

Life Sciences

The global pharmaceutical industry has undergone fundamental changes in recent decades. Regulatory and quality controls continue to put pressure on pharmaceutical manufacturers and threaten their ability to produce product in a cost and time efficient manner. As a result product quality and safety has increased however, so too has the cost of production. Key characteristics of the pharmaceutical sector include:

- High R&D, patent and capital costs
- Increasing competition from generic manufacturers
- Strict FDA regulatory standards
- Six Sigma demand for product quality standards
- Requirement for shorter product development life cycles
- Effects of a global economic downturn
- Lack of plant-wide data visibility and collaboration

Automsoft Solutions for Life Sciences

Automsoft has six of the top ten global pharmaceutical and biotech companies as customers and continues to be at the forefront of process control and optimization technology development. Automsoft's Life Sciences solutions are designed to meet industry and company-specific needs of global pharmaceutical, biotechnology and biomedical manufacturers.



rapidPharma™ rapidPharma by Automsoft is a robust and powerful distributed data historian capable of high-speed data capture and retrieval of pharmaceutical process and batch data empowering plant-wide data intelligence and production optimization.

rapidPharma collects and serves pharmaceutical process data sourced from enterprise-wide manufacturing systems including Lab Information Systems (LIMS), Warehouse Control Systems (WHSE), Batch Execution Systems (BES), PLCs, DCS and SCADA. Each produce vast amounts of process data points that describe lab outputs, production flow-rates, semi-batch (mechanical) and batch (manual) processing outputs, real-time asset performance, product transfer, dispensing and packaging performance.

In addition, rapidPharma is uniquely designed to comply with 21 CFR Part 11 and FDA guidelines on Process Analytical Technology (PAT) implementation.

Batch management & optimization: rapidPharma interfaces with external Batch Execution Systems enabling complete centralization of disparate batch data. rapidPharma simplifies data retrieval and storage of complex S88 batch data. Lab technicians and engineers can perform bespoke batch analysis reports, review variables, conduct batch comparisons and identify optimum recipes for future replication.

Alignment with FDA PAT guidance: rapidPharma supports the FDA Process Analytic Technology framework by enabling multivariate data integration, data and process analytical chemistry tools, process and end-point monitoring and control, as well as an interface with continuous improvement and knowledge management tools.

FDA 21 CFR Part 11 Compliance:

> **Security:** rapidPharma leverages operating system level security sub-systems to enable administrators to control and manage user

> **Audit Trail:** rapidPharma records each human interaction with the rapidHistorian system in a discrete, tamper-proof, self-auditing Audit Database. Administrators can use rapidPharma's Audit Reporting Tool to generate completely traceable audit records of all interactions.

> **Electronic Signatures:** Using digital signature technology, rapidPharma enables the application of electronic signatures (comprising user name, time and purpose of signing) which can be applied to reports.

Optional rapidPharma functional add-ons include:

Batch Reporting, Audit Reporting, Server High Availability, Network High Availability, Data Replication, OPC Caching and Redundancy.

Automsoft

Technology Highlights

- > FDA 21 CFR Part 11 and PAT capable
- > ASHRE, ANSI & ISO compliant
- > High-speed data compression & storage
- > Application & data independent
- > DDE/Net DDE Support
- > Web services/SOA
- > OPC Compliant (HDA, DA, UA, A&E)
- > Multiple data source compatibility (ODBC, OPC, OLE/DB, ADO.NET, SQLServer, Oracle and web services)
- > Centralized data management & visibility
- > Complex data interrogation – Calculation Engine, Excel add-in
- > Extensible information model
- > Alarm & event management
- > Extensive visualization tools – graphics & animated instrumentation
- > Integrated security, & user authentication & audit traceability
- > Server & network high availability
- > Comprehensive backup, OPC caching & redundancy
- > Anytime, anywhere access
- > Open web services data distribution

About Automsoft

Automsoft is one of the world's premier providers of advanced data historian and process optimization solutions. Automsoft's rapidHistorian™ and nuViews™ product suite enables powerful and secure high-speed data retrieval, vast storage capacity, complex analysis and sophisticated visualization. Founded in 1997, Automsoft has a global customer base of thousands of installations across diverse industrial sectors including Power & Utilities, Renewable Energy, Maritime, Manufacturing, Life Sciences and Oil & Gas. Today, Automsoft is at the cutting-edge of cleantech solution development enabling advanced meter data aggregation, smart grid integration and smart building management.

Automsoft has international offices in the US, Europe, Middle East & Asia. For more information, please visit <http://www.automsoft.com>.



nuaViews™

nuaViews is a rich Internet application (RIA) authoring system and the industry's most advanced data visualization and process optimization solution. nuaViews is ideal for large pharmaceutical plants, enabling complete centralization of production process data so that users in remote locations can access, analyze and execute decisions based on live process data results. Remote users can also quickly access process data for assets that may be located in physically secured or restricted areas of a pharmaceutical plant. nuaViews' features include:

• **Web-based enterprise dashboard:** nuaViews' user-friendly web interface delivers a wealth of operational data and analysis functionality via a single and secure web-based dashboard. From lab technicians, to process engineers and boardroom executives – each can quickly view and interrogate data, perform bespoke trending and analysis, and generate and view run-time reports that reveal instant snapshots of production performance.

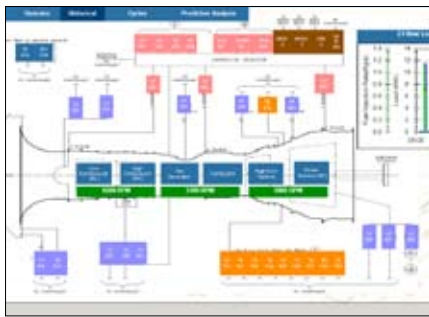
• **Open plant process data management:** Using its Report Service, nuaViews interfaces with legacy control systems to request and retrieve data via HTTP ensuring customers retain network integrity and obtain enhanced enterprise data visibility and accuracy across a plant network.

• **Advanced charting & visualization tools:** nuaViews' powerful data visualization tools transform numeric data points into mimics that dynamically update when viewed at run-time. nuaViews' web-interface allows management to remotely view real-time control gauge simulations for assets located in secure or sterile areas of the plant ensuring quick issue isolation and resolution.

• **Calculation Engine & predictive modeling:** nuaViews' Calculation Engine enables users to perform powerful historic process and batch data analysis and modeling to reveal optimum process conditions that deliver profitable, high-quality and efficient output.

Automsoft
Life Sciences Customers

- Schering-Plough
- Pfizer
- Wyeth
- Baxter
- Akzo Nobel
- DSM
- ConvaTec
- Roche
- Genzyme



Automsoft Benefits for Life Sciences

- **Comply with FDA 21 CFR Part 11** with rapidPharma's audit trail, data security and electronic signature functionality.
- **Reduce operating costs** by minimizing materials wastage, eliminating inefficiencies and maintaining plant asset longevity to prevent production down-time.
- **Accelerate time to market & increase yields** by refining batch recipes and processes and optimizing workflows that shrink life cycles and increase production output rates.
- **Bolster production quality, security & safety standards** through rapidPharma and nuaViews' comprehensive alarm and event management, process analysis, user authentication and audit management tools.
- **Standardize data visibility** via rapidPharma's distributed software and nuaViews web-enabled access to a single, centralized database of enterprise process performance.
- **Achieve plant-wide collaboration** across all stages of the production chain to ensure business and regulatory goals are achieved.
- **Increase ROI** for existing plant assets, control systems and IT applications with Automsoft's open and seamless data and application interfacing and ongoing OEE analysis.

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