from the 2nd millennium BC, although the hymns recorded in it are believed to be older, is the first Indic text dealing with medicine. It describes plant-based drugs to counter diseases.^[21] The earliest foundations of ayurveda were built on a synthesis of selected ancient herbal practices, together with a massive addition of theoretical conceptualizations, new nosologies and new therapies dating from about 400 BC onwards.^[22] The student of Āyurveda was expected to know ten arts that were indispensable in the preparation and application of his medicines: distillation, operative skills, cooking, horticulture, metallurgy, sugar manufacture, pharmacy, analysis and separation of minerals, compounding of metals, and preparation of alkalis.

The Hippocratic Oath for physicians, attributed to 5th century BC Greece, refers to the existence of "deadly drugs", and ancient Greek physicians imported drugs from Egypt and elsewhere.^[23]

Medieval pharmacology

Al-Kindi's 9th century AD book, De Gradibus and Ibn Sina (Avicenna)'s The Canon of Medicine cover a range of drugs known to Medicine in the medieval Islamic world.

Medieval medicine saw advances in surgery, but few truly effective drugs existed, beyond opium (found in such extremely popular drugs as the "Great Rest" at the time)^[24] and quinine. Folklore cures and potentially poisonous metal-based compounds were popular treatments. Theodoric Borgognoni, (1205–1296), one of the most significant surgeons of the medieval period, responsible for introducing and promoting important surgical advances including basic antiseptic practice and the use of anaesthetics. Garcia de Orta described some herbal treatments that were used.

Modern pharmacology

For most of the 19th century, drugs were not highly effective, leading Oliver Wendell Holmes, Sr. to famously comment in 1842 that "if all medicines in the world were thrown into the sea, it would be all the better for mankind and all the worse for the fishes".^{[25]:21}

During the First World War, Alexis Carrel and Henry Dakin developed the Carrel-Dakin method of treating wounds with an irrigation, Dakin's solution, a germicide which helped prevent gangrene.

In the inter-war period, the first anti-bacterial agents such as the sulpha antibiotics were developed. The Second World War saw the introduction of widespread and effective antimicrobial therapy with the development and mass production of penicillin antibiotics, made possible by the pressures of the war and the collaboration of British scientists with the American pharmaceutical industry.

Medicines commonly used by the late 1920s included aspirin, codeine, and morphine for pain; digitalis, nitroglycerin, and quinine for heart disorders, and insulin for diabetes. Other drugs included antitoxins, a few biological vaccines, and a few synthetic drugs. In the 1930s antibiotics emerged: first sulfa drugs, then penicillin and other antibiotics. Drugs increasingly became "the center of medical practice".^{[25]:22} In the 1950s other drugs emerged including corticosteroids for inflammation, rauwolfia alkaloids as tranquilizers and antihypertensives, antihistamines for nasal allergies, xanthines for asthma, and typical antipsychotics for psychosis.^{[25]:23–24} As of 2007, thousands of approved drugs have been developed. Increasingly, biotechnology is used to discover biopharmaceuticals.^[25] Recently, multi-disciplinary approaches have yielded a wealth of new data on the development of novel antibiotics and antibacterials and on the use of biological agents for antibacterial therapy.^[26]

In the 1950s new psychiatric drugs, notably the antipsychotic chlorpromazine, were designed in laboratories and slowly came into preferred use. Although often accepted as an advance in some ways, there was some opposition, due to serious adverse effects such as tardive dyskinesia. Patients often opposed psychiatry and refused or stopped taking the drugs when not subject to psychiatric control.

