

Digitalization of the pharmaceutical and biotech industry

Committed to continuous improvement

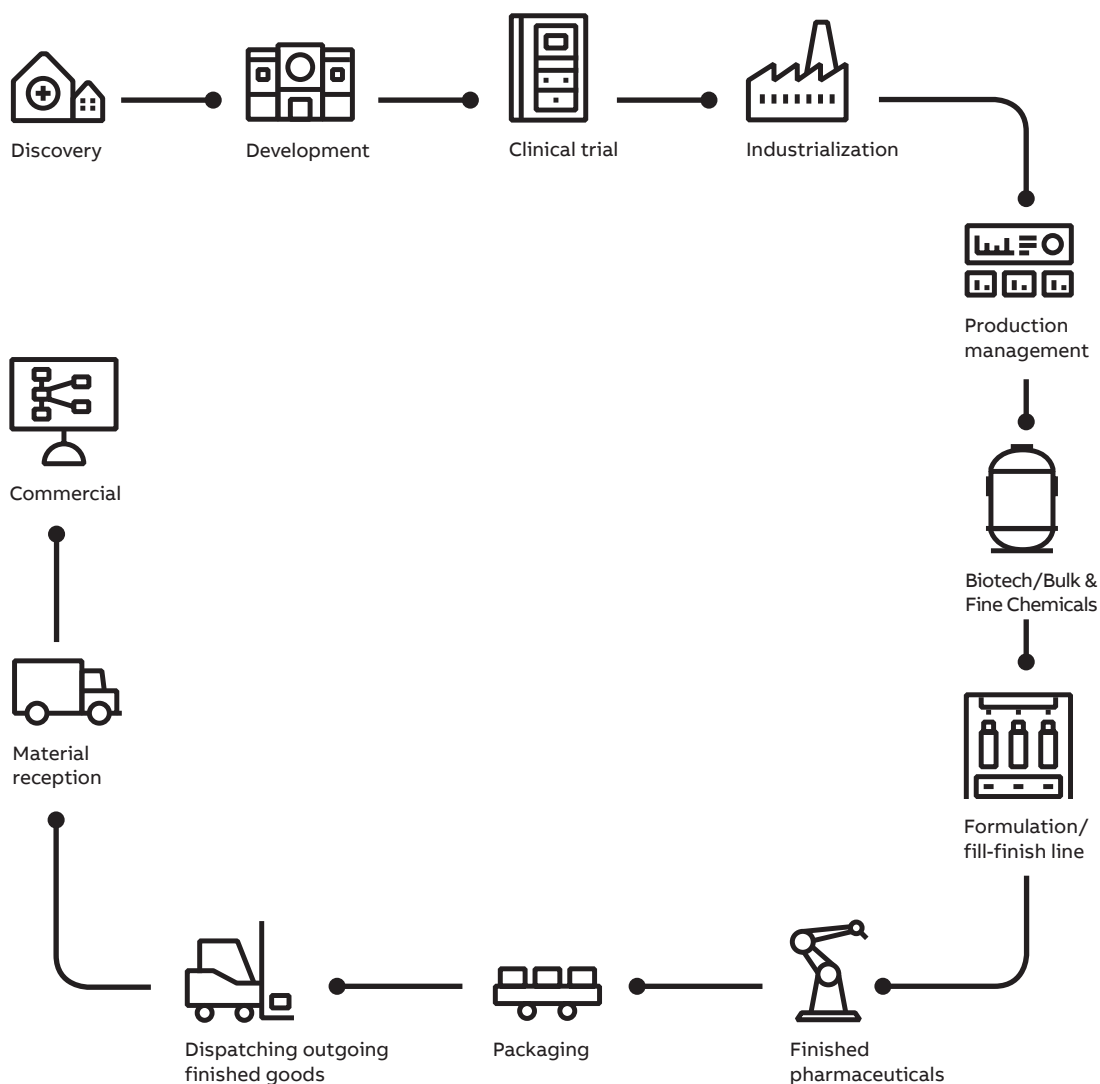
ABB addresses the demands of the pharmaceutical and biotech industries, including the need for high product quality, regulatory requirements, speed to market, cost efficiency and more.

