Process analytical technology
PAT for the life sciences industry

Power and productivity
for a better world™

PAT for life sciences

A quality by design (QbD) approach using process analytical technology (PAT) requires more than a collection of analyzers and models. It requires people who understand the life sciences industry in order to gain tangible benefits from the data and the right products to allow data to be captured, processed and stored in a regulatory compliant manner — plus lifecycle support to enhance the benefits of the capital invested. We at ABB have the expertise, the solutions and the support that your business requires.

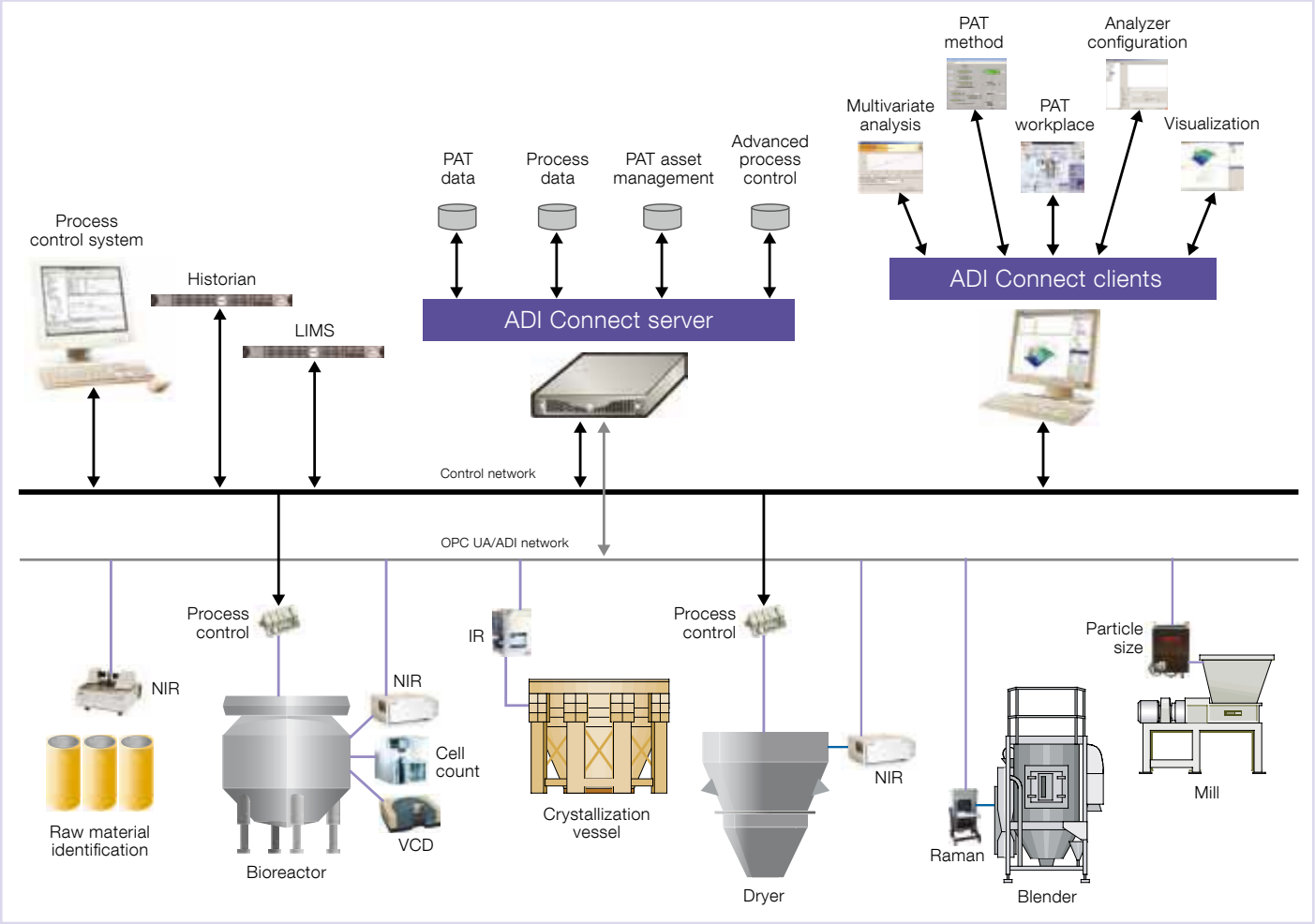
The benefits of PAT with ABB's analyzer device integration (ADI)

ADI integrates with your manufacturing operations environment so the right data is in the right place at the right time to facilitate intelligent manufacturing decision making. This avoids the production inefficiency and unnecessary cost that can result from the delays in responding to process disturbances when using offline quality assurance tests.