Governments have been heavily involved in the regulation of drug development and drug sales. In the U.S., the Elixir Sulfanilamide disaster led to the establishment of the Food and Drug Administration, and the 1938 Federal Food, Drug, and Cosmetic Act required manufacturers to file new drugs with the FDA. The 1951 Humphrey-Durham Amendment required certain drugs to be sold by prescription. In 1962 a subsequent

amendment required new drugs to be tested for efficacy and safety in clinical trials.^{[25]:24-26}

Until the 1970s, drug prices were not a major concern for doctors and patients. As more drugs became prescribed for chronic illnesses, however, costs became burdensome, and by the 1970s nearly every U.S. state required or encouraged the substitution of generic drugs for higher-priced brand names. This also led to the 2006 U.S. law, Medicare Part D, which offers Medicare coverage for drugs.^{[25]:28-29}

As of 2008, the United States is the leader in medical research, including pharmaceutical development. U.S. drug prices are among the highest in the world, and drug innovation is correspondingly high. In 2000 U.S. based firms developed 29 of the 75 top-selling drugs; firms from the second-largest market, Japan, developed eight, and the United Kingdom contributed 10. France, which imposes price controls, developed three. Throughout the 1990s outcomes were similar.^{[25]:30-31}

Controversies

Controversies concerning pharmaceutical drugs include patient access to drugs under development and not yet approved, pricing, and environmental issues.

Access to unapproved drugs

Governments worldwide have created provisions for granting access to drugs prior to approval for patients who have exhausted all alternative treatment options and do not match clinical trial entry criteria. Often grouped under the labels of compassionate use, expanded access, or named patient supply, these programs are governed by rules which vary by country defining access criteria, data collection, promotion, and control of drug distribution.^[27]

Within the United States, pre-approval demand is generally met through treatment IND (investigational new drug) applications (INDs), or single-patient INDs. These mechanisms, which fall under the label of expanded access programs, provide access to drugs for groups of patients or individuals residing in the US. Outside the US, Named Patient Programs provide controlled, pre-approval access to drugs in response to requests by physicians on behalf of specific, or "named", patients before those medicines are licensed in the patient's home country. Through these programs, patients are able to access drugs in late-stage clinical trials or approved in other countries for a genuine, unmet medical need, before those drugs have been licensed in the patient's home country.

Patients who have not been able to get access to drugs in development have organized and advocated for greater access. In the United States, ACT UP formed in the 1980s, and eventually formed its Treatment Action Group in part to pressure the US government to put more resources into discovering treatments for AIDS and then to speed release of drugs that were under development.^[28]

The Abigail Alliance was established in November 2001 by Frank Burroughs in memory of his daughter, Abigail.^[29] The Alliance seeks broader availability of investigational drugs on behalf of terminally ill patients.

In 2013, BioMarin Pharmaceutical was at the center of a high profile debate regarding expanded access of cancer patients to experimental drugs.^{[30][31]}

Access to medicines and drug pricing

Essential medicines as defined by the World Health Organization (WHO) are "those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford."^[32] Recent studies have found that most of the medicines on the WHO essential medicines list, outside of the field of HIV drugs, are not patented in the developing world, and that lack of widespread access to these medicines arise from issues fundamental to economic development - lack of infrastructure and poverty.^[33] Médecins Sans Frontières also runs a Campaign for Access to Essential Medicines campaign, which includes advocacy for greater resources to be devoted to currently untreatable diseases that primarily occur in the developing world. The Access to Medicine Index tracks how well pharmaceutical companies make their products available in the developing world.

World Trade Organization negotiations in the 1990s, including the TRIPS Agreement and the Doha Declaration, have centered on issues at the intersection of international trade in pharmaceuticals and intellectual property rights, with developed world nations seeking strong intellectual property rights to protect investments made to develop new drugs, and developing world nations seeking to promote their generic pharmaceuticals industries and their ability to make medicine available to their people via compulsory licenses.

Some have raised ethical objections specifically with respect to pharmaceutical patents and the high prices for drugs that they enable their proprietors to charge, which poor people in the developed world, and developing world, cannot afford.^{[34][35]} Critics also question the rationale that exclusive patent rights and the resulting high prices are required for pharmaceutical companies to recoup the large investments needed for research and development.^[34] One study concluded that marketing expenditures for new drugs often doubled the amount that was allocated for research and development.^[36] Other critics claim that patent settlements would be costly for consumers, the health care system, and state and federal governments because it would result in delaying access to lower cost generic medicines.^[37]