This is achieved using products, solutions, services and expertise that enhance productivity and energy efficiency for new and existing applications — while also reducing validation costs and time to market of new biotech and pharmaceutical products.

ABB's life sciences solutions help industry to:

- Navigate a challenging market environment
- Address business needs
- Identify key ROI opportunities
- Reduce time to market
- Decrease production costs
- Reduce capital expenditure costs
- Increase production flexibility
- Enable real-time product release

ABB reduces engineering efforts by fully integrating its life sciences solutions throughout a process.



Achieve your business goals

Working in close collaboration

With their decades of application know-how, ABB's experts, working in close collaboration with its customers, can engineer a solution that perfectly matches a company's business goals. Whether that is improving productivity, introducing modular automation or reducing environmental impact of a manufacturing process, ABB has the products, systems and services for success.

Support throughout the lifecycle

ABB provides consultative services for process automation systems and IT validation to ensure regulatory requirements are met.

Its automation and manufacturing solutions improve plant productivity, product quality and process throughput, while reducing overall operating costs.

Capturing lost profit

As a project evolves throughout its lifecycle phases, ABB captures lost profit opportunities. It achieves this through an extensive portfolio of products, systems and services tailored to pharmaceutical and biotech applications, from first concept through development and manufacturing to decommissioning.

Key deliverables include process automation, batch and recipe management, facility automation, collaborative production management (CPM), integrated control and electrical systems, consulting and process analytics including process analytical technology (PAT).

Other benefits of engaging with ABB include:

- R&D and project execution facilities in Europe, the Americas and Asia
- Established global partner network
- Market leaders with a large installed base in pharmaceutical, biotechnology, biopharma and biomedical
- Fully engineered solutions and products for process control, safety, energy and information management systems
- Industry-specific process solutions, maintenance consulting and service



Digital technologies

The foundations for future facilities

ABB Ability™ System 800xA

ABB Ability™ System 800xA control system lies at the heart of ABB's life sciences solutions. System 800xA enables compliance with the FDA's 21CFR Part 11 through electronic batch recording, dual signature access, verification and audit trails, as well as certification, modeling and calibration tool integration. These solutions meet both GxP and non-GxP requirements.

- **Operations** — Provides a consistent method for accessing enterprise-wide data and for interacting with multiple applications from any connected workstation in the plant or office.
- **Engineering** — The integrated engineering and application change management environment efficiently supports the complete lifecycle of the automation project, from planning, through configuration and library management, to commissioning and operation.
- **Control and I/O** — A comprehensive suite of standards based hardware and software meets the needs of total plant control. Controllers are complemented with a full line of industrial I/O interfaces to suit all plant environments.
- **Information management** — Powerful information management software collects, stores, retrieves and presents historical, process and business data to enhance the usefulness of data from all operations and enables CPM (collaborative production management).

- **Asset optimization** — Asset optimization software exploits the wealth of plant resident information to assess and report equipment conditions in real-time to reduce costly corrective and preventive maintenance and optimize maintenance and calibration workflows.

ABB Ability™ Manufacturing Operations Management

ABB Ability™ Manufacturing Operations Management (MOM) is a comprehensive, scalable and modular software suite maximizing visibility, knowledge and control throughout the complete manufacturing domain. It is the natural extension and complement to the real-time control system.

By turning large amounts of industrial data into actionable information, the MOM software helps daily operations improve, by ensuring subsequent shifts run more efficiently than the last.

MOM directly supports stakeholders working in the plant and business side of a company, by collecting, storing, combining and translating industrial data from business, control and monitoring systems into meaningful, actionable information. Such users work with the overall plant operations in the areas of data analysis, reporting, production planning/execution, quality and asset management.



