Speeding pharmaceuticals to the marketplace

Industrial^{IT} solutions for the Life Sciences industry

Behind every aspirin you take are complex manufacturing operations, supply chains and government regulations – three potential sources of headache 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 unique knowledge of both the industry and the regulatory environment, ABB has taken a closer 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, as in most other industries, priorities often shift to accommodate changes in consumer preferences, competition, manufacturing resources and regulations. One priority, though, 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, therefore, need production equipment and applications that move materials swiftly and consistently from clinical research and development, through each processing stage, regulatory review and approval, on to the consumer.

ABB has taken a fresh, whole-enterprise approach to the pharmaceutical and biotechnology industry. It begins at the level of individual sensors and touches every aspect of the manufacturing cycle as well as complete eBusiness solutions. Every product and application in the ABB portfolio is designed to:

■ Accommodate single or multiple products and paths, stand-alone or integrated operation.

■ Be compliant with industry regulations and standards.

■ Consist of components which can be readily validated.

■ Provide backward compatibility to existing systems.

■ Provide an upgrade path to automated, intelligent enterprise management and planning.

■ Maximize the customer's return on investment.

This whole-enterprise approach provides the fully integrated solutions ABB's customers require to be more competitive.

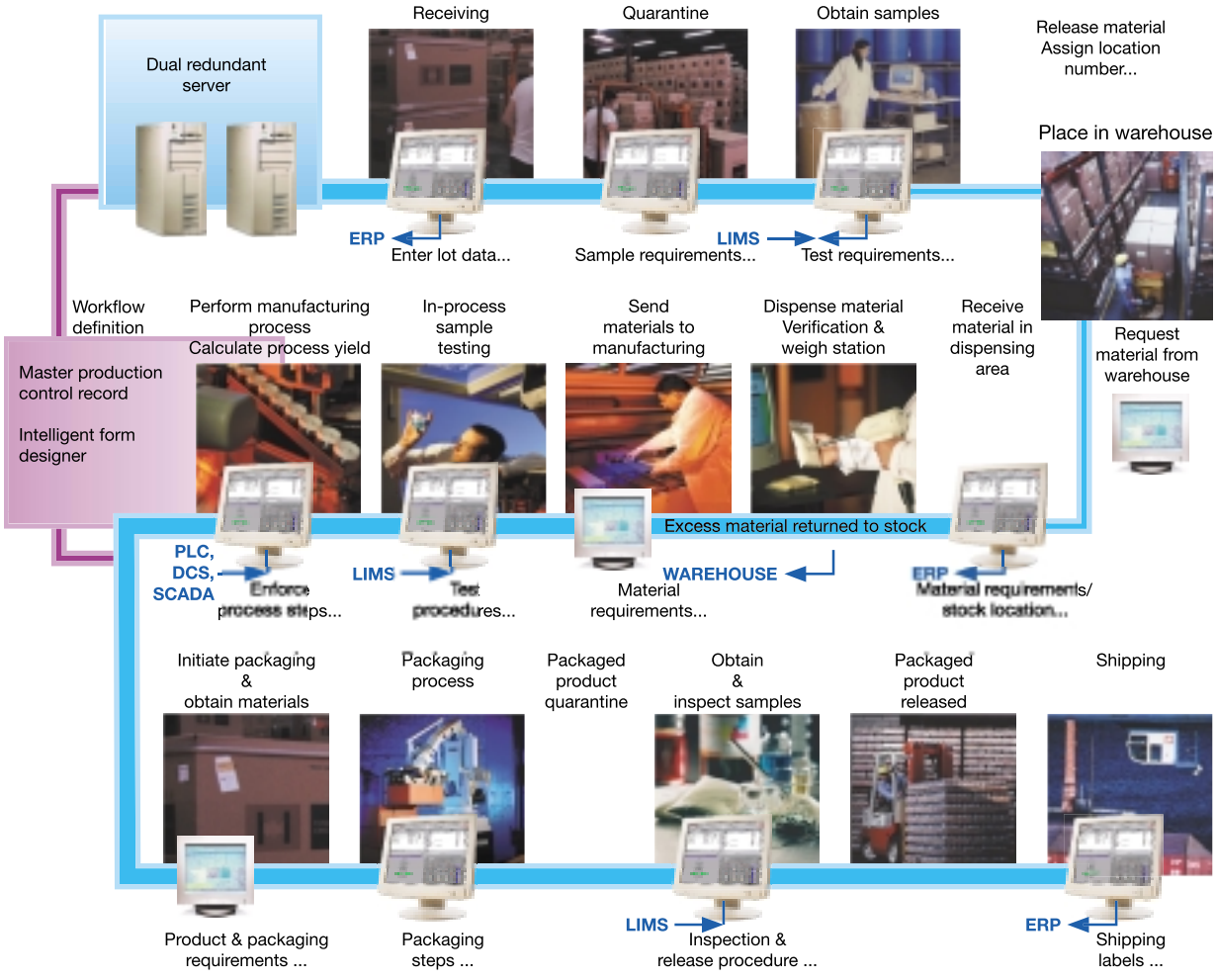
Maximizing return on investment

In pharmaceutical manufacturing there are two main stages:

■ The production of an active ingredient or drug.

■ The conversion of the active ingredient into products suitable for

Workflow in Pharmaceutical Manufacturing



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 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 by being based on ABB's Industrial^{IT} architecture. Value is added by incorporating hygienic design into each product. Instruments are certified for clean-in-place (CIP) and/or sterile-in-place (SIP) capability. Fewer and more predictable stops for cleaning result in a significant saving.

Robots for receiving, packing and palletizing

Robotics products from ABB 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.

In fact, ABB has combined process control with recipe and equipment management. Our batch control application provides an overview of batch production, manages a library of master recipes and recipe building blocks, schedules batches, allows run-time 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.

Electronic Batch Record systems from ABB 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 creates documents that enforce each process step and collect the appropriate data