Novartis fought a protracted battle with the government of India over the patenting of its drug, Gleevec, in India, which ended up in India's Supreme Court in a case known as Novartis v. Union of India & Others. The Supreme Court ruled narrowly against Novartis, but opponents of patenting drugs claimed it as a major victory.^[38]

Environmental issues

The environmental impact of pharmaceuticals and personal care products is controversial. PPCPs are substances used by individuals for personal health or

cosmetic reasons and the products used by agribusiness to boost growth or health of livestock. PPCPs comprise a diverse collection of thousands of chemical substances, including prescription and over-the-counter therapeutic drugs, veterinary drugs, fragrances, and cosmetics. PPCPs have been detected in water bodies throughout the world and ones that persist in the environment are called Environmental Persistent Pharmaceutical Pollutants. The effects of these chemicals on humans and the environment are not yet known, but to date there is no scientific evidence that they have an impact on human health.^[39]

7. סיכום ומסקנות

א. מערכת ניהול ייצור MES

מערכות ניהול ייצור (Manufacturing Execution Systems) באות לתת מענה לדרישות מגזרים רחבים בתעשייה, הדורשים שילוב ורטיקאלי בין רמת הייצור ורמת הניהול. הן מצמצמות את הפער בין הפלטפורמה הטכנית של מיכון וציוד לבין העולם המסחרי יותר של ה-ERP ושל מערכות הניהול. נוצרו תקנים כמו S95 לאפיין את המערכות האלה. מערכות מתוחכמות אלה נותנות פתרונות משולבים ומודולאריים עבור ייצור, כוח-אדם ואיכות, ומספקות זרימה חלקה של המידע. כמו כן הן מספקות פונקציות חשובות בתחומי הרישום, המידע, ההערכה והתכנון- והופכת אותם לזמינים יותר עבור מנהלי עבודה ולוחות זמנים בלחיצת כפתור. אינטגרציה מושלמת לתוך סביבת הייצור היא חיונית ליעילות ההשתלבות של מערכות ניהול הייצור. מערכת MES מתקדמת מספקת אפשרות של הכנסת נתונים דרך מסופי רצפת הייצור או השתלטות אוטומטית על נתונים מהמכונות, הציוד, אמצעי המדידה או כל מתקן היקפי אחר. מערכת ה-MES אינה מחליפה את מסופי תפעול והמכונות אבל בהחלט יכולים להשתלב עמן.

ב. התייעלות בייצור

- הקטנת עלויות האתחול ותקופות חוסר הפעילות ע"י הגברת שקיפות עם המדידה
- הגברת שקיפות הזמנות הייצור ע"י מעקב ופיקוח על ההזמנות. פרטים מדויקים על סטאטוס ההזמנה ועל התקדמותה זמינים עבור ניתוח אובייקטיבי ובקרת עלות.
- שיפור זמני ריצפת הייצור עם אפשרויות תכנון הזמנות בהתאם למידע הנוגע למשאבים הנדרשים והזמינים (מכונות, אנשים, חומרים וכלים).
- שיפור לוגיסטיקת החומרים והייצור עם פיקוח ושליטה על זרימת החומרים מעבר לייצור, אחסון ביניים וכלל מאגרי החומרים. כמו כן מעקב אצווה.
- ייעול ניהול הכלים והמשאבים ע"י שמירת היסטוריה וקביעת זמני התחזוקה לפי זמני עבודה בפועל.
- אוטומציה של הכנת המכונות לפי לוח ההזמנות (כמו טעינת תוכנית NC) להקטנת זמני האתחול.

ג. מערכות ה-MES בתשלובת מערכות SCADA - מקשרות בין שתי שכבות המידע

בארגון: ריצפת הייצור ומערכת התכנון. מערכות ה-MES אינן מחליפות את מערכות ה-SCADA אלא משתלבות עמם. הדגש במערכות ה-MES הוא התכנון, שיפור המדדים, וה-KPI. ואילו מערכות ה-SCADA מנהלות מידע בזמן אמת במיתקן התעשייתי בדגש על מתקן תהליכי. כאשר מערכות אלו משולבות, ניתן למקסם הייצור והתייעלות הפס בעיקר בתכנון יעיל ובחיסכון בבלאי המערכות ועלויות הפסולים וחומר הגלם. במצבים בהם מפעל תעשייתי משקיע משאבים עצומים לקראת פרויקט ERP, ומופתע לגלות כי תוצאות הפרויקט אינן מכסות את כל צרכי המחשוב של המפעל. את הבעיה ניתן לזהות לרוב בשלב אפיון והגדרת דרישות המערכת, שם מנסים יצרני ERP לכופף את דרישות המחשוב מצד