Our PAT solutions give you the ability to use a wide range of process analyzers in conjunction with integrated chemometric prediction and model building tools to provide an online, inline or at-line quality measurement in close to real time. The consolidation of different analyzers into a single platform by following the OPC analyzer device integration standard provides a common way of working with different analyzer vendors. This, combined with our model data export tool, significantly reduces time-consuming activities such as analyzer integration and data synchronization.

Our analyzer device integration (ADI) platform is both open and secure, enabling tight integration with our 800xA integrated control system or with other third party control systems. This provides direct feedback to the manufacturing process, which can lead to earlier identification of product variations, allowing corrective action to be taken sooner and leading to less waste.

Dedicated workflows can be configured to control operator interaction when taking at-line measurements or for taking "grab samples" for verification purposes. Spectral, predicted and metadata can be stored online together with offline lab sample data. This provides both a data-rich historical record and a data source that furthers process understanding and enables future model development. Our ADI platform facilitates "right first time" decision making, reduces inefficient work cycles and enables regularity compliance. ADI delivers the right data to the right people at the right time helping to reduce product variation, reduce cycle time and allow real-time release.



ABB's integrated PAT solution

Instant payback with QbD

The immediate benefits of QbD for the manufacturer are more predictable scale-up effects, the ability to bring new production sites on-line faster and to understand and avoid manufacturing failures. In addition, manufacturers who implement a risk-based quality management approach (ICH Q9) and an appropriate quality management system (ICH Q10) can expect further benefits from:

- Effective quality processes where the level of effort, formality and documentation is proportional to risk
- Process validation based on a product life-cycle approach
- Efficient manufacturing optimized through continuous improvement
- Reduction in end-product testing and realization of real-time release

"We will not release any new products unless they are using PAT."

Global Pharmaceutical Company IFPAC

ABB's comprehensive and extendable solution

Our solutions for PAT and automation, based on our System 800xA, are applicable to the complete product lifecycle — from development, through scale-up to manufacturing. We provide 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 configurator and industry standard analyzer interfaces.

Seamless scalability from development to manufacturing
The ABB solution for PAT integrates analytical and automation products in a flexible and scalable platform. It provides a single configuration for multi-vendor analytical instrumentation, data acquisition and central storage of all analyzer and process related data.

Data management, visualization and advanced control
The PAT data management and control platform allows users to manage analyzer control parameters, store analyzer data and perform multivariate data analysis for process monitoring and process control.

Integrated quality management system
The PAT data management and control platform also meets all regulatory requirements. It allows users to implement QbD and continuous manufacturing approaches as defined by FDA, EMA regulatory agencies.

Enterprise connectivity and productivity tools
Our manufacturing execution system (MES) bridges the vertical integration gap between business and manufacturing systems, delivering significant new opportunities to increase productivity.

Our SmartClient provides intelligent data access and viewing functions to assist all levels of personnel in making quick, informed decisions and taking the appropriate action, thereby improving performance.

Enterprise connectivity solutions (ECS) and SmartClient reduce the total cost of ownership (TCO) for integration of ERP and plant systems by using a standard product for all vertical integrations, rather than a custom developed, point-to-point solution.

Integrated data management system
Integrated data management is a critical issue when the analytical model is being used to control a process in real time or for real-time release.

Data systems have typically grown as islands in R&D manufacturing, filling a specific niche for which they were designed. Companies hold a significant amount of 'forgotten' data about their existing products in disparate systems such as LIMS, ERP, EBR and MES but also in proprietary IT solutions. Looking to the future it is critical to the success of QbD and the concept of continuous improvement to be able to access all data linked to a particular product and process to identify the root causes of product and process performance deviations.

Questions to be answered include what data to store, in what format, where, what metadata (data, time, etc.) is required and how the data is retrieved and/or archived.