Digital applications

Paving the way for life sciences solutions

Shop Floor Integration for Life Sciences

Today, many solutions for the life science industry are not fully integrated, requiring high efforts in engineering and synchronization of data between the manufacturing execution system (MES) and distributed control system (DCS). Especially in GMP productions (GMP = Good Manufacturing Practices) this has as a crucial influence on time to market, quality and profitability.

ABB's Shop Floor Integration for Life Sciences provides a validated, integrated and seamless solution from shop floor to enterprise resource planning (ERP). It helps users meet their regulatory requirements, produce high product quality, achieve fast time to market and benefit from significant cost savings.

Shop Floor Integration brings together manufacturing execution systems (MES) and System 800xA Batch Management. It features automatic parameter assignment and automatic synchronization of System 800xA Batch

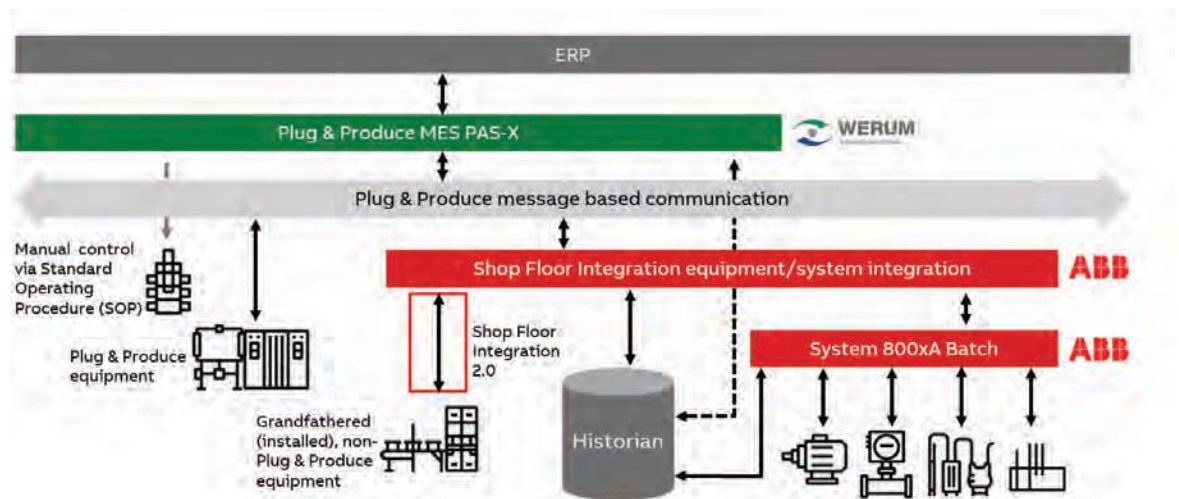
Management recipe procedures and MES. It prevents production bottlenecks and reduces cycle times to lower inventories, free up capacity and increase efficiency.

The automated integration significantly reduces the engineering effort required especially with the high validation requirements in a GMP production environment.

Shop Floor Integration is an extension to the MOM (see page 4) offering and runs as a native connectivity. The connectivity uses OPC Unified Architecture (UA), which is a modern industrial communication protocol that is open, secure, efficient and cross-platform and is ideal for IoT communication.

A message-based communications system sends and receives instruction between the MES and the production equipment. This provides regular synchronization between the systems and communicates data such as quality, setpoint and consumption.

Smart equipment integration with Shop Floor Integration 2.0



- Significantly reduces the time to market when setting up new production plants and processes
- Improves agility and speed for new product introduction
- Significantly reduces the operation cost by avoiding manual interactions and by automating operations
- Considerably reduces efforts and cost involved in regulatory compliance and validation
- Uses a highly secure and reliable modern message-based architecture

The latest version of Shop Floor Integration allows for the creation of a digital twin of the existing system prior to installation. This reduces engineering, validation and testing time and minimizes the plant's downtime. Using this solution, engineers save between 40 to 70 percent of the time spent on integrating systems when compared to existing solutions. This gives engineers the opportunity to test the running of the line in the digital world before any connection is made in the real world.