הלקוח, ולהתאימן למערכת המחשב אותה ברצונם לספק. **מערכות MES נותנות מענה לפעילות תזמון ייצור** – מתן מענה להזמנת שיווק אשר אותה יש להכניס מידיית לייצור ומאפשרת למנהלי הייצור ואנשי התפ"י לתכנן ולתזמן את ההזמנות ישירות ממערכת ה-ERP אל מכונות הייצור. מפעלים שבחרו לזמן את המשאבים באמצעות מודול תזמון הייצור במערכת ה-MES דיווחו על הצלחות והקטנת זמני הכינון ולו בזכות הקשר שבין מערכת התזמון לבין ריצפת הייצור. לפני כל הרצה של מודול ה-Scheduling במערכת ה-MES, מבוצע עדכון לגבי תפוקת המכונות בזמן אמת. מערכות תזמון המיושמות כחלק ממערכת ה-ERP "מנותקות מהשטח" ואינן מכירות באילוצים המתרחשים בזמן אמת. מערכת Scheduling המיושמת כחלק ממערכת ה-MES, יודעת על המתרחש בזמן אמת

ד. **Key performance Indicator - KPI**

אוסף מדדים לבצוע מדידה השוואתית בין ערכים. קיימים סוגים רבים של הנהגים בחברות יצרניות, לדוגמה: מספר תקלות במוצר בפועל לעומת מספר תקלות רצוי, המאפשר על סמך מדדי איכות לנתח את איכות הייצור של התהליך; כמות חזויה לייצור לעומת הייצור בפועל; כמות חומרי גלם חזויה על פי התכנון לעומת הצריכה בפועל.

ה. **Theory Of Constraints - TOC**

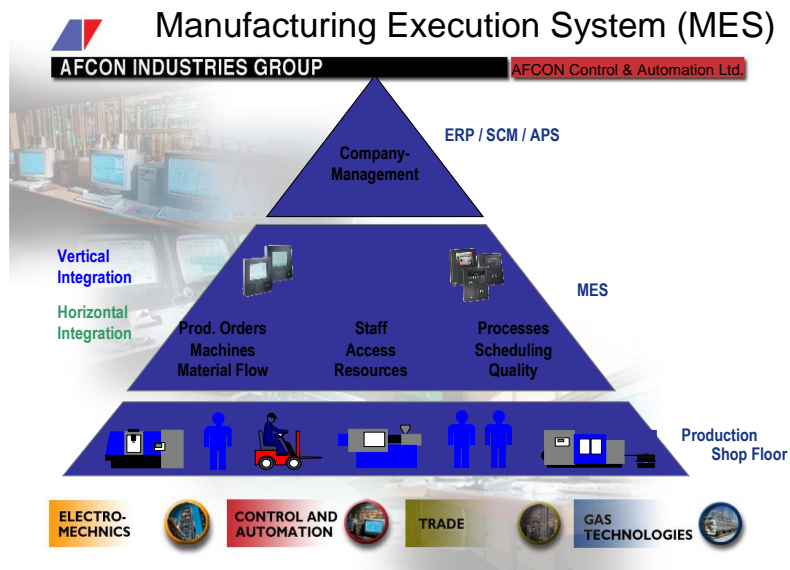
מתבססת על ההנחה שבכל ארגון קיים צוואר בקבוק אשר מפריע בהשגת המטרה ורק איתורו ושיפורו ישפר את התפוקה של המערכת כולה. אם לדוגמה, קיימות במפעל פשוט שתי מכונות אשר פועלות בזו אחר זו לייצור מוצר מסוים, האחת יכולה לעבוד על 10 מוצרים בשעה והשנייה על 20, הרי שבמקרה זה האילוץ הוא המכונה הראשונה ושיפור המכונה השנייה לא יעזור במאום. כדי לטפל בצווארי הבקבוק קיים התהליך החמש שלבי למיקוד המערכת:

