

SIEMENS

MES – real-time response to market changes

Pharmaceutical and Life Science Industries

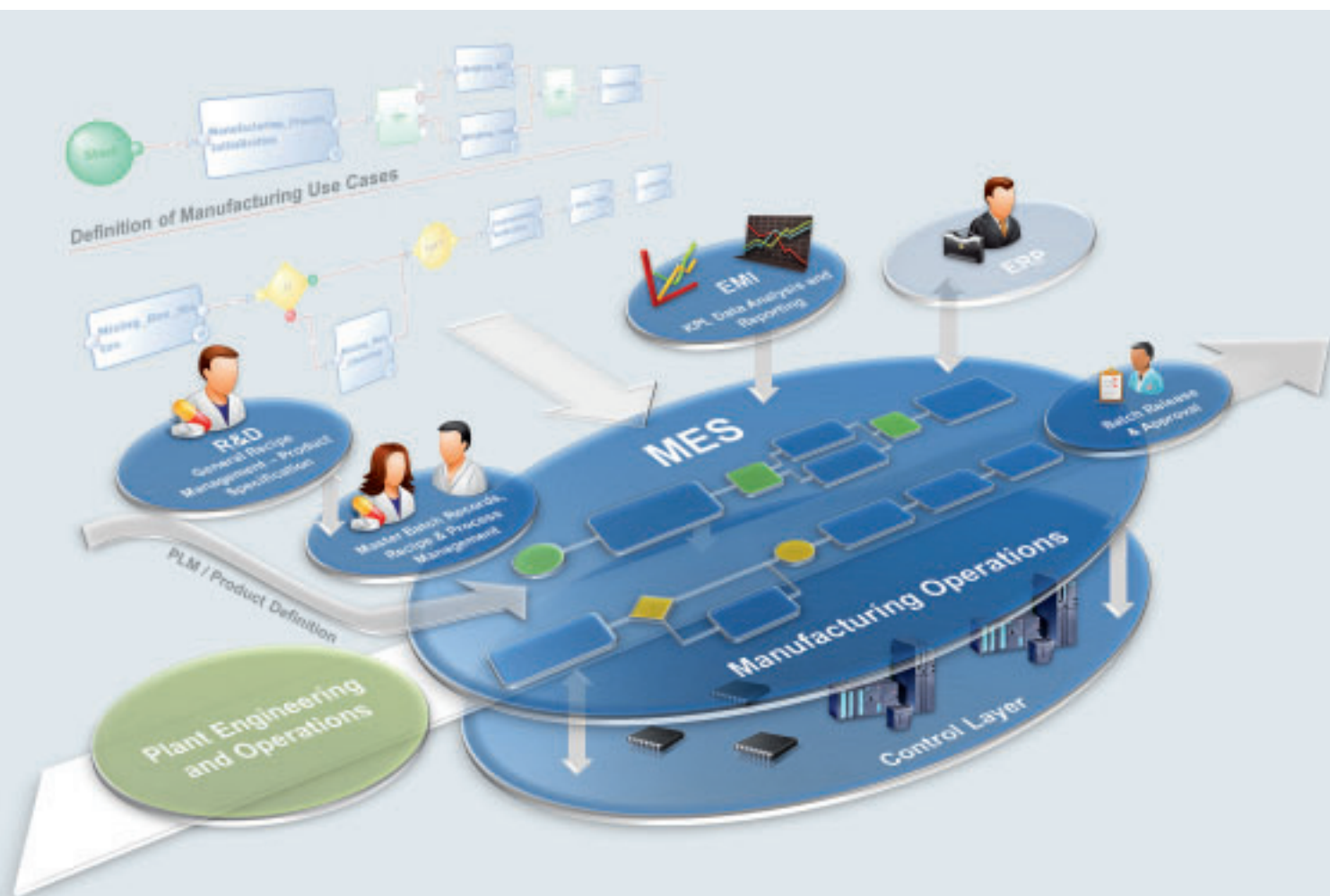


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Life science industry gears up for challenges

The life science industry is currently facing many challenges, including increased competition, cost pressures, regulatory compliance, and patient safety standards, as well as reduced time-to-market. In order to ensure better and faster production, global life science companies must deploy solutions that help them respond to market changes both quickly and appropriately.

A critical tool to achieve this is an efficient manufacturing execution system (MES) that supports timely execution. The development and implementation of MES in the life science industry has been clearly defined by world regulatory institutions such as the U.S. Food and Drug Administration (FDA).



SIMATIC IT for Life Sciences

Operational excellence at and across plants

With SIMATIC IT for Life Sciences, you benefit from out-of-the-box, pre-validated MES features, along with a sound validation package that reduces validation effort and cost. As a modular, scalable MES, SIMATIC IT for Life Sciences bridges the gap between the lab and the shop floor by integrating and optimizing development, quality, and manufacturing processes.