Digital twin reduces engineering costs

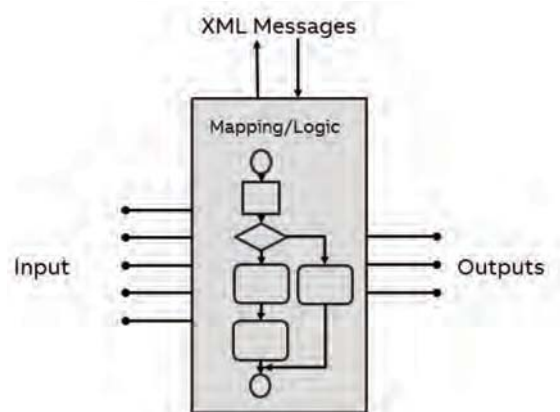
To communicate with installed equipment which, at present, cannot benefit from the plug & produce message-based communication, ABB is creating a digital twin.

A digital twin is a model that mirrors the functionality of the installed machinery.

There are several inputs from the machine and some outputs to control the machine. There are also messages coming in and out, such as start and stop machine or setpoints to control the equipment in different ways.

The digital twin maps the messages together with all the logic needed to control the equipment.

From the PAS-X MES or the MBR/EBR perspective this approach makes a huge saving as the digital twin deals with the mapping or state logic in the PAS-X system.



Digital applications

Paving the way for life sciences solutions

Importance of plug & produce

Plug & produce is the next level of connecting software and hardware throughout a pharma facility. The aim is to provide a fast and easy integration of machines and automation systems into a pharmaceutical production environment. This is a prerequisite for those companies striving towards implementing Industry 4.0 solutions.

At the heart of the plug & produce concept is the ISA95 model. The model consists of the three levels, shown in Figure 1. Level 0-2 (shop floor) is where the distributed control system (DCS) is positioned and is often isolated within the operational technology (OT) department. Level 3, meanwhile, is the layer for the manufacturing execution system (MES) and is often isolated within the information technology (IT) department. Level 4 provides the connectivity to enterprise resource planning (ERP) functionality.

A digital factory of the future will see a convergence of the IT and OT systems and departments. The aim of plug & produce is to simplify how different parts and levels of a production communicate with each other within the ISA95/ S88 layer. This is achieved by providing cost effective, standardized, cyber secure and robust solutions throughout the complete life cycle of a facility's operations.

The key is for all levels to communicate digitally. In a good manufacturing practice (GMP) environment this is even an imperative, as data integrity is key for quality production.

Benefits of plug and produce integration

By integrating the MES (Level 3) and the DCS-batch (Level 0-2), engineers, shop floor workers and plant management gain from increased flexibility and higher productivity. The integrated solution achieves:

- Standardized and transparent process flow from ERP production order to batch control recipes
- Simplified communication structures between automation and quality management system
- Significantly reduced engineering effort creating recipes and master batch records (MBRs) with up-load, download and synch functionality between DCS and MES
- Higher flexibility to apply changes to the process
- Ability to connect any equipment to the message bus even based on classic OPC
- Combined/integrated concept for data handling (master data, users, data collection)

For pharmaceutical companies this translates to:

- Significantly reducing the time to market for setting up new production plants and processes
- Improved agility and speed for new product introduction
- Significantly reducing the operation cost by avoiding manual interactions and by automating operations
- Considerably reducing efforts and cost involved in regulatory compliance and validation
- Using a modern message-based architecture that is designed to be highly secure and reliable

GMP Engineering (how can 800xA help with GMP engineering)



Integrated operations and control systems

ABB provides a variety of platforms for different applications and projects including:

ABB Ability™ System 800xA

- Scalable extended automation system for plantwide integrated operations, process control and support for regulated industries

Freelance DCS

- Compact process control system for small to medium size applications in every industry