- שלב א' - איתור אילוץ המערכת
- שלב ב' - החלטה כיצד לנצל את האילוץ (יש לוודא שהאילוץ מבצע רק דברים שהוא יכול לבצע באופן בלעדי)
- שלב ג' - כיפוף שאר המערכת לאילוץ (יש לסדר את המערכת כולה בצורה בה האילוץ יוכל לעבוד כל הזמן. בשאר המערכת מדד הנצילות אינו רלוונטי, הנצילות לא אמורה להיות מקסימאלית אלא מתאימה לאילוץ)
- שלב ד' - פריצת מגבלות האילוץ (יש לנסות להגדיל את יכולותיו של האילוץ ככל האפשר)
- שלב ה' - במידה שהאילוץ נדד למקום אחר במערכת יש לחזור לשלב הראשון, בכך נמנע מן ה**אינרציה** להיות האילוץ.

ו. **מערכת ה- SCADA/HMI** - מטפלות בשליטה, בקרה, ניטור ומעקב בזמן אמת אחר

תהליכים המתרחשים בפועל באולם הייצור. בקרה זו מתבצעת ע"י קישור ישיר של בקרי המכונות למערכת הממוחשבת, מחד, ולמערכת ה-ERP המפעלית, מאידך. קישורים אלה מאפשרים קבלת והצגת נתוני אמת בזמן-אמת, השוואת פעילויות, כמויות מיוצרות וקצב התקדמות הייצור לדרישות ולתקנים, בקרת תקלות, מעקב עצירות וגורמים נוספים המשפיעים על תפוקות ויעילות הייצור, קבלת התרעות על חריגות וקבלת נתונים קיימים ומחושבים בזמן-אמת כגון: נתונים טכניים של מכונות (זמן מחזור, טמפרטורה ונתונים נוספים הנמצאים בבקר), מסך פתיחה המציג את המכונות, מה מיוצר כעת, האם המכונה

בתקלה או בעצירה ומהי סיבת העצירה, כמה יוצר עד כה יחסית לדרישה, מהו קצב התקדמות הייצור, השוואה בין משמרות ועוד.



- ז. **מתן מדדי ייצור בזמן אמת** – בעוד שה- ERP יספק למפעל יצרני מדדי ייצור On line, מערכת ה- MES תספק מדדי ייצור בזמן אמת Real Time. מפעלים תעשייתיים שבחרו לטפל במדדי הייצור במסגרת מערכת ה- ERP הבינו בדיעבד כי אין הרבה שימוש במדד היעילות הכולל OEE אותו מספקת מערכת ה- ERP. מדדי הייצור המחושבים במערכת ה- ERP אינם מאפשרים למפעל להגיב בזמן אמת לבעיות ברצפת הייצור. יישום מודול מדדי הייצור במערכת ה- MES מאפשר למנהלי ייצור לראות בזמן אמת מסך Dash-Board כולל המספק נתוני אמת מרצפת הייצור ולחזות בצורה גראפית ברורה במצב הנוכחי של כל מרכז עבודה (קו או מכונה). דרך הפורטל הארגוני ניתן להעמיק בפרטים עדכניים לגבי תפוקות המכונה או הקו, פרטים עדכניים אודות פקודת העבודה, המשמרת, כמויות פחיתים, ותקלות פתוחות. מפעלים בישראל שיישמו את מדדי הייצור במערכות ה- MES מדווחים על שיפורים מתמידים בתפוקות הייצור, והגברת הניצולת. היכולת להגיב לשינויים במשק תחרותי ותאפשר בזכות "הרמת" ריצפת הייצור אל גובה העיניים.
- ח. **OEE (Overall Equipment Effectiveness)** - מדד משולב לניתוח יעילות תהליך הייצור, הכולל נתוני איכות, ביצועי משאבי הייצור וזמינותם לייצור. בעולם מקובל לציין מדד זה כמכפלה של שלושה פרמטרים: איכות, זמינות וקצב ייצור; ומדד "טוב" נחשב כנתון OEE מעל 85%
- ט. **מתן מענה למלאי בתהליך** – במפעלים רבים יש מלאי בתהליך בשווי של מיליוני דולרים "מפוזר" על ריצפת הייצור ללא בקרה. עגלות, משטחים, גלילים, כלובים, ואמצעי שינוע מלאי בין מרכזי העבודה במפעל, אינם מנוהלים במערכת ה- ERP. דיווח המלאי אל ומאת מערכות ה- ERP מתבצע על פי רוב בתחילתו וסופו של תהליך הייצור. לא אחת, בעת ביצוע ספירת מלאי תקופתית מתגלים פערים עצומים בין המלאי שחשבנו שמצוי על ריצפת הייצור לבין המלאי הנמצא על הרצפה בפועל. מערכת MES תשכיל לטפל, לנהל, ולעקוב אחר כל תנועת מלאי המתבצעת תוך כדי תהליך הייצור. במפעלים יצרניים שבחרו לנהל