A single integrated data platform like System 800xA and ADI Connect simplifies all the above operations and make the interfacing with all third-party systems easier. Information management tools make all related data sets visible, enable closing the loop with the process and manage the critical quality data for each cGMP production.

"An independent evaluation convinced us that the ABB 800xA is the most advanced and versatile control system in the market today. This system integrates process control, manufacturing automation, and data management into an intuitive and facile common platform."

Biomanufacturing Training and Education Center, Raleigh, North Carolina

Simple analytical integration

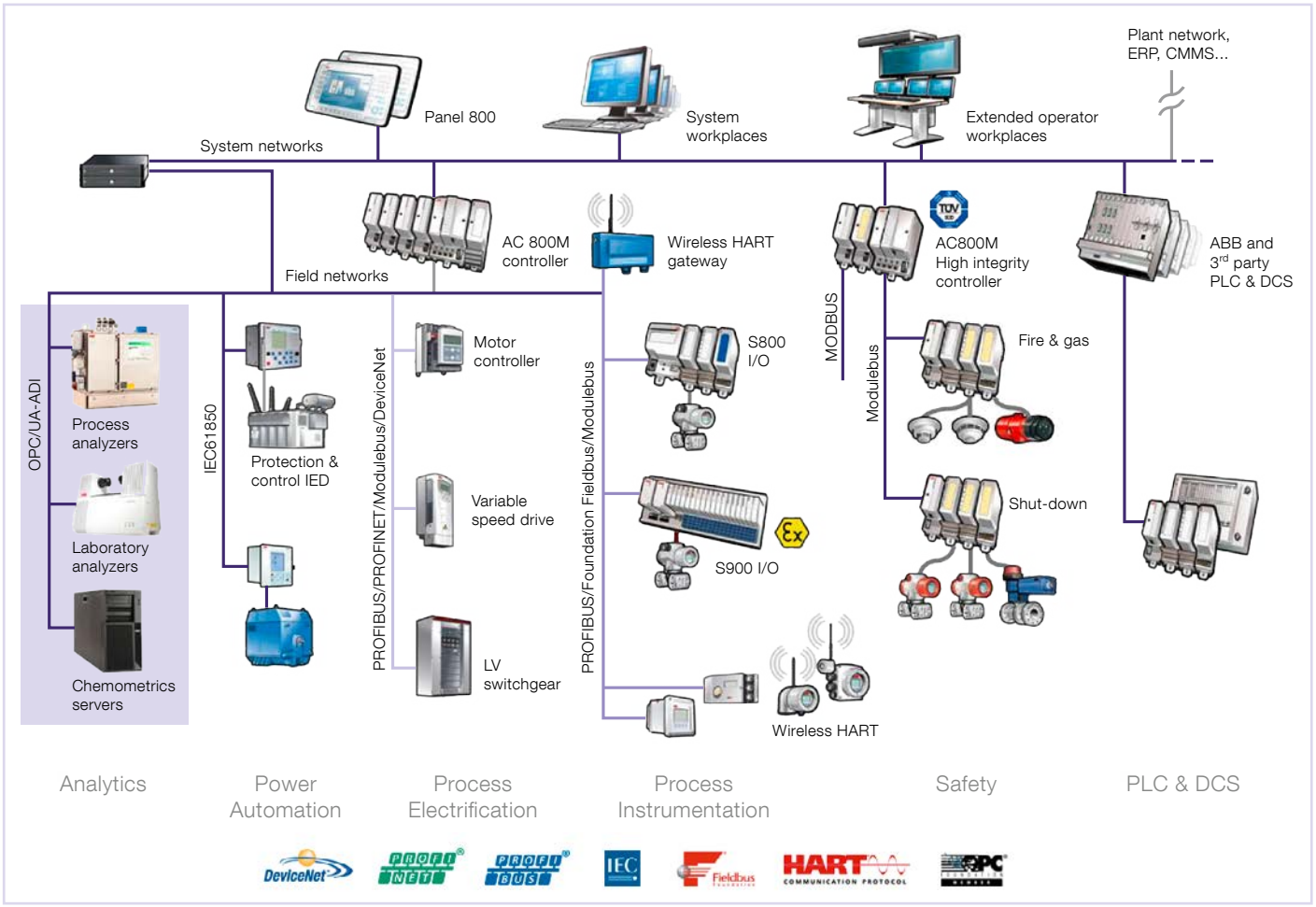
System 800xA features Analyzer Device Integration Connect (ADIc), a device interface that allows System 800xA to integrate with analyzers and chemometric predictors. ADIc also supports the integration of analyzers to manufacturing systems such as enterprise resource planning (ERP), manufacturing execution systems (MES) and production management systems.

