

ABB Life Sciences

Speeding pharmaceuticals to the marketplace



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Industrial IT solutions for the Life Sciences industry. Behind every aspirin you take stand complex manufacturing operations, supply chains, and regulations--three potential sources of headaches for the pharmaceutical and biotechnology industry. They sound like three separate issues, and that's how they were approached in the past. Now, based on its unique knowledge of both the industry and the regulatory environment, ABB Life Sciences has taken another look at how manufacturing, supply chain, and compliance systems interact. The result is a range of products, applications, and services that speed up delivery and regulatory approval at every stage in a drug's history, all the way to the checkout counter.

In the pharmaceutical and biotechnology industry, priorities often shift to accommodate changes in consumer preferences, competition, manufacturing resources, and regulations. One priority remains constant: to make high-quality products and deliver them to the marketplace quickly. Pharmaceutical manufacturers measure time-to-market in millions of dollars per day. Those figures are driven by such factors as the limited patent life of new drugs. Manufacturers need manufacturing equipment and applications that move materials swiftly and consistently from clinical research and development, through each processing stage, through regulatory review and approval, and on to the consumer.

ABB Life Sciences brings a fresh, whole-enterprise perspective to the pharmaceutical and biotechnology industry. It is uniquely positioned to do this because of its long-term partnerships with worldwide pharmaceutical and biotechnology customers and because it can draw on more than one hundred years of experience with regulated industry. The expertise of ABB begins at the level

of individual sensors, touches every aspect of the manufacturing cycle, and then moves beyond to complete e-business solutions. Every product and application in the Life Sciences portfolio:

- Accommodates single or multiple products, single or multiple paths, stand-alone or integrated operation
- Is compliant with industry regulations and standards
- Consists of components which can be readily validated
- Provides backward compatibility to existing systems
- Provides an upgrade path to automated, intelligent enterprise management and planning
- Maximizes the customer's return on investment

With its new Industrial IT approach and single-point responsibility, ABB Life Sciences has grown used to encountering success stories up and down the manufacturing line.

Ensuring a competitive advantage

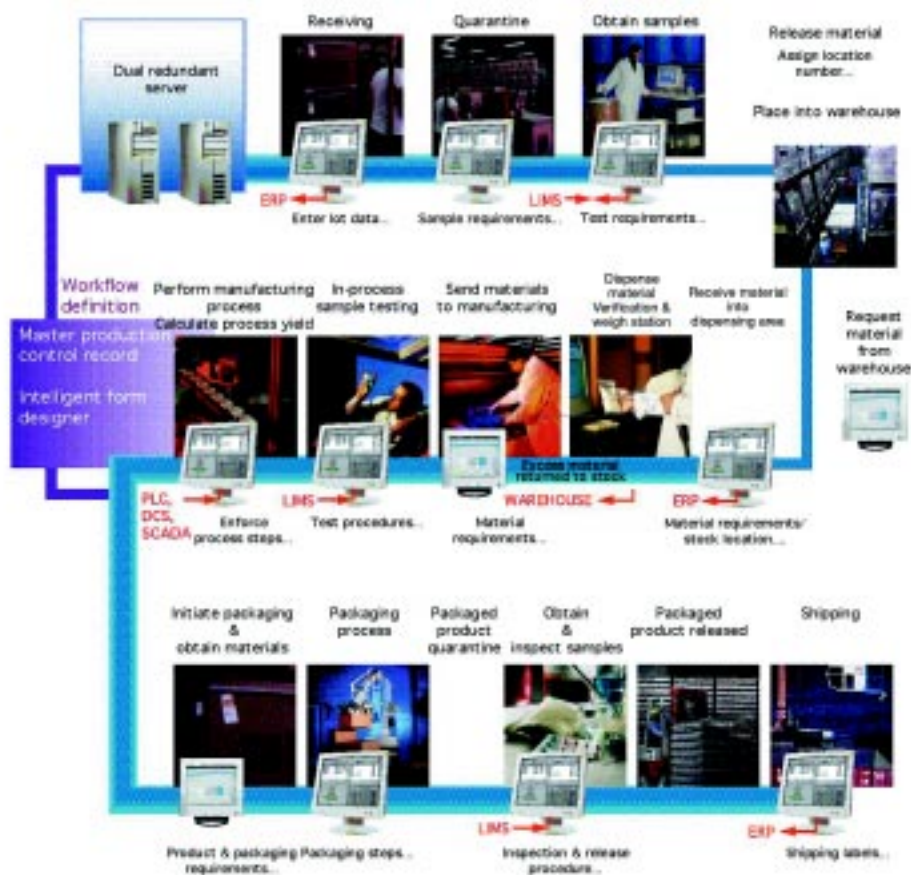
ABB recently installed an electronic batch record (EBR) system in a pharmaceutical plant that was struggling to generate, update, and track paper documents. Some of those documents--recipes and procedures--actually drove the manufacturing process, and others were needed to demonstrate regulatory compliance. The EBR system replaced paper with electronic documentation, complete with electronic signatures and audit trails. It eliminated costly and time-consuming manual paper management. After installation of the EBR system, a smaller staff processed twice as many work orders in one-third of the time with fewer errors and deviations. Work order backlog dropped 80 percent in the first year alone. The return on investment was 22.7 percent.