מלאי בתהליך הייצור במערכת ה-MES אין כל סטייה או חריגה בעת ביצוע ספירת מלאי בין המלאי בפעול למלאי כפי שמופיע במערכת ה-MES. מערכת ה-MES מעודכנת בכל פעולת שינוע מלאי ברצפה הן בצורה אוטומטית והן באמצעות אביזרי זיהוי מתקדמים דוגמת קוראי בר-קוד ורכיבי RFID.

י. **קיצור זמן אספקת מוצר ללקוח** - קיצור זמן אספקת מוצר ללקוח וזאת באמצעות ביטול זמן מת של מכונה ע"י מציאת תחנות שאינן עובדות באופן רציף או שהינן צוואר בקבוק. בכך ניתן לחסוך זמן ולכמתו לכסף ולייצר לעצמנו מוניטין מול הלקוחות.

יא. **עקיבות מוצר Tracing & Tracking** - מערכת MES מאפשרת קבלת רזולוציה פרטנית אודות חומרי הגלם שנצרכו עבור מוצר מוגמר ברמת אצוות החומר. כמו כן הרזולוציה ניתנת אודות המשאבים שנצרכו לייצור המוצר כגון מכונות וכוח אדם. תעשיות שונות מחויבות לרמת עקיבות שונה. בעוד שבתעשיית המזון והתרופות נדרשת עקיבות פרטנית אודות הרכיבים והאמצעים השונים שנדרשו לייצור, בתעשיות אחרות רמת העקיבות הנדרשת נמוכה יותר. מפעלים תעשייתיים שהשכילו ליישם את עקיבות המוצר במערכת ה-MES השיגו רמת עקיבות פרטנית ויכולת לקבל מידע בדיעבד אודות חומרי הגלם הספציפיים מהם יוצר מוצר מוגמר מסוים. לדבר חשיבות רבה במקרים חריגים של Recall - הודעה על החזרת מוצרים לספק עקב כשל בתהליך הייצור. במקרים אלו רזולוציה פרטנית של עקיבות המוצר תאפשר לצמצם את מימדי ה-RECALL ולזהות בצורה פרטנית יותר את המוצרים והסדרות הפגומות.

יב. **שיפור תהליכי ייצור** - ניסיון שנצבר ואופן הצגת הנתונים בזמן אמת מאפשר למפעל להוריד באופן מתמיד את עליות הייצור, הורדת כמות פסולים וכו'.

יג. **אבטחת איכות** - מתן מענה מלא בזמן אמת לכל פעילות האיכות במפעל כולל הפקת תעודות איכות, הפקת דוחות SPC ברמת דיוק גבוה בזמן אמת. החשיבות האמיתית של איכות מתגלה כאשר היא חסרה. לחוסר איכות יש השלכות דרמטיות מהירות: אי שביעות רצון של הלקוחות, גירעון במכירות ומוניטין פגוע, אשר ברוב המקרים, לא ניתן להחזיר. מודולי התוכנה חייבות להצטיין במודולאריות, בידידותיות למשתמש.

