Solutions for life sciences
Satisfying the automation needs of the biotech and pharmaceutical industries
A commitment to continuous improvement

“As a leading supplier of products, solutions, and services to the life sciences industries, ABB is uniquely positioned to meet the current and future business and regulatory needs of the life sciences industry.”

ABB Value Proposition for the Life Sciences Industry White Paper, ARC

ABB addresses the needs of the life sciences industry, including product quality, regulatory, speed to market, cost efficiency and more. This is done with products, solutions, services and expertise that enhance productivity and energy efficiency for new and existing products — while also reducing validation costs and time to market of new biotech and pharmaceutical products.

ABB’s life sciences solutions help you:
- Navigate a challenging market environment
- Address your 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

To put it simply, ABB reduces your engineering efforts — all our life sciences solutions are fully integrated.
Achieve your business goals

What ABB provides
You can improve productivity and reduce the environmental impact of your manufacturing processes. ABB’s global consulting and engineering services experts partner with and listen to your experts. Information gathered from you, together with our significant application knowledge developed over many years in the life sciences industry enables ABB to develop a strategy for you, a strategy for achieving your business goals.

Solutions for the entire life of your product
ABB provides consultative services for process automation systems and IT validation to ensure regulatory requirements are met. Our automation and manufacturing solutions have been shown to improve plant productivity, product quality and process throughput, while reducing overall operating costs. We provide a vast and constantly enlarging portfolio of Life Sciences products and services to enhance your market advantages, from first concept through development and manufacturing to decommissioning. As your project evolves through the lifecycle phases, we are able to capture lost profit opportunities that would otherwise be missed.

– ABB has created regional execution centers in Europe, the Americas and Asia to address R&D and project execution
– We have also established partners with expertise and local proximity to your site
– We are market leaders with a large installed base in major industries, including pharmaceutical, biotechnology, biopharma and biomedical
– We deliver fully engineered solutions and products for process control, safety, energy and information management systems
– ABB offers industry-specific process solutions, maintenance consulting and full service
– 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).
Extended Automation System 800xA (System 800xA) is the base control system from which our life sciences solutions emerge. System 800xA enables your 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** — Process Portal, the industry’s most intuitive system interface, 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** — Our integrated engineering 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** — Our 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.

“Our product is released quicker and more efficiently, but just as safely, as before our control system upgrade. By reusing the control logic that makes the product, we spent less time validating, which saved a lot of money. It’s actually been exhilarating to see how easy it’s been to evolve at our own pace. Using ABB’s evolution path saved us a lot of time and money.”

David Kavanaugh, Process Control Systems Engineer Bayer Berkeley, on evolution of his control system to System 800xA
The power of integration

“ABB’s System 800xA technology and international engineering team has enabled Gedeon Richter Plc. to successfully automate its world class biotechnology facility in Hungary. The plant will manufacture mammalian cell fermentation based biopharmaceutical products driven by fully automated and integrated process automation, building management and environment monitoring system. The significance of the project to Hungary in bringing high-value jobs and advanced technology to the country was marked by the appearance of Hungarian prime minister Viktor Orbán at the opening ceremonies.”

Gedeon Richter on the implementation of System 800xA in their biotechnology plant in Debrecen, Hungary
Batch and recipe management for primary production

800xA Batch Management is a comprehensive recipe management, batch and procedural control software package that provides improved regulatory compliance and consistent product quality. It provides the tools necessary to support the market’s changing focus from traditional supervisory batch management to production management by supporting integrated production historian and production schedule interface for batch as well as procedural control applications in continuous and discrete processes.

It also provides the evolution path for ABB’s traditional batch systems.

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

As a key component of our life science offering, ABB’s manufacturing execution system (MES) provides a highly scalable and modular ISA95-based solution that encompasses comprehensive MES functionality.

Our MES capabilities include:

– 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.
– 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.
– Paperless manufacturing — electronic batch record.

Key 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
ABB enables PAT through its xPAT (eXtended Process Analytical Technology) solution suite. It enables biotech and pharmaceutical manufacturers to implement quality by design (QbD) and real-time product release programs. Our PAT and automation solutions are applicable to the complete product lifecycle — from development, through scale-up to manufacturing.

Through the use of Aspect Object™ technology, ABB provides an integrated environment for ease of engineering, data and process visualization, data management, multivariate advanced statistical process control and enterprise connectivity. Interoperability with analyzers is assured by a common configuration and industry standard analyzer interfaces based on OPC/UA-ADI technology. These technologies enable better process understanding, leading to increased innovation during manufacturing and optimization.

PAT and QbD principles can be applied equally to primary manufacturing, biological primary manufacturing, secondary manufacturing and all types of pharmaceuticals. Benefits are derived in all areas, including individual unit operations or small groups of unit operations that are part of a batch, such as raw material identification, bioreactor, crystallization, dryer, blender and mill processes. Continuous manufacturing and tableting are also optimized by implementation of PAT.
Analytical products for manufacturing and quality assurance

Analytics
ABB is the global leader in products, systems and solutions that combine process, application and environmental knowledge to create greater value for our customers. Our portfolio of analytical offerings combines online and laboratory analyzers, advanced process control and application knowledge.

We offer the widest range of process analyzers from any single supplier. Key analytics deliverables include:
- Process gas chromatographs and photometers
- Physical property analyzers
- Continuous gas analyzers
- Continuous emission monitoring systems
- FT-IR & FT-NIR lab and process analyzers
- PAT solutions
- System integration & fabrication
- Engineering, application and support services

ABB is an established provider of process instrumentation to the life sciences industry. We meet your needs for accuracy and reliability while meeting or exceeding international standards and regulations for process equipment and installations.

“ABB’s xPAT system allows us to consolidate bioprocess information from a variety of sources into a single system. Our scientists and engineers can accelerate process development and release batches in real time when the data from our in-line and at-line process analyzers are together with the standard outputs from our bioreactor, such as pH and dissolved oxygen.”

Rick Lawless, Associate Director, Strategic Support, Golden LEAF Biomanufacturing Training & Education Center
Instrumentation for manufacturing and quality assurance

**Instrumentation**

ABB’s instrumentation for the biotech and pharmaceutical industries includes:
- Hygienic process connections
- Clean-in-place (CIP) and sterilization-in-place (SIP) capability
- Configuration protected against alteration (21 CFR Part 11)
- EHEDG certified design and FDA approved materials of construction for sensor bodies and fill fluids for the following instruments:
  - pH/ORP and conductivity
  - Pressure transmitters & sensors
  - Magnetic flowmeters
  - Coriolis mass flowmeters
  - Temperature transmitters & sensors
- All welded, remote-seals as standard for high temperature and high vacuum applications, including:
  - Distillation columns
  - Lyophylizers
  - Evaporators
  - Reactors

Wide range of measurement and data capture instruments for every application, from hydrogenation to wastewater:
- Temperature transmitters and sensors
- Pressure transmitters and remote seals
- Multiple types of flowmeters
- Water and fluid analyzers
- Concentration and density measurement
- Recorders, controllers and indicators
- HART, Foundation Fieldbus and PROFIBUS compatible instrumentation
Solutions for manufacturing lines

Software solution for overall equipment effectiveness (OEE)

Increasing manufacturing capacity
When faced with increasing demand, factory management has a choice: make large investments in new plant equipment or explore capacity opportunities with existing manufacturing equipment.

What is the real performance?
We help customers determine the real effectiveness of their plant and identify dependencies.

Examples include:
- Our OEE software tools showed that the quality of capsules affected the number of interruptions. Fewer unplanned stops would have quickly paid back the cost of higher quality capsules.
- Management observed a difference in output for two nearly identical beer production lines. An on-line analysis, based on real-time signals, showed that minor stops of less than 5 minutes (and the reasons for the stops) had not been reported in logbooks.

OEE KPI software module
ABB’s performance measurement and analysis software automates data collection from installed machines and equipment. It helps to locate problems and the root causes of losses so that corrective actions can be taken.

The software tools:
- Detect and record the use and status of your machines and the output, online and in real-time
- Calculate and show online key performance indicators (KPIs)
- Analyze the production, line and machine data
- Create reports and export data to other systems
- Provide preconfigured graphics and displays of performances
- Can be easily installed and connected to existing equipment

Theoretical production time
Planned production time
Planned down time
Planning factor (PF)

Gross operation time
Unplanned down time losses
Equipment failure
Setup & adjustment
Actualit factor (A)

Net operating time
Speed losses
Minor stops
Matured speed
Performance factor (P)

Valuable operating time
Quality losses
Defects in process
Start-up losses
Quality factor (Q)

Overall Equipment Effectiveness
\[ \text{OEE} = \text{A} \times \text{P} \times \text{Q} \]
Total productivity = OEE \times PF
ABB solutions for life sciences

Environmental Contamination Monitoring Control System (EMCS) for class A isolators in sterile production and drugs filling lines

ABB has introduced the ECMS automation package for 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.
Solutions for secondary manufacturing

Packaging and robotics
Our 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

Facility 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 is concerned with maintaining 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 particular batch along with the ability to verify who took any actions that may have affected those conditions.

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

Features and benefits include:
- Achieve 10–15% savings on compliance reporting and validation costs
- A common System 800xA 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

“Fewer changeovers with less handling result in more secure operations. The advanced robotic system from ABB makes it easier for the production line to change over to a new order or batch.”

Rikard Collin, Head of the Packaging Department, AstraZeneca
Electrical, power and energy efficiency

**Electrical integration**
Process automation and electrical integration is the next frontier in delivering a unified environment that will drive production improvements. The next generation of plant operators will no longer make decisions based only on process data but on the bottom line (profit) as well.

ABB has created a solution with System 800xA that seamlessly integrates electrical control with process control within a plant. ABB has accomplished full plant integration by taking advantage of the IEC 61850 standard.

There are many benefits of electrical and process automation integration with ABB’s System 800xA — including a (typically) 20% reduction in capital expenditures and operating expense!

To learn more, read ABB’s Integrated Process and Power Automation brochure (request literature number 3BSE062087).

**Making energy more productive**
We can contribute to energy efficiency improvements in two key ways. First, by providing specialists capable of appraising and monitoring how energy is used and of identifying specific areas for improvement. Second, by providing the equipment, systems and solutions to reduce energy consumption and losses, improve productivity and manage equipment and processes more effectively.

**Motors and drives**
ABB is a pioneer in digital AC and DC motor speed control solutions. Our dependable single and multi-drive systems help to improve your process and reduce the cost of ownership for your plant. Low and high voltage motors and generators, suitable for variable speed drives, cover all standards and protection types used in the life sciences industry.

AC and DC drives are scalable and designed to be used with both AC and DC motors. Each drive includes all the components needed for total lifecycle asset management:
- Engineering standards and tools
- Tested application standards
- Maintenance tools

Drives can be integrated with any control system, thanks to flexible communication capabilities. Configuration and diagnostic tools are PC-based.

20% productivity increase through improved operator visibility of entire plant assets
Large System 800xA user
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

Our 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.