But ABB's whole enterprise approach meant that the EBR system achieved more than efficient data management. The system also enforced regulatory compliance and current Good Manufacturing Practices (cGMP) across several manufacturing lines

and three work shifts. Batch-to-batch consistency, quality, and productivity increased. With electronic records to document and validate every step in the process, regulatory agencies were able to fast-track the customer's products through review and approval. Faster manufacturing, verified quality and consistency, and earlier approval gave this ABB customer a tremendous competitive advantage.

A major pharmaceuticals production plant in Ireland achieved similar results from its ABB advanced control system. With integrated equipment management, resource planning, and up-to-the minute plant information, the system optimized the plant throughput. In developing the new applications software, ABB realized tremendous savings for the client by developing the detailed specifications based on the original control system documentation and specifications. The inherent capability built into the system will enable MES functionality and the ERP integration in the future.

Workflow in pharmaceutical manufacturing



Maximizing return on investment



Pharmaceutical manufacturing has two main stages:

- The production of an active ingredient or drug
- The conversion of the active

ingredient into products suitable for administration (tablets, capsules, liquids, creams, and so on)

A given plant may process several products in different forms simultaneously. Each product is formulated according to a specific recipe and follows specific manufacturing procedures. Every step in every process must be tracked and validated to comply with stringent consumer and environmental standards and regulations.

The pharmaceutical and biotechnology industry is under pressure to maintain quality, consistency, and compliance from product to product and from batch to batch. Among other goals, the industry strives to consistently measure and dispense dosages, minimize the storage time of active ingredients, precisely track deviations, manage resources, keep the entire plant in line with industry and government standards--and still contain costs. ABB Life Sciences responds to all these concerns. Its products and applications not only meet the supply chain, processing, and regulatory demands placed upon the industry but also maximize return on investment.

Instruments, analytics, electric drives, and electrical systems

The ABB product line includes sensors, controllers, analyzers, chromatography, scaleable open control systems, electric drives and electrical systems, such as transformers and uninterruptible power supplies. This equipment integrates seamlessly with existing and future control systems. Once again, ABB Life Sciences adds value to its offering by incorporating hygienic design right into each product. Instruments are certified for clean-in-place (CIP), sterile-in-place

(SIP) capability. Fewer and more predictable stops for cleaning result in significant savings.

Robots for receiving, packing, and palletizing

ABB robotics move all forms of products and packages--from a single ingredient in a vaccine to a pallet of vitamins. Individualized systems receive, package, and store products with flexibility, minimal maintenance, and maximum efficiency. Installation and adjustments to new packaging requirements are rapid and simple.

Warehouse and inventory management

ABB applications optimize warehouse logistics and furnish real-time warehouse information, to reduce storage times, improve the use of storage areas, improve tracking and planning, and reduce warehouse costs. Inventory management provides forward and reverse traceability of materials, equipment, and personnel.

Batch automation

ABB is a long-time leader in process automation systems and products for batch processing industries, including batch control, electronic batch record keeping, and the design of intelligent documents, recipes, and procedures.

ABB has combined process control with recipe and equipment management. Its batch control application provides an overview of batch production, manages a library of master recipes and recipe building blocks, schedules batches, allows runtime modifications, and manages resources to improve performance and shorten cycle times. The Recipe Procedure Diagram (RPD) exceeds ISA S88.01 standards by providing more information (on state, mode, and status) than the standards require.

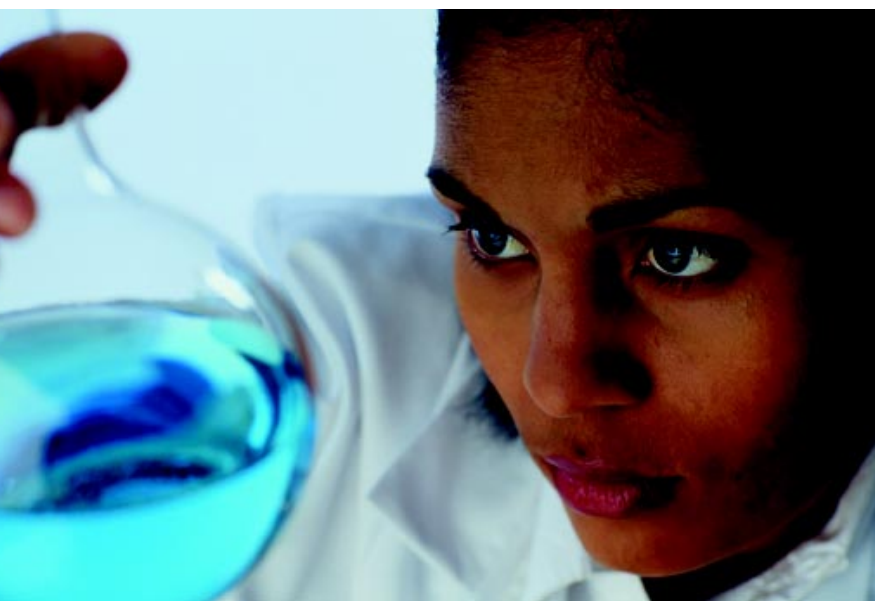


ABB's EBR systems supervise, record, track, and store data on batch events. The individual modules--Weigh and Dispense, Electronic Logbook, Batch Record Manager, and Reports--interface to planning systems and other applications. ABB's Intelligent Forms Designer (IFD) creates intelligent documents and forms that enforce each process step and collect the appropriate data (including electronic signatures) for batch records.