It provides real-time production execution and analysis to help optimize production activities from order creation to finished goods. Seamlessly integrated with automation and business systems, SIMATIC IT for Life Sciences helps you manage your entire plant operations on a global scale.

Benefits at a glance

- **Trust:** As a long-time partner to the pharmaceutical industry, the Life Sciences Competence Center from Siemens can draw upon many years of experience to provide life science companies with the right MES software and services to help them achieve operational excellence.
- **Customization:** Profit from a modular, flexible, and scalable MES platform that meets the ISA-95 standard.
- **Market responsiveness:** Ensure optimal manufacturing by bridging the gap between R&D and manufacturing.
- **Validation:** Benefit from a wide range of pre-validated MES functionality, along with a package that reduces validation effort and cost.
- **Compliance:** Be assured of full compliance with GxP and FDA procedures.
- **Integration:** Create a 'one-stop shop' – from control and automation to MES, ERP, and even PLM activities – thanks to Totally Integrated Automation from Siemens.
- **Operational excellence:** Capitalize on optimized manufacturing processes, constant quality, full regulatory compliance, shortened time-to-production and time-to-market.



SIMATIC IT Suites: a structured offer for manufacturing operations

From ERP integration to process automation, from real-time data evaluation and research and development process optimization to speeding up the introduction of new products, the SIMATIC IT Suites cover it all. Choose SIMATIC IT for a structured approach to manufacturing operations – and achieve intelligent production for optimum market responsiveness.



Production Suite for synchronized processes

Based on the ISA-95 standard, the SIMATIC IT Production Suite synchronizes business processes with manufacturing processes, collecting and providing production and quality data. The scope of MES functionality as well as the number of plants covered is fully scalable to your needs.

R&D Suite for shorter time-to-market

Designed specifically for the process industry, the SIMATIC IT R&D Suite software platform manages all R&D-related workflows and data, and links the R&D environment with the production floor to speed up time-to-market.

Intelligence Suite for real-time enterprise

The SIMATIC IT Intelligence Suite translates real-time manufacturing data into key performance indicators (KPIs) for business managers. To achieve this, vast amounts of plant data from different systems are collected in a unique real-time data warehouse – enabling decision-makers to make their business decisions at plant speed.

Specific library for Life Sciences

SIMATIC IT for Life Sciences comes with a library of compliance-ready modules for typical life science applications, such as weighing and dispensing. Included is a sound validation package that facilitates industry validation, quality certification, and regulatory compliance.

MES – the foundation for operational excellence

For life science manufacturers, a SIMATIC IT deployment pays off fast. Profit not only from increased quality and regulatory compliance but also from effective manufacturing, shorter time-to-market, and enhanced performance management.



Regulatory compliance

SIMATIC IT for Life Sciences ensures compliance with international regulations and standards. Complete manufacturing traceability, audit trails, effective sample management, batch genealogy, electronic batch recording, e-signatures, and Laboratory Information Management System (LIMS) facilitate information retrieval and batch release by exception.

Paperless manufacturing

Using electronic records and signatures, SIMATIC IT for Life Sciences supports the accurate and paperless management of a large volume of documents. Benefit from faster information exchange and retrieval, less need for storage space, fewer human errors, good data integration, KPIs, and advanced information queries.

Continuous process optimization

SIMATIC IT for Life Sciences simplifies and secures complex lab and manufacturing processes, whether manual or automated. Directed manufacturing, real-time non-conformance communication, material flow management, and e-batch review by exception are just a few features that ensure better performance.

Cost reduction and increased quality

With SIMATIC IT for Life Sciences, real-time data monitoring and analysis improve process understanding and control. This significantly reduces the risk of errors, scrap, and process delays, thereby ensuring enhanced productivity, safer production, higher quality, and shortened cycle times.

End-to-end integration

As part of Totally Integrated Automation, SIMATIC IT for Life Sciences offers seamless integration – from field and control level through to operations and management, thus ensuring operational reliability, optimal manufacturing, and market responsiveness.

Increased manufacturing visibility

With SIMATIC IT for Life Sciences, performance management and analytical tools enable cross-site performance comparison and reporting. Having better process visibility improves asset utilization and performance, thus contributing to operational excellence and enhancing your ability to run your global business more effectively.



Out-of-the-box and pre-validated: MES functionalities for the life science industry

SIMATIC IT for Life Sciences meets the standards of world regulatory institutions such as the U.S. Food and Drug Administration (FDA) and supports life science industry processes with several new key features.



