Ensuring product safety, quality and regulatory compliance

Statistica provides validated analytics for pharmaceutical, medical device, food and regulated manufacturing environments.

Easily combine and analyze the most up-to-date data from disparate systems with Statistica. This powerful analytics solution minimizes risk by making it simple to rapidly detect emerging issues and take corrective actions. Plus, it satisfies the most stringent regulations by providing a secure and validated analytics environment, while delivering auditable workflows and reports for regulated manufacturing. With Statistica, you can feel confident that you're meeting the highest standards for product safety, quality and regulatory compliance. Statistica makes it easy to satisfy FDA decrees for GxP process monitoring and Process Analytics Technology (PAT) compliance.

Statistica can help you:

- **Comply with FDA and ICH guidelines** — Minimize the amount of time and paperwork required to demonstrate regulatory compliance for your analytics and reporting platform.

- **Rapidly detect manufacturing issues** — Reduce scrap, rework and quality issues with advanced quality-control analytics, root-cause analysis and validated reports.

- **Deliver accurate data to customers and suppliers** — Access the latest information to better understand product manufacturing via secure web portals.

- **Empower engineers and process experts** — Provide teams with flexible tools to proactively identify and resolve emerging issues.

"Process data, LIMS data, quality tools, multivariate tools, and compliance reporting are all accessible through one system… the system can be accessed remotely and securely by external customers through their web browsers."

Statistician, Manufacturing Technical Services, Global Biopharmaceutical Manufacturing Company

Benefits:

- Achieve regulatory compliance
- Optimize processes
- Improve product quality
- Simplify analytics
- Combine data from disparate sources
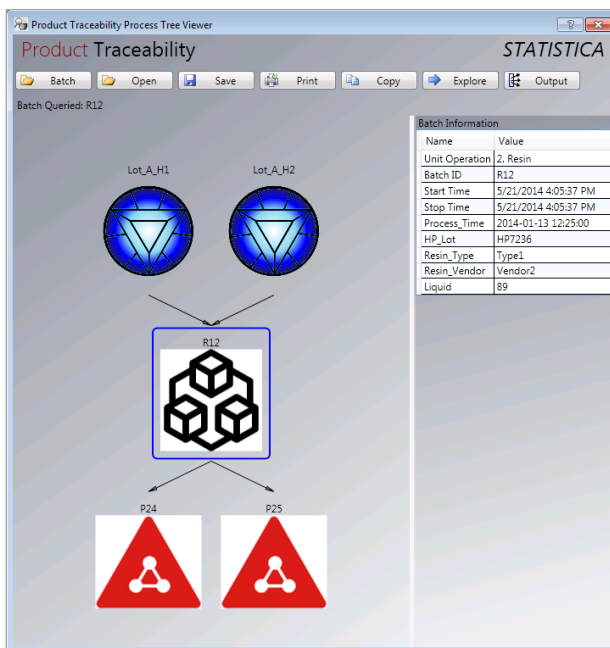
Statistica's product traceability module

- **Manage materials sourcing variability** — Increase supply chain visibility, both upstream and downstream, to better track the sourcing of ingredients.

- **Optimize processes** — Identify and resolve bottlenecks, improve supply chain processes and more.

Features

Achieve regulatory compliance — Gain a fully configurable, secure and auditable analytics platform that's compliant with major regulations, including FDA 21 CFR Part 11, Sarbanes-Oxley, and ISO 9000, 9001 and 14001.

Specialized data access — Use connectors to OSI PI™, laboratory information management systems (LIMS) and manufacturing execution systems (MES).

Product traceability — Monitor, analyze and understand the movement of materials and batches throughout the production process.

Stability and shelf-life analysis — Ensure toxicological, microbiological, physical and chemical stability and shelf-life analytics methodologies meet technical requirements and regulations set forth by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceutical for Human Use (ICH) and the U.S. Food and Drug Administration.

Standardized compliant deliverables — Document and validate user requirements, functional specifications, validation plans, test plans and other processes.

Built-in audit trail with rollback — Maintain a record of all changes; gain the ability to quickly revert to the previous state if something was overlooked.

Quality control, SPC and Six Sigma — Use a comprehensive toolset for statistical process control (SPC), process optimization and quality imperatives, including design of experiments to improve production quality for complex manufacturing processes.

Monitoring and alerting — Centralize and automate the continuous monitoring of processes and product parameters.

Self-service customer portal — Monitor manufacturing parameters through a secure and configurable web-based portal.

Validated web data entry — Enter data via a web browser to minimize errors and allow for double-blind data entry with rule-based validation of fields as well as approval roles.

LiveScore — Implement real-time scoring for predictive analytics within your manufacturing environment.

Components

Statistica analytic solutions for regulated manufacturing include:

- **Advanced Statistics and Data Miner** — Provides a comprehensive selection of data analysis and mining solutions with powerful model development and deployment tools as well as database and data warehouse integration. Optional solution packages are available for specific applications and domains.

- **Enterprise Server** — Delivers analytic and business intelligence applications via centrally managed queries, analysis and report templates and dashboards.

- **Web Data Entry** — Enables easy configuration of data entry scenarios for each unit of operation; includes integrated workflow/approvals and analytics.

- **Monitoring and Alerting Server** — Automates the continual monitoring of hundreds or thousands of critical process and product parameters.

- **Product Traceability** — Simplifies mapping of complex (batch) processes to perform meaningful analytic reporting. Integrates with LIMS and MES systems to perform root-cause analysis over selected process steps.

- **PI Connector** — Integrates directly with data stored in PI data historian; streamlines and automates analysis for applications such as Process Analytics Technology (PAT).

- **Stability and Shelf-life Analysis** — Provides a complete and fully auditable solution for shelf-life analysis and reporting. Applies a standardized approach to single and multiple batch studies, pooled and separated per-batch estimation (separate intercept, separate/common slope, poolability tests) and all common procedures for shelf-life estimation.

About Dell Software

Dell Software helps customers unlock greater potential through the power of technology — delivering scalable, affordable and simple-to-use solutions that simplify IT and mitigate risk. This software, when combined with Dell hardware and services, drives unmatched efficiency and productivity to accelerate business results.

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