These batch automation systems aren't tool kits but full-fledged, robust, flexible, "plug and produce" applications. Each system interfaces with the others and integrates with existing and future plant systems, including MES and intelligent planning and management systems. Every component is readily validated and regulatory compliant from the start.

Clean room design and automation

Like ABB's batch automation systems, ABB's clean rooms feature standard validatable components. They're constructed with interconnecting modules that can be arranged to meet the customer's individual requirements. The clean rooms come enabled for automation, including MES. For example, ABB can install a control system to automatically manage and audit cleaning steps and sequences, and can ensure that all the requirements of validation are met.



Manufacturing execution systems (MES)

ABB's manufacturing execution systems (such as Produce IT ME and FlowStream) manage production materials, equipment, personnel, recipes, process instructions, and facilities while uniting planning with shop-floor control. They help model, identify, and address problems before they occur. Process operations continuously improve in quality and efficiency. In fact, ABB's Produce IT ME lowers operating costs for regulated industries by 15 to 20 percent.

Comprehensive in scope and intuitive in use, Produce IT ME is the first manufacturing execution system created from separate validatable applications. That means that ABB can seamlessly customize the system to satisfy the plant's specific manufacturing and process conditions. All the features and functions required for regulatory compliance are built in.

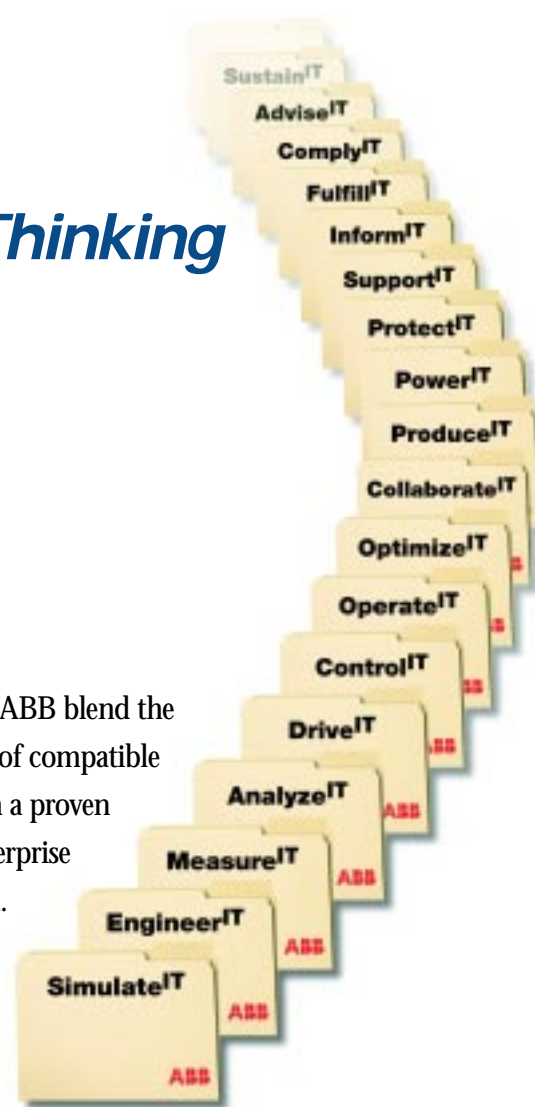
Fully compliant and forward looking

The ABB Life Sciences portfolio is compliant with and works in line with the appropriate industry standards and regulations, including FDA, ISA S88, current Good Manufacturing Practices (cGMP), Good Automated Manufacturing Practices (GAMP), and CIP/SIP. Precision measurement devices are certified calibrated. Hardware and software components are readily validatable. Automation systems and modules support Oracle and SQL Server (the industry standard database environments) and work on Windows, Unix, and VAX platforms. They incorporate and build upon the Base Ten family of products and ABB's award-winning Industrial IT technology.

For the pharmaceutical and biotechnology industry, ABB Life Sciences offers a continuously expanding product line and knowledge-base, from a single analyzer to integrated, e-enabled suites of next generation automation software and hardware. As pharmaceutical and biotechnology companies launch new products, venture into new global markets, and face new regulatory and manufacturing issues, they can depend on ABB Life Sciences to pave the way.

Industrial^{IT}

The Next Way of Thinking



Industrial IT solutions from ABB blend the industry's broadest portfolio of compatible knowledge components with a proven architecture for *real-time* enterprise automation and information.

For more information on ABB products and solutions in Life Sciences, please visit us at:
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