

STATISTICA®

Shire

Specialty biopharmaceutical company reaps data analysis and process efficiencies

Shire's Rare Diseases Business Unit implements Statistica for single-point access to real-time process data — streamlines tasks, reduces risk, saves money

Case Study



COMPANY PROFILE

Company

Shire

Industry

Specialty
biopharmaceutical



Country

United Kingdom

Employees

5,300+

BUSINESS NEED

Shire's Rare Diseases Business Unit needed a validated data capture and analysis tool to conduct statistical process control, monitor processes and identify areas of improvement.

SOLUTION

Replacing a mix of in-house scripts and tools, Statistica gave Shire Internal Manufacturing controlled access to validated, real-time process data in support of manufacturing operations management across the enterprise.

BENEFITS

- Seamless, unified data presentation
- Flexible, scalable data entry forms
- Validated interface with Laboratory Information Management System (LIMS)
- Automatic distribution of predefined control charts
- Efficient cross-site process and product comparison

Established in 1986, Shire is a specialty international biopharmaceutical company that provides treatments in neuroscience, rare diseases, gastrointestinal and internal medicine.

The company's U.S. operations of its Rare Diseases Business Unit had been using a complex network of heterogeneous systems, including LIMS, Excel and JMP, to manage vast amounts of manufacturing data. Employees could manually collect and report on key findings but ensuring accuracy was extremely time-consuming.

The division decided to replace these systems with a single solution that would provide controlled access to validated process data in support of manufacturing operations management. The key requirement was for an off-the-shelf application with validatable output and demonstrated use in the biopharma industry.

After careful evaluation, the organization selected Statistica's advanced analytics platform. The division implemented the solution in three environments across multiple sites: development, validation and production. Statistica helped custom build a validated connection that would enable the importing of historical Laboratory Information Management Systems (LIMS) data for statistical process control (SPC). Thanks to the division's excellent use case and requirements documentation that mapped to Statistica's out-of-the-box functionality, the project team was able to efficiently execute the system validation and reduce the time needed for implementation.

"The availability of Statistica's validated data system for Internal Manufacturing represents a significant step toward better understanding of our process technology and higher business efficiency."

- Gloria Gadea-Lopez, Director of Manufacturing Systems, Shire





“Implementing Statistica is a critical milestone along our continuous improvement journey to ensure the robust and uninterrupted supply of quality drugs to our patients.”

- Pat Sacco, Senior Vice President of Manufacturing Systems, Shire



The Statistica graphical workflow management interface, