

Simatic IT eBR is part of the Siemens solution platform for industry software and automation

### Simatic IT eBR

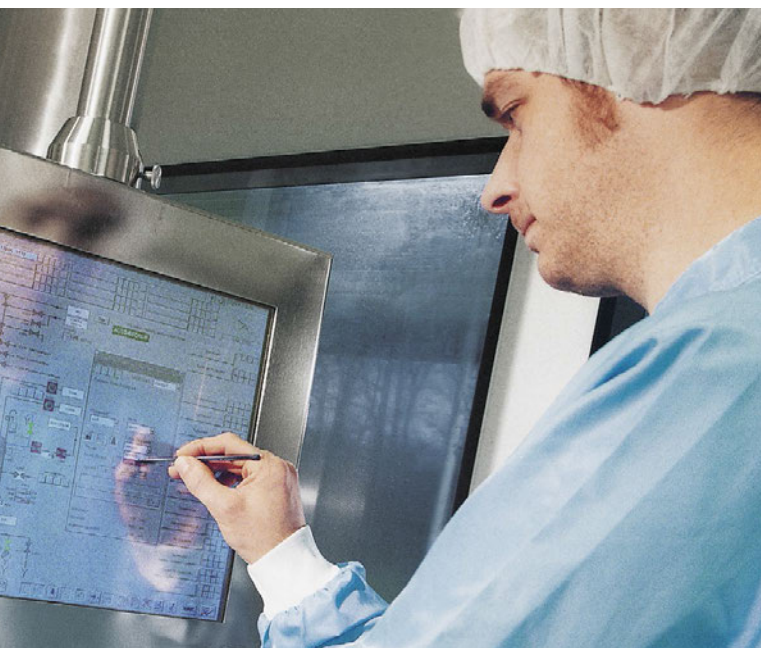
# Pushing past paper

One barrier to more efficient manufacturing in the pharmaceutical industry is the frequent use of paper-based processes. Consequently, the pharmaceutical industry is increasingly using modern IT and automation solutions to make the move to paperless manufacturing. With Simatic IT eBR, Siemens facilitates the implementation of electronic batch management and provides added benefits through seamless integration of the manufacturing execution system and control level.

By taking a risk-based approach to pharmaceutical manufacturing, regulatory bodies have encouraged pharmaceutical companies to adopt the available technologies to improve production efficiency and performance. Specifically, both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have published guidelines that specify how to create and manage quality production records in an electronic system to provide an electronic record that precisely details how a drug has been produced. An electronic

batch record (eBR) system for paperless manufacturing must encompass three steps: design, execution, and review. To facilitate the review and release process and reduce the workload for quality assurance teams, reviews should be exception based. In principle, the eBR adopts the traditional paper-based production procedures established by the manufacturers in the pharmaceutical industry. Production processes are specified in an easy-to-use and flexible master batch record (MBR) that serves as a template for a general recipe for how to produce a

pharmaceutical product. The MBR contains the product specification (what is produced); the work procedures, conditional framework, equipment, and workflow (how to produce); the critical quality attributes (how the product and process is verified); and the necessary tests for ensuring product quality (how to prove product quality). The eBR approach in its most basic form can be an electronic representation of previously paper-based processes (paper-to-glass). However, eBR can also help streamline workflows and eliminate errors and deviations by



Simatic IT eBR enables complete paperless manufacturing

## Technical features

Simatic IT eBR enables paperless manufacturing and gathers critical data in an electronic format, offering a comprehensive set of out-of-the-box features:

- Vertical integration from the enterprise resource planning (ERP) level to the automation level
- Batch and operations management (including operator guidance and production steps)
- Materials and inventory management (weighing, dispensing, mixing) at the container level (with ERP integration)
- Equipment management over the complete lifecycle of the plant
- Sample management (with laboratory information management system [LIMS] integration)
- Deviations/alarms/alerts management
- Batch reporting
- Full batch and materials genealogy
- Batch release by exception

using the capabilities of state-of-the-art IT systems and by networking the electronic batch information with other production systems, such as laboratory information management systems (LIMS), distributed control systems (DCS), and building automation systems. Such integration enables higher production quality (Right First Time) and facilitates batch review and release.

### Minimizing risks, exploiting opportunities

While pharmaceutical companies have long been aware that introducing paperless manufacturing will provide substantial benefits, they have been hesitant to introduce such systems on a large scale due to concerns regarding the actual costs, risks, and benefits of paperless manufacturing.

An eBR solution covers the processes and requirements of both the production of active pharmaceutical ingredients and the secondary processes and must be capable of handling very complex operations. A given plant will execute as many as 300 recipes that can involve several thousand process parameters and several hundred production steps.

### Integration provides added benefits

Until recently, there were no truly integrated solutions for paperless manufacturing that could encompass the manufacturing execution system (MES), production, and automation levels and that could integrate both manual and automated processes. With Simatic IT eBR, Siemens now presents a solution that can bridge the gap between ISA-95 and ISA-88 standards for interfacing MES and automation, batch control, and manufacturing IT. The solution helps guide manufacturing operations, whether manual or automated, via seamless interaction between the MES, automation system, and enterprise resource planning (ERP) system. Siemens' solution for eBR management offers native integration between the MES and the DCS layer. This expedites the design, execution, and review steps of eBR and provides real flexibility in the MBR design. In the DCS, a robust and powerful batch engine manages complex low-level S88.01 recipes related to automatic control of the process, while the selection of the master recipe name and version makes all master recipe information available for use in the MES design tool. Additionally, Simatic IT eBR integrates with

the Simatic IT R&D Suite, which covers typical R&D activities such as development of new products, product maintenance, and product enhancement, as well as quality information with the LIMS component Unilab. There is also an integration with the Preactor APS software for production planning and scheduling. This helps streamline operations across the entire product lifecycle.

### Streamlining processes

With Simatic IT eBR, companies can more easily introduce paperless manufacturing based on electronic MBRs and become more efficient in their operations without compromising quality and product safety – in both manual and highly automated environments. Thanks to the seamless integration between batch processing in the DCS and workflow management in the MES, Simatic IT eBR can streamline and significantly accelerate the implementation of a solution for paperless manufacturing, reducing typical implementation times from one year to only months for one recipe. ■

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