SIMATIC IT for Life Sciences in detail: functional highlights

R&D Suite

The dedicated R&D Suite software platform integrates R&D and manufacturing processes, workflows, and data. Tools make it easy to define and manage corporate specifications, recipes, and bills-of-materials on a global scale. Electronic Lab Notebook functionality and formula workbench enable search and re-use of all existing research data. General recipes can easily be transferred from R&D workflows to manufacturing operations.

Master Recipe and Batch Record Management

Master Batch Records (MBRs) enable paperless manufacturing and process optimization by containing all relevant data: the master recipe, valid SOPs, detailed work instructions, workflows, and process data – such as In-Process Controls (IPCs), Critical Process Parameters (CPPs), and Critical Quality Attributes (CQAs). MBRs enable graphical process modeling and reusability of sub-records and sub-processes. Corporate recipes designed in the R&D Suite can easily be retrieved to assign plant-specific information.

Weighing & Dispensing

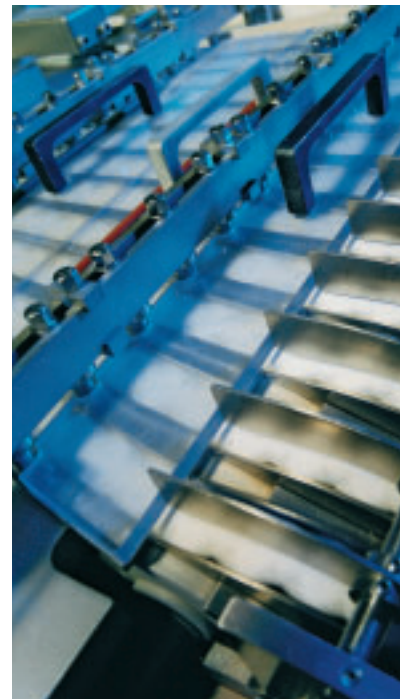
The Weighing & Dispensing module ensures consistent weighing of all material types, based on recipe specification, as well as the accurate data collection required for batch tracking and documentation. Automatic controls and calculations eliminate the error risks and speed up the weighing cycle.

Production Execution and Electronic Batch Records (eBR)

Seamlessly integrated with ERPs, SIMATIC IT for Life Sciences makes production execution and documentation of batches simple, fast, and secure – from order management to delivery of finished drugs. In the event of a deviation, an immediately displayed alert enables timely corrective action. All process steps are documented, thus ensuring compliance with international regulations and making paperless manufacturing a reality.

Batch Release & Approval

The highly reliable Batch Release & Approval module enables efficient batch release through review by exception. Automatically generated execution and alert reports make it easy for dedicated signatories to assess relevant information for batch approval or rejection.



Integrated Quality: IPC, SPC, LIMS & PAT

Quality is integrated in the production process with at-line and off-line quality management.

At-line quality is ensured by a series of procedures and methods to monitor, analyze, and control biological, chemical, and physical hazards in processes and operations. The Statistical Process Control (SPC) tool predicts significant deviations that may result in rejected products. UNILAB the Laboratory Information Management System (LIMS) optimizes the collection, analysis, and reporting of quality data in the lab and on the production line, ensuring off-line quality. SIMATIC IT for Life Sciences also connects with SIPAT, the Siemens solution for Process Analytical Technology requirements, ensuring in-line quality.

Audit Trail & Genealogy

SIMATIC IT for Life Sciences records all operations for product and regulatory review purposes. It provides 21CFR Part 11 compliance, providing access control, e-signatures, audit trail, forward and backward genealogy, data security, and electronic records.

Track & Trace

The Track & Trace module controls and pilots material flows in real time – from ingredient receipt in the warehouse to dispatching. It provides a comprehensive material tracking and tracing system, down to the container/lot level, performing automatic checks on quality and inventory at each step of production.