(including electronic signatures) for batch records.

These batch automation systems are not toolkits, but robust, flexible, 'plug-and-produce' applications. Each interfaces with the others and integrates into existing and future plant systems, including Manufacturing Execution Systems and intelligent planning and management systems. Every component is validated and regulatory compliant from the start.

Clean room design and automation

ABB's clean rooms are constructed with interconnecting modules that can be arranged to meet the customer's individual requirements. Standard components which can be readily validated are used throughout. The clean rooms come enabled for automation, including Manufacturing Execution Systems. 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

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.

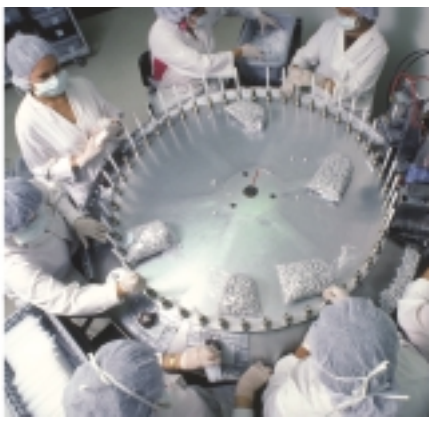
Comprehensive in scope and intuitive in use, Produce^{IT} ME is the first Manufacturing Execution System to be created from separate validatable applications. ABB can therefore seamlessly customize the system to satisfy the plant's specific manufacturing and process conditions.

All the features and functions required for regulatory compliance are built in. Our Manufacturing Execution System for secondary pharmaceutical manufacturing is 21 CFE Part 11-compliant[1)]. Produce^{IT} ME replaces the need to present paper-based work instructions to the operator. Produce^{IT} ME also records all batch events – routine and exception – and captures them in paperless electronic records.

Providing 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 replaces paper with electronic documentation, complete with electronic signatures and audit trails. This effectively eliminates costly and time-consuming manual paper management.

1) The FDA Code of Federal Regulations '21 CFR Part 11' defines criteria under which the FDA considers electronic records, electronic signatures and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.



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.

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 across several manufacturing lines and three work shifts. Batch-to-batch consistency, quality and productivity all 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 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 Manufacturing Execution Systems functionality and the Enterprise Resource Planning integration in the future.

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 can be readily validated. Automation systems and modules support Oracle and SQL Server (the industry's standard database environments) and work on Windows, Unix and VAX platforms. They incorporate and build upon ABB's award-winning Industrial^{IT} technology.

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 to streamline their processes and speed them on their way.

(For more information on ABB products and solutions in Life Sciences go to www.abb.com/pharmaceuticals.)