



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 the Life Science Industry

Operational excellence at and across plants

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

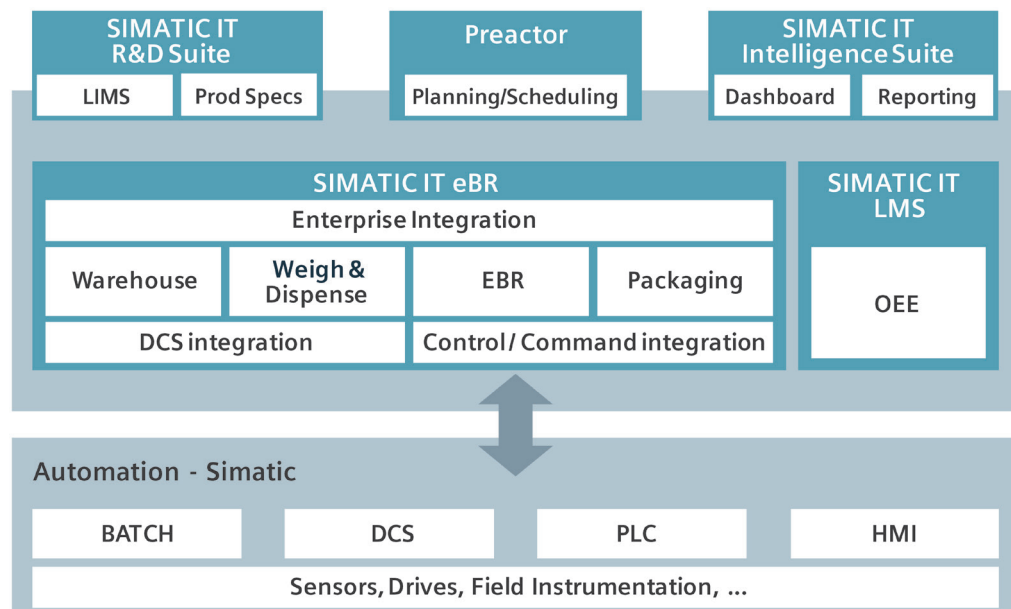
It provides real-time production execution and analysis to help optimize production activities from order creation to finished goods. Seamlessly integrated with automation and business systems, SIMATIC IT helps you manage your entire plant operations on a global scale.

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
- Control and monitoring of materials consumed and returned in and out of packaging
- Line Monitoring System for analysing and monitoring plant performance and downtime (OEE)
- Competence Center to provide customer support

Benefits at a glance

- **Trust:** As a long-time partner to the pharmaceutical industry, the Life Sciences Competence Center from Siemens benefits from many years of experience in providing 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 Portfolio: 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 Portfolio cover it all. Choose SIMATIC IT for a structured approach to manufacturing operations – and achieve intelligent production for optimum market responsiveness.



R&D Suite for shorter time-to-market

Designed specifically for the process industry, the SIMATIC IT R&D Suite software platform includes Unilab the LIMS (Laboratory Information Management System) solution from Siemens and manages all R&D-related workflows and data, and links the R&D environment with the production floor to speed up time-to-market.

SIMATIC IT eBR

SIMATIC IT eBR is the solution for complete paperless manufacturing and full eBR. SIMATIC IT eBR provides advanced features to design, streamline and manage operation processes. Powered by an advanced workflow, SIMATIC IT eBR can be used to direct manufacturing, recording and centralising all information required for eBR review and enabling release by exception.

SIMATIC IT eBR is based on the proven SIMATIC IT XFP solution that has enabled multiple plants worldwide to improve visibility and efficiency in their entire facilities.

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.