Asset Performance Management

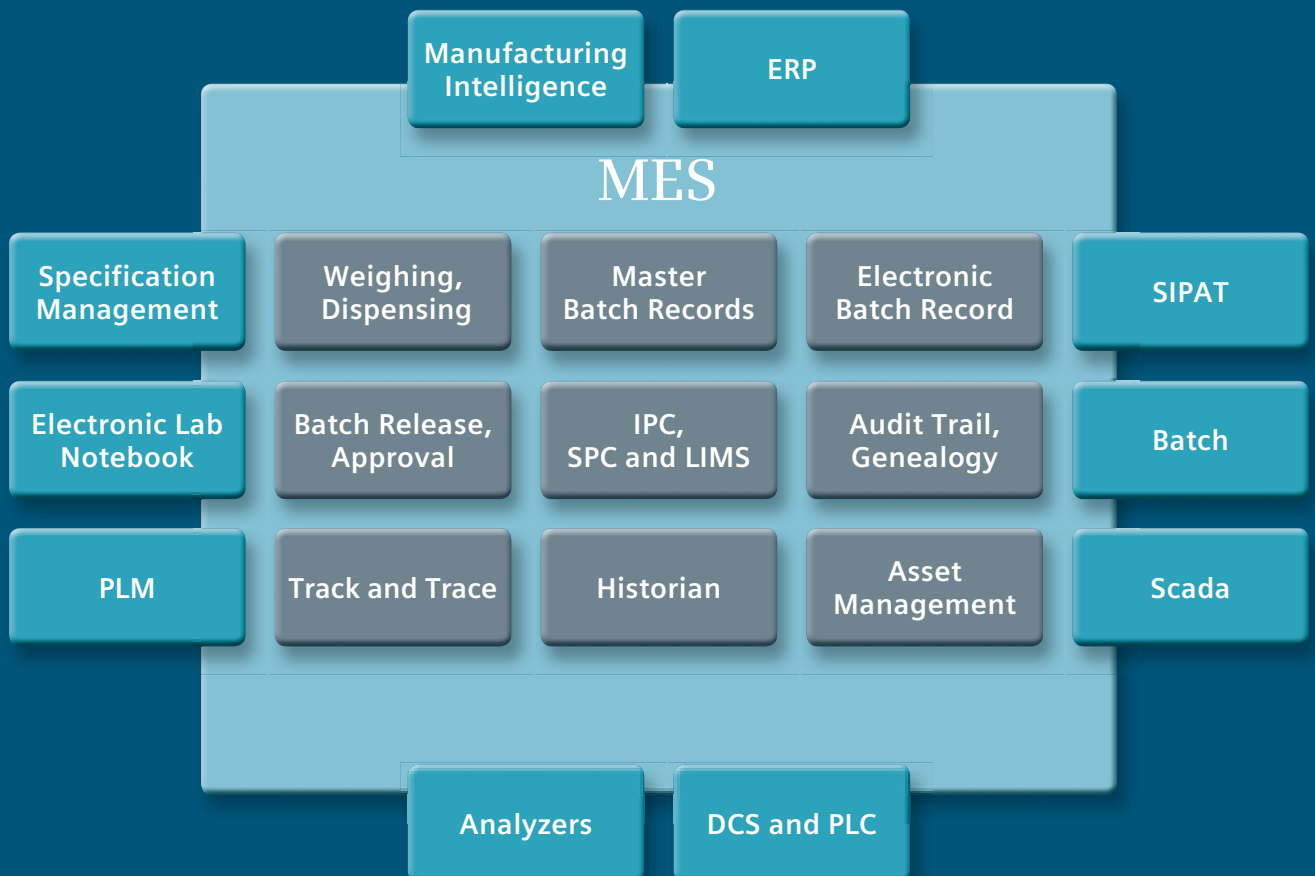
Asset Performance Management bundles OEE, maintenance, and manufacturing intelligence functionalities. From equipment effectiveness, breakdown analysis, maintenance, and spare parts management to KPIs and dashboards, it combines all that is required for optimized asset utilization, energy savings, effective plant management, and manufacturing visibility. Modules are also available separately.

Historian

The Historian module collects, tracks, compiles, contextualizes, and aggregates all plant-related information from real-time sources like eBRs, automation systems, SCADA, LIMS, and relational database systems. Thus, process data is made available with the appropriate granularity and contextualization for manufacturing intelligence.

Manufacturing Intelligence

With its manufacturing intelligence capabilities, SIMATIC IT for Life Sciences translates valuable data collected from MES into usable information. Management can instantly view dashboards, scorecards, multi-site KPIs, and analytics to help them make appropriate decisions on a plant or corporate level.



Intuitive workflow design

With the new graphical workflow configuration engine, it is easy to perform assessments during the project phase, define master batch records, and execute the workflow. Simply choose tasks for the workflow from a menu of activities and control tasks, and then connect them graphically to create production process workflows, production cycles and steps, work instructions, and quality-check milestones.

Life science specific library

The library in SIMATIC IT for Life Sciences offers compliance-ready material weighing, calibration management, components listing, label printing, generation of hazard and precaution warnings, and management of expiration dates.

Sound validation package

SIMATIC IT for Life Sciences contains the guidelines for effective validation of an MES project at a life science site.

It also comes with a quality assurance software release certificate, regulatory compliance information, an internal test process report, an operational qualification, and a traceability matrix that ensures that all GMP (Good Manufacturing Practice) functionalities have been tested.

Main features specific to life science

- A graphical workflow configuration engine
- Automatic creation of an electronic batch record, and instructions displayed for every manufacturing step
- Weighing and dispensing features, including compliance-ready material weighing and pharmaceutical label components
- Everything necessary for industry validation, quality certification, and regulatory compliance
- Life Science Competence Center to provide customer support

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