



■ Simatic IT for Life Sciences

# Best-of-Breed MES Library for Life Sciences

Siemens unveils Simatic IT for Life Sciences to enable pharmaceutical manufacturers to reduce time to market while still ensuring safety and meeting regulatory requirements.

The life science industry is currently facing many challenges, including increased competition, cost pressures, regulatory compliance, ensuring patient safety, and reducing time to market. Being able to manufacture products better and faster has become critical for the life science industry. Achieving operational excellence is the required strategy for today's life science manufacturers.

Efficient manufacturing requires consolidating and optimizing the various manufacturing resources available, including equipment, people, processes, and products. A manufacturing execution system (MES) can address this key requirement by delivering production and quality information that enables the optimization of production activities from order creation to finished goods. Siemens has been active in the pharmaceutical industry for many years and has integrated its pharmaceutical industry and MES expertise into the new Simatic IT suite for the life science industry.

Simatic IT for Life Sciences is a modular, scalable MES that conforms to the ISA-95 standard. It bridges the gap between the lab and the shop floor by integrating and optimizing development, quality, and manufacturing processes. Within the Siemens concept of Totally Integrated Automation (TIA), it offers integration capabilities extending from the field and control level to the operations and management level, thus ensuring optimal manufacturing and market responsiveness. Simatic IT for Life Sciences offers

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out-of-the-box and prevalidated MES features together with a sound validation package, ensuring fast deployment and low total cost of ownership (TCO).

### Industry-specific MES solution leveraging cross-industry platform

Simatic IT for Life Sciences combines best-of-breed features from Elan Software with the Simatic IT MES platform. The MES meets the standards of world regulatory institutions such as the US Food and Drug Administration (FDA) and supports life science industry processes with several new key features.

A major feature is the Manufacturing Process Management relying on graphical workflow technology, built on Microsoft's Workflow Foundation Server. It is used to perform assessments during the project phase, define master batch records, and execute the workflow. From a menu of activities and control tasks, the user chooses tasks for the workflow and connects them graphically. The workflow engine is also integrated into Simatic IT R&D for defining preliminary process steps during specification management. These recipes can be imported and detailed in the Production Suite. This feature offers pharmaceutical companies the opportunity to define recipe production specifications in the MES environment. Users can create production process workflows, production cycles and steps, work instructions, and quality-check milestones.

During the execution process, an electronic batch record (eBR) is automatically created, based on a master batch record template. Work instructions are displayed on the screen and operators are guided step by step through the manufacturing execution process. The eBR is an extension of the standard Production Execution module of Simatic IT, which also enables production data recording, material consumption and declaration, and paperless guided manufacturing. 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.

### Prevalidated MES solution for low TCO

Simatic IT for Life Sciences is a prevalidated, configurable software suite that enables use of the GAMP (Good Automated Manufacturing Practice) V, category 4, validation procedure. This is considerably simpler and cheaper than category 5, which is used for custom applications.

Simatic IT for Life Sciences comes with a sound validation package that meets customer and industry requirements. It contains the guidelines for effective



The Simatic IT library for Life Sciences offers compliance-ready modules for typical life science applications such as weighing and dispensing

### Main features

- ▶ Business Process Management to graphically design R&D and manufacturing processes
- ▶ 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 needed for industry validation, quality certification, and regulatory compliance
- ▶ Life Science Competence Center to provide customer support

validation of an MES project at a life science site. It also comes with a quality assurance software release certificate, regulatory compliance information, and a traceability matrix that ensures that all GMP (Good Manufacturing Practice) functionalities have been tested. Another important document delivered is the internal test process report that details the testing strategy applied internally. Last but not least, the validation package includes the operational qualification. The validation package enables customers to capitalize on supplier experience at all stages of validation, reducing validation effort and cost. The official release of Simatic IT for Life Sciences is summer 2011. However, the implementation of MES projects in the life science industry has already started with the beta release. ■

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