Line Monitoring System

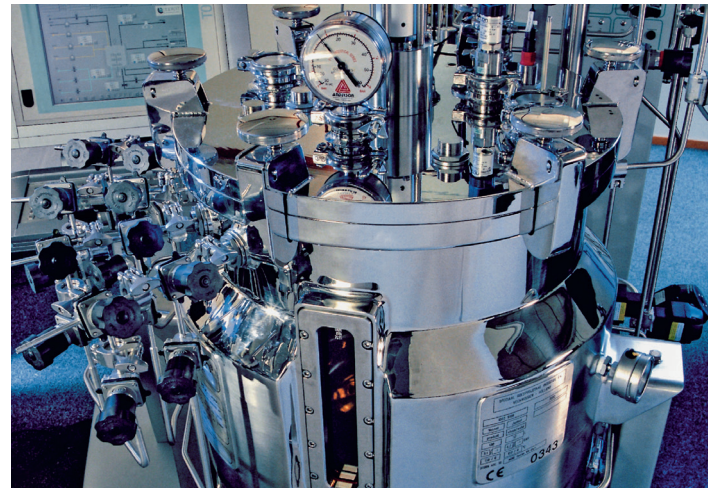
The SIMATIC IT Line Monitoring System module which is available separately, makes it possible to monitor plant-floor performance to achieve at-line visibility and control.

Preactor - APS

Preactor provides the glue that connects back office applications such as ERP with production. It enhances the decision making process by allowing finite / infinite capacity planning and scheduling. For medium / long term planning Preactor generates production scenarios by calculating net production quantities by balancing rough cut capacity with demand, enhancing the S&OP process. For short term detailed scheduling, Preactor considers both material and plant constraints to create feasible plans as frequently as required.

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

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

Cost reduction and increased quality

In the SIMATIC IT for Life Sciences portfolio, 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

Siemens provides true eMBR through a native integration between the MES system and the automation system, allowing easier configuration and less complexity. A unified user interface also allows the operator to navigate more easily and efficiently.

Increased manufacturing visibility

With SIMATIC IT, 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.



SIMATIC IT for Life Sciences in detail: functional highlights

Warehousing - Smart Shop Floor Logistics

The Warehouse module controls and pilots material flows in real time, from ingredient receipt in the warehouse to dispatching. It provides a comprehensive materials tracking system, down to the container/lot level, performing automatic checks on quality and inventory (FIFO, FEFO rules, quantity, etc.) at each step of production.

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.

Packaging

SIMATIC IT eBR enables operators and managers to view the status of the packaging process and control the consumption, use and return of packaging and manufactured materials throughout the packaging process.

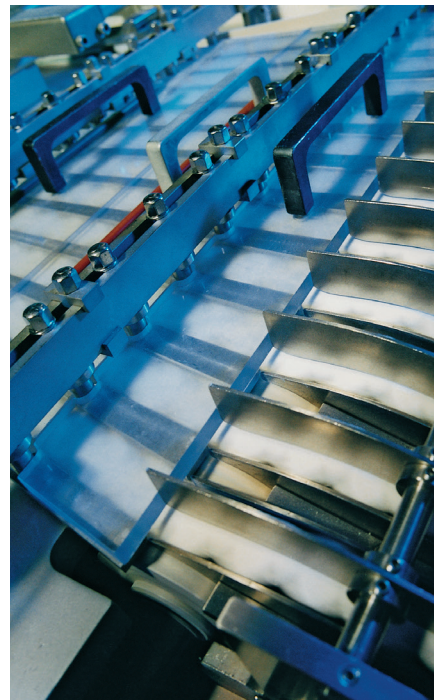
Master Recipe and Batch Record Management

Electronic Master Batch records (eMBR) 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). An eMBR enables graphical process modeling and reusability of sub-records and sub-processes.

Production Execution and Electronic Batch Records (eBR)

Seamlessly integrated with ERPs, SIMATIC IT 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 & 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. SIMATIC IT also connects with SIPAT, the Siemens solution for Process Analytical Technology requirements, ensuring in-line quality.

LIMS

SIMATIC IT 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.

Audit Trail & Genealogy

SIMATIC IT 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

SIMATIC IT has the ability to control and pilot material flows in real time - from ingredient quality and inventory at each step of production.

Line Monitoring System

The line-monitoring capability allows manufacturers to monitor and improve production efficiency and optimize performance, through the automatic collection and contextualisation of production data in real time directly from the factory floor. Principal features within LMS include Plant Floor Monitoring, Downtime management and analysis (DTM/OEE) and Centralized Reporting.

Manufacturing Intelligence

With its manufacturing intelligence capabilities, SIMATIC IT has the capability to translate valuable data collected 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.

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Siemens AG
Industry Sector
Pharmaceutical and
life science industries

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