Compact HMI

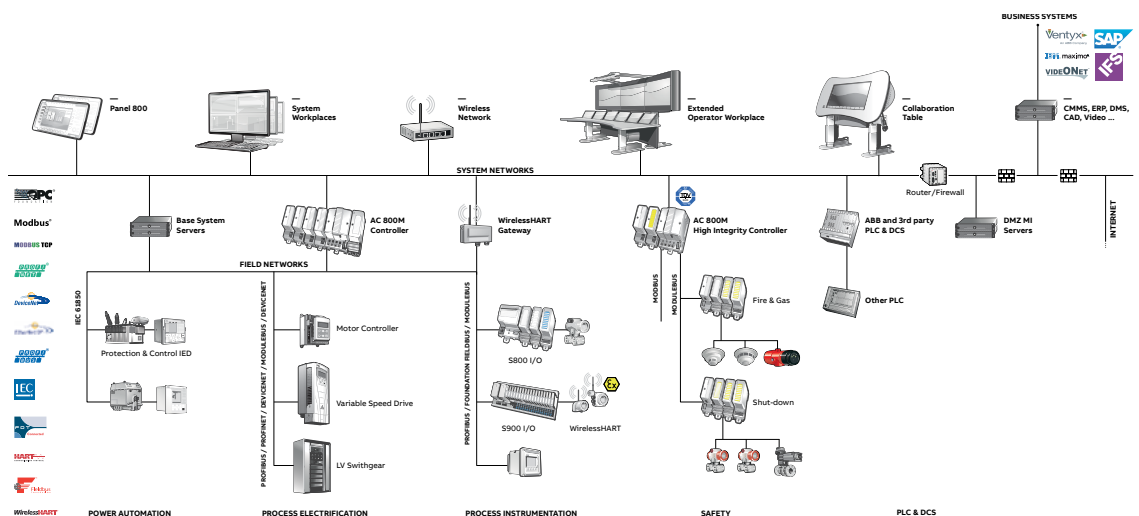
- SCADA for entry level automation and third party PLC

Programmable logic controllers

- AC 700F for machinery/ packaging and discrete I/O management
- AC500 for manufacturing industry and motion control



ABB Ability System 800xA architecture



Batch and recipe management for API production

At the heart of API production is ABB Ability™ System 800xA's integrated portfolio of products, systems and services that includes total solutions for all phases from discovery to medicine release.

These solutions enable compliance with industry standards and regulations while meeting the challenges of reducing product release time, handling real-time product releases, maintaining batch records, increasing production and reducing costs.

ABB Ability™ System 800xA Batch Management
ABB Ability™ System 800xA Batch Management is a powerful application software package for configuring, scheduling and managing batch operations improving batch production profitability, consistency and traceability.

It provides the tools necessary to support the market's changing focus from traditional supervisory batch management to production management. This is achieved by supporting integrated production historian and production schedule interface for batch, as well as procedural control applications in continuous and discrete processes.

System 800xA Batch Management is aligned with industry standards such as ISA88, ISA95, IEC 61512, and IEC 62264. It is further enhanced by ABB's extensive batch automation expertise.

For manufacturing processes subject to licensing and inspections by regulatory bodies such as FDA, MHRA, TGA, EMA, CDSCO, WHO, CFDA, System 800xA Batch Management provides the tools needed to achieve compliance.

ABB Ability™ System 800xA Batch Management provides:

- Unsurpassed functionality in recipe management, batch and procedural control, safety and security
- Agility and control to respond to increasing production demands in real-time
- Reduced lifecycle costs
- Reduced production downtime
- Flexible recipe management
- Exception procedures — beyond the S88 model
- Configure error handling logic within the recipe
- Resource management and scheduling
- Eliminate shift inconsistencies
- Reduce scrap/off-spec material
- Regulatory compliance support
- Business system connectivity



Manufacturing execution systems

Manufacturing execution systems (MES) play an essential role in achieving sustainable competitive advantages in the life science industry. MES enables higher plant efficiency and productivity as well as greater flexibility and agility throughout the production processes.