Analytical integration brings extensive benefits. Vendor-independent analyzer & chemometric integration means that all your chosen devices can be managed through a single user-interface, thereby reducing deployment and training costs. The integration also simplifies the implementation of predictive models as analyzer and process data are combined seamlessly and the management and execution of methods is centralized.

Analytical integration also leads to a continuous improvement of analytical operations. There is a central, historical storage of all analytical, process and lab calibration data, and rich model data extraction will leverage your investment.

In addition there is full control and monitoring of analytical devices through conformance to OPC ADI, and the system can be expanded to meet your future needs.

System 800xA architecture



Know your process — measure it!
Critical quality attributes (CQA)

The ability to measure is the key to ensuring product quality and performance. With ABB measuring what is happening in situ, you only need to focus on the final product. Our PAT solution helps you manage, interpret and act on the resulting data, turning it into actionable knowledge to enhance production and ultimately, the quality of your product.

Comprehensive analyzer coverage

We design, manufacture and market high performance, affordable FTIR and FTNIR spectrometers as well as turnkey analytical solutions and spectroradiometers for remote sensing. Our capabilities encompass one of the largest portfolios in the world for laboratory, at-line and process FTIR analyzers. They perform real-time analysis of the chemical composition and/or physical properties of a process sample stream.

We have over 50 years of multi-industry analyzer experience. Our analyzers are low drift for highly repeatable measurements and the excellent reproducibility allows calibration transfer between analyzers.

Industry standard analyzer interfaces

Analyzer integration for PAT presents a unique set of challenges. There is a large variety of analyzers, provided by multiple vendors, which provide many different types of critical data. The best way to accomplish the level of analyzer integration required for PAT is through broadly-adopted open standards.

We actively supported the adoption of the OPC Analyzer Device Integration (ADI) standard and have released ADI Connect product against the specification which leverages ADI standard and power of System 800xA.

We provide high level interfaces to analyzers to make acquisition parameters available through preconfigured solutions. Mathematical calculations are performed on data to generate value predictions. Results are trended locally; and alarms provided. All vector and scalar data is collected and can be published through a standard communication protocol.

Process applications
Raw Material ID
Blending
Drying
Extrusion
Compression
Coating
Packaging
Fermentation
Bioreaction
Crystallization
Lyophilization
Solvent Recovery

Measurement capabilities
API concentration
Content uniformity
Confirm material ID
Coating thickness
Biomass measurement
Impurity concentration
Out gas monitoring
Purity
Lubricant uniformity
Moisture
Coating coverage
Nutrient concentration
Optical density

ABB — your partner

We will partner with you to identify key ROI areas based on our vast, multi-application experience. Working with you, we focus on the areas of highest payback first, and provide justification for change, including capital expenditures. We lower your lifecycle costs. As a single-source supplier, we make all your projects easier to manage. Our large R&D budget, resources and wealth of experience work to your advantage.

We work with you to reduce your time to market, decrease your production costs while increasing production flexibility, and to enable real-time product release. You benefit not only from our application knowledge but also from our regulatory validation expertise.

Our affordable, comprehensive and extendable solutions provide you with:
- Seamless scalability from development to manufacturing
- Data management, visualization and advanced control
- Industry standard analyzer interfaces
- Enterprise connectivity and productivity tools

As an ABB customer you profit from our global infrastructure that includes our 24x365 hotline support, our global logistics centers for spare parts and our local service and support centers around the world. Our support includes software maintenance as well as engineering, calibration and consultancy services.

"ABB's unique approach to PAT systems and solutions puts them in an excellent position to meet the future business and regulatory needs of this industry while driving down the total cost of ownership (TCO)."

ARC white paper: ABB Value Proposition for the Life Sciences Industry

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