SIEMENS

Electronic Batch Record

Paperless Manufacturing

Robust and flexible processes with paperless manufacturing

Innovations for the pharmaceutical industry

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A paperless recipe for pharmaceutical success

Faced with growing cost pressures, regulatory and safety guidelines as well as increasingly diverse product portfolios, pharmaceutical manufacturers are continuously looking for ways to improve production processes. A new electronic batch record solution enables completely paperless manufacturing within regulated processes. It supports operational and manufacturing efficiency in both manual and highly automated environments – from the design of the batch record to the release of the batch report.

SIMATIC IT eBR – simplifying batch record management

With SIMATIC IT eBR, Siemens offers a software solution for electronic master batch record management that enables native integration between the manufacturing execution system (MES) and the distributed control system (DCS) using SIMATIC PCS 7 and SIMATIC BATCH. SIMATIC IT eBR expedites the design, execution, review and release of master batch records (MBR) and electronic batch records (eBR).

It also enhances MBR design flexibility by providing all of the master information from SIMATIC BATCH to the MES design tool. SIMATIC IT eBR seamlessly integrates DCS batch processing with MES workflow management, thus streamlining and accelerating solution implementation for paperless manufacturing. What's more, recipe implementation can take only a few months to complete.

DESIGN

- Intuitive tool – no IT skills required
- Reduction of development effort and risk between MES and DCS
- Ability to develop and reuse standardized libraries for process operations

Master Batch Record

EXECUTE

- Paperless process
- Faster and safer data acquisition
- Secure and control the exchange between DCS and MES
- Improved manufacturing control

Electronic Batch Record

REVIEW

- Single point of review of all batch relevant information
- Review by exception: Fast and safe review already through the production process

Batch Review & Approval

Good reasons to go paperless

Paperless manufacturing offers several advantages when compared to traditional procedures. Enabling a more detailed recording of process data, conditions and results, it helps build error-resistant processes that are more robust and less prone to deviations. It can also significantly reduce the time and effort associated with entering data, documentation complexity and, of course, overall paperwork.

Equipment and workflow coordination

Paperless manufacturing secures materials and equipment usage and workflow. It prevents batch loss and reduces discard, especially human error-related losses. What's more, it minimizes exceptions and the associated effort of investigating and developing corrective action plans, thereby improving cycle times.

One-point batch management

Paperless manufacturing simplifies batch record management by providing a single point of storage and access to all batch-related documents. It reduces the time and effort spent on batch record preparation, maintenance, review and release. In addition, it minimizes delays and the time needed to access information from the master batch record.

Ensured compliance

Paperless manufacturing provides a simple framework for effective action and documentation as well as enforces compliance with standard processes, procedures and regulations.

Complete paperless manufacturing with SIMATIC IT eBR

With SIMATIC IT eBR, Siemens has developed a dedicated MES solution for the pharmaceutical industry that enables complete paperless manufacturing and full electronic batch recording. SIMATIC IT eBR provides advanced features for designing, streamlining and managing production operations and processes – both manual and automated – via seamless integration between the MES, automation and enterprise resource planning (ERP) systems.

Reliable and robust
The SIMATIC IT eBR module ensures the reliable acquisition and robust management of critical process data.

Getting it right every time
As a highly advanced batch record data management solution, SIMATIC IT eBR makes certain that the right materials are in the right place at the right time with the right status and handled by the right people.

Central data storage
For review by exception, SIMATIC IT eBR generates, captures and centrally stores all of the information needed for quick access, thus helping to speed up batch review and release.

Optimized resources and processes
Fully compliant with FDA and GMP regulations and prevalidated to meet all current standards for pharmaceutical manufacturing, SIMATIC IT eBR optimizes batch manufacturing processes and helps streamline resources, equipment allocation and standard operating procedures (SOPs).
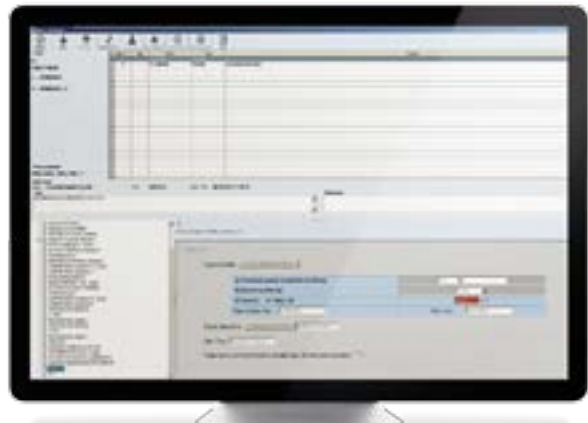
Tremendous flexibility
By simplifying the design, execution, review and release of master batch records and electronic batch records, SIMATIC IT eBR provides tremendous flexibility for accommodating product variety and diversity.

A proven platform
SIMATIC IT eBR is based on the proven SIMATIC IT XFP solution, which has been used to improve the visibility and efficiency of entire operations at multiple plants worldwide.

Batch review and release with SIMATIC IT eBR

Integrated solution for paperless manufacturing

SIMATIC IT eBR supports the exchange of information and models between the automation and paperless workflow landscapes. Both a top-down, management level implementation and bottom-up, automation-driven implementation are very quickly set up. Implementation can be performed in only a few weeks as opposed to several months with other solutions.
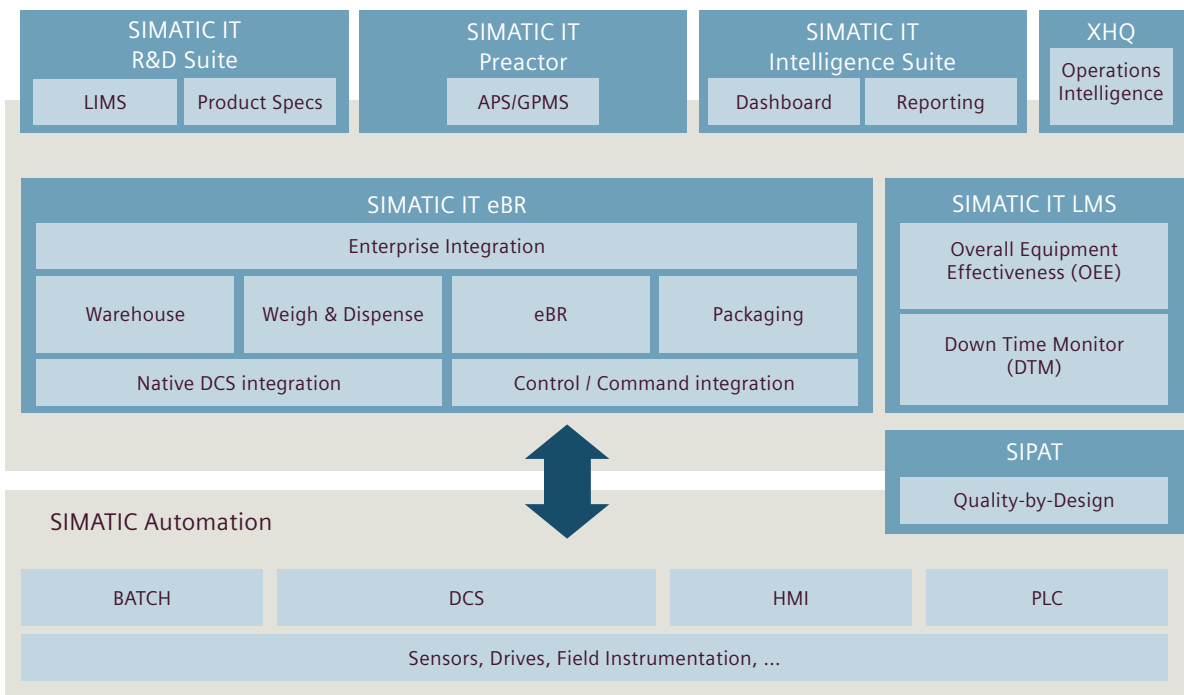
The greater paperless payoff

Using electronic records and signatures, SIMATIC IT supports the accurate and paperless management of large volumes of documents. The result is faster information exchange and retrieval, a reduced need for storage space, fewer human errors, good data integration, KPIs and advanced information queries.

End-to-end integration

Siemens provides true paperless manufacturing through native integration between the MES system and the automation system, thereby enabling easier configuration and reduced complexity. A unified user interface also allows the operator to navigate more easily and efficiently.

Portfolio overview

SIMATIC IT R&D Suite		SIMATIC IT Preactor	SIMATIC IT Intelligence Suite		XHQ
LIMS	Product Specs	APS/GPMS	Dashboard	Reporting	Operations Intelligence

SIMATIC IT eBR

Enterprise Integration

Warehouse	Weigh & Dispense	eBR	Packaging

Native DCS integration	Control / Command integration

SIMATIC IT LMS

Overall Equipment Effectiveness (OEE)

Down Time Monitor (DTM)

SIPAT

Quality-by-Design

SIMATIC Automation

BATCH	DCS	HMI	PLC

Sensors, Drives, Field Instrumentation, ...

Paperless manufacturing highlights at a glance

Warehousing – smart shop floor logistics
The warehouse module controls and pilots material flows in real time, from ingredient receipt in the warehouse to product dispatch. 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 every production step.

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

Packaging
With SIMATIC IT eBR, operators and managers are able to monitor the status of the packaging process as well as control the consumption, usage and return of packaging and manufactured materials throughout the process.

Master recipe and batch record management
As the basis for paperless manufacturing and process optimization, electronic master batch records (eMBR) incorporate all relevant data. These include 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). eMBRs also enable graphical process modeling, all of which can be managed by SIMATIC IT eBR.

Production execution and electronic batch records (eBR)
Seamlessly integrated with ERPs, SIMATIC IT makes production execution and batch documentation simple, fast and secure – from order management to finished product delivery. In the event of a deviation, an immediately displayed alert enables timely corrective action. All process steps are documented to ensure compliance with international regulations.

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.

Learn more:

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Discover our ideas for a strong future in the pharmaceutical industry.

The benefits of paperless manufacturing at a glance.