- שיפור תכנון הביקורת ע"י שילוב חכם בתכנון הייצור
- שיפור איסוף נתוני הביקורת כאשר מפעילי מכונות יכולים לתעד את נתוני הייצור והביקורת באותו המסוף או המחשב.
- שיפור השליטה בתלוות מעצם האוטומציה של תיעוד הייצור ונתוני בקרת האיכות.
- שיפור ניהול ציוד הבדיקות.

יד. **מודול ה-SPC (Statistical Process Control)** משמש לביצוע בקרת תהליכי ייצור, לניהול אבטחת איכות ולניתוח תוצאות מדידה. המודול קורא אוטומטית מדגמים של נתונים ממצלמות, בקרי מכונות, צב"ד ומכשירי מדידה אשר להם יכולת התחברות ל-PC, ומאפשר גם קלט ואיסוף ידני. המודול אוסף, קולט ואוגר נתונים, מנתח את התוצאות, ומציג תוצאות SPC בזמן אמת. באמצעות פעילויותיו אלה משפר מודול ה-SPC את איכות הייצור, מביא להקטנת כמות הפריטים הפסולים, מסייע להגדלת שביעות רצון הלקוחות ומסייע להשגת איזון בין איכות לכמות. בשילוב מודולים נוספים של המערכת, מודול זה מבצע גם חיזוי תקלות.

טו. **ניהול משאבי עובדים** - עם הקמת התשתית לאיסוף מדויק של זמני העבודה של

המכונות, ניתן יהיה לשלבם עם נתוני זמני עבודת העובדים. מערכת ניהול היצור יכולה לתת מענה לחישוב תמריצים מדויק לפי העבודה המבוצעת. בנוסף, חלוקת משאבי כ"א ע"פ קווי הייצור, המכונות והמשמרות באופן אופטימאלי.

טז. תחזוקת מתקן – תכנון תחזוקה עבור המתקן כולל מכונות, ציוד וכו' תוך התחשבות

בפרמטרים של פעילות הייצור ובעיקר שילוב פעילות התחזוקה במערך.

מערכת אחזקה מטפלת בניהול אחזקה המפעלי, לרבות: פעילויות אחזקת שבר, אחזקה מתוכננת ומונעת, ניהול תיק מכונה, רישום אוטומטי וניתוח תולדות ציוד, מעקב צריכת חלקי חילוף, ניהול ספקים וקבלנים, ניהול תקציבי ועלויות אחזקה, ניהול מלאי עצמאי מעקב מונים וצריכת אנרגיה. המודול מאפשר קלט תקלות ישירות מבקרי המכונות (אסקלציה), העברתן לגורם המטפל ובקרת הטיפול שבוצע עד לסיומו ולהפעלת המכונה מחדש. בנוסף, מודול האחזקה יכול לשמש גם לניהול אחזקת מבנה, פעילויות משק ועוד.

- **חיזוי התקלות** מתריע על התנהגות סטטיסטית בלתי תקינה של המכונות, מגמות בלתי סבירות וכד' עוד בטרם חרגו מגבולות הבקרה. בכך מתאפשר לבצע פעולות תיקון ואחזקה עוד בטרם ארעה התקלה, ולחסוך משמעותית בזמני עצירת מכונות ובכמות הרכיבים הפסולים.

8. רשימת מקורות

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ניהול מערכות מידע תעשייתיות

קבלת החלטות בהקמת מערכת מידע תעשייתית

Criteria of Decision Making Process with Industrials
Information Systems

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- מנהל מכירות רובוטים וקווי ייצור חברת אימדיקול
- ניהל את מחלקת ה-MES ובקרה תעשייתית בחברת אפקון בקרה ואוטומציה
- מנהל מכירות מחלקת קבלנים אזור מרכז בחברת כרומגן מערכות סולאריות
- מנהל מכירות תחום קבלנים בחברת טיסנקרופ, ישראל