ABB collaborates with the leading pharmaceutical MES supplier, Werum IT Solutions on control system solutions for life science industries.

The collaboration complements ABB's control systems offering with the latest MES technology, which is seen as a key component for efficient production workflows in the life science industry. Together, ABB and Werum IT Solutions deliver full scope engineering and validation solutions according to the GAMP5 guideline, and comply with regulations, such as FDA (21 CFR part 11).

MES capabilities include:

- **Electronic Batch Recording (EBR):** Efficient electronic batch documentation is one of the most important objectives in introducing an MES to pharmaceutical production. With PAS-X Electronic Batch Recording all MBRs are electronically executed and the processes and results are documented in compliance with the

applicable statutory provisions. EBR ensures an error-free and guided execution of the entire production process and right-first-time manufacturing.

- **Track & Trace Serialization Aggregation (T&T) -** enables the pharmaceutical industry to comply with anti-counterfeiting requirements for medical drugs. It provides serialization and aggregation functionality for packaging processes and integrates the ERP and the global repository with the shop floor packaging equipment and line controllers.
- **Production order management:** ensuring effective, flexible and reliable order execution including bi-directional integration of enterprise resource planning (ERP) with the plant floor, comprehensive workflow management and an up to date production order status overview.
- **Quality management:** in-process quality control supporting the operators by enforcing quality and compliance measures and keeping track of any deviation from the product, process, procedure or specifications.
- **Weigh & dispense:** improved productivity, safety and accuracy of weighing operations by guiding operators with intuitive, user friendly instructions.



- **Material management:** enabling full control and transparency of materials from raw material reception to intermediates and finished goods including complete product traceability and genealogy.
- **Equipment management:** Administers and monitors cleaning procedures and statuses for all types of production-related objects. This includes MBRs and rules for cleaning scales, work rooms, containers, production equipment, setup parts and toolkits. Electronic paperless equipment logbooks keep status lists, cleaning rules and histories for individual container types.
- **Warehouse management:** better utilization of storage space, accurate and up-to-the-minute quantity and location data, transparency of material movements in and between the storage areas and elements in the production.
- **Standard operating procedures (SOPs) –** bringing consistency to manual operations by guiding the operator through each step with the required production and safety instructions and checks
- **Material flow & inventory** - secures in-plant material flow throughout the pharmaceutical manufacturing process. It contains sub functions for manual and automatic transport control as well as in-plant administration of shop floor storage areas.
- **Process Quality Control** - captures events and deviations enabling companies to drastically reduce batch review and release time and to implement Review by Exception. It ensures a continuous monitoring of the production quality.

Benefits include:

- Greater visibility and control of activities, materials and resources
- Reduced lead time and production costs
- Increased production throughput and product quality
- Improved labor utilization, reduced inventory levels, higher quality
- Reduced efforts involved in regulatory compliance
- Improved agility and speed for new product introduction and responsiveness for changes in customer or market demand
- Reduced environmental impact by lowering energy consumption through process improvements.
- Lower manufacturing costs and improved efficiency by optimizing the manufacturing process.

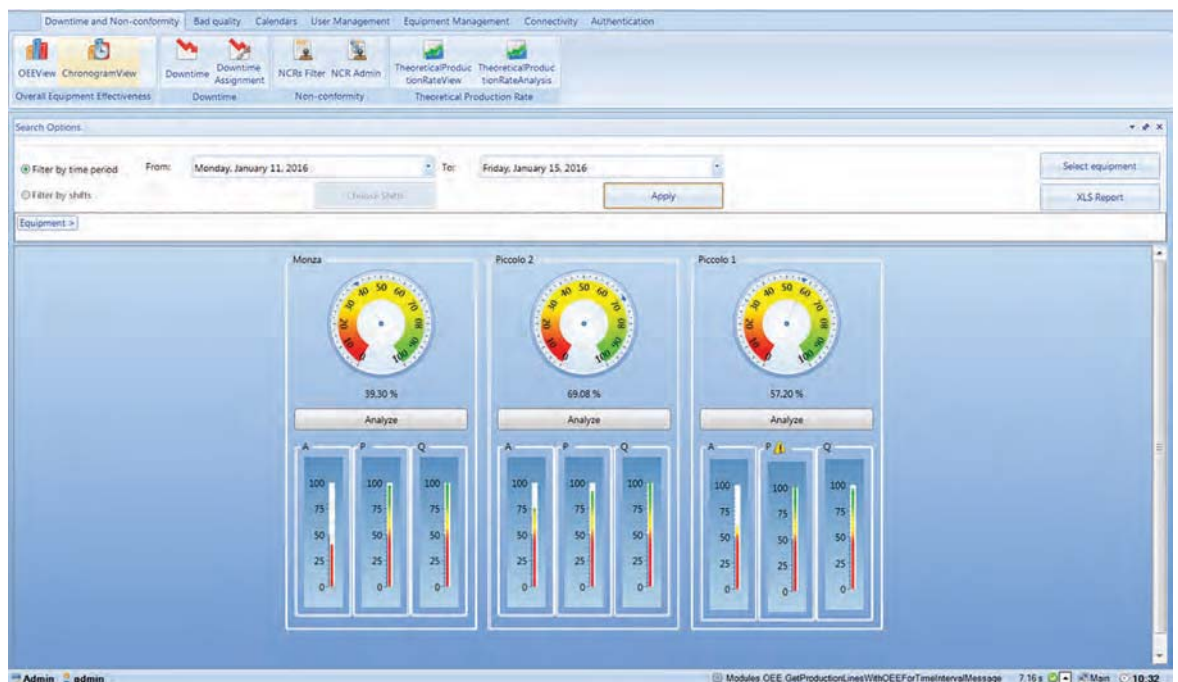


Overall equipment effectiveness (OEE) software

Out-of-the-box software that helps uncover hidden potential and motivate production teams to maximize equipment utilization, uptime and quality. ABB OEE software enables customers to calculate and analyze overall equipment effectiveness measure in real time, based on data collected from their production processes.

Benefits:

- Brings awareness of OEE to everyone in your organization
- Helps manage production efficiency through shared goals
- Helps understand where to find potential for improvement
- Helps prioritize actions in order to improve efficiency
- Helps find and solve production bottlenecks
- Real-time measurement for fast interaction, solving the problems before they become problems
- Accumulation of historical data for analyses and benchmarking purposes
- Automatic analyses and prioritization of the causes behind lost capacity
- Industry-independent



Facilities management

Factory automation

ABB's Facility Automation Solution (FAS) addresses the needs of all large enterprises and is particularly well-suited to pharmaceutical and biotechnology applications. It provides a library of pre-engineered and pre-tested modules which can be used during rapid deployment of the solution.

The solution maintains the physical environment of the manufacturing area in a known state. It makes it possible for customers to report accurately on the environmental conditions during and after the manufacture of a batch along with the ability to verify who took any actions that may have affected those conditions.

The solution is built upon ABB Ability™ System 800xA. Being scalable, it can control the critical functions of a single zone, an entire building, a facility or campus or the complete enterprise.

- Achieve 10–15 percent savings on compliance reporting and validation costs
- A common platform across the enterprise reduces the total cost of ownership
- Industrial HVAC: This is an FDA 21 CFR Part 11 compliant solution which is the industrial equivalent of functionality found in commercial grade building management systems (BMS)
- Solution can easily be partitioned into good manufacturing practice (GMP) and non-GMP configurations while gaining efficiencies associated with a single automation platform

Environmental Contamination Monitoring Control System (EMCS)

The ECMS automation package targets sterile manufacturing lines that are subject to GMP Annex 1. This integrated solution manages viable particulate sampling and controls non-viable particulates using structured recipes to monitor critical areas inside isolators during the production phases.

EMCS can be integrated in existing plants to control the CQAs (critical quality attributes) profiles and the environmental status. It does this by managing sensors, actuators, in-process samples, particle counters, biological impactors and new-generation rapid biological detection systems.

GMP Annex 1 requires the detection of particles sized between 0.5 µm and 5 µm and also a specific air flow profile through the biological impactors where the Petri dishes are housed. ECMS manages the particle counters and maintains the flow rate profile by controlling valves according to the mass flow-meter readings as per the GMP Annex 1 requirements.

The EMCS program generates deviation alarms and allows the operators to perform bio-decontamination sequences on a batch production and sterilize the isolator by using VHP — vapors of hydrogen peroxide. The EMCS system is equipped with both ABB Essential Automation and 800xA Extended Automation lines, which have a modern and modular DCS-based architecture. EMCS is supplied in a rack version, suitable for pharmaceutical applications, complying with 21CFR part 11, and can be standalone or integrated into a wider automation system.

Picking, packing and serialization

Packaging systems and robotics

ABB's robots provide flexibility and repeatability. They can operate in clean room environments and wash down areas. From unloading to filling, from picking to packing to palletizing, ABB robots handle multiple functions automatically.

- Fast changeovers
- Small footprint, high performance
- Transform a two-dimensional, conveyor-based operation to a three-dimensional operation
- Better use of both vertical and horizontal space
- Save significant floor space
- High accuracy, low maintenance
- 65,000 hours mean time between failures
- 99.8% availability
- Easy to install, maintain and adjust

Case reference

A global pharmaceuticals firm needed to automate a pharmaceuticals packaging operation. The situation was a challenging one, with four different carton sizes and three different product cases. Flexible packaging systems with integrated robots was the answer. An easy to use PC-based operating system made both training and operations very easy. The system can automatically change over as cartons and cases change. And in the first ten months of production, the system had zero down time.



Consulting, project and lifecycle services

Driving productivity in the process industries through people, processes and technology

ABB has professionals worldwide, offering consultancy solutions that deliver operational excellence in energy, safety, maintenance and reliability.

Additional service areas include:

- Plant integrity
- Operational improvement
- Maintenance management systems (SAP, Maximo)
- Environmental impact
- Logistics
- Projects and engineering
- PAT readiness assessment

Regulatory compliance

ABB's team of specialists offers solutions tailored to your compliance needs, including ongoing compliance audits and support. In addition, services for preparation and execution for further regulatory compliance activities are available including:

- Risk based strategic validation planning
- Validation project management
- Streamlined validation documentation
- 21CFR11 assessment
- Data integration
- Electronic batch records

Business and operational strategy

We start with your business objectives, identify opportunities, and help you develop your business strategy. Our innovative, customized solutions allow you to accelerate change in your organization at the pace you choose. We support all phases of the value chain, from supply strategy, through internal operation to customer delivery.

Working with our customers, we identify opportunities to:

- Fix deficiencies in your current plant operations
- Improve performance with technologies that have well defined economic benefits
- Upgrade your facilities for advanced process control and optimization
- Train your personnel
- Improve lifecycle maintenance
- Improve asset management
- Reduce the costs of regulatory compliance



Partners

ABB has a network of local delivery partners whose expertise is the life sciences industry. These delivery partners are certified ABB solution providers. No question or project is too large or too small for this team of experts.

After-sales services

ABB handles parts, field service and customer support as well as evolution and modification of ABB products and systems, including drives, motors, switchgears, DCS, transformers, instrumentation and control systems.

Education and training

ABB offers a comprehensive portfolio of customizable education and training programs that can be delivered as on-site training, at ABB University or as self-study online. They include:

- Products
- Process
- Technology
- Management
- Regulatory compliance

Reliability consulting

ABB's plant asset management solutions and services increase asset reliability and productivity while maximizing the return on your maintenance investments. Asset performance baselines are set, while real-time assessment of KPIs and asset optimization solutions identify performance gaps and improvement opportunities. Continuous improvement services assure asset availability and an increased return on production assets, resulting in a sustainable benefit.

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ABB Control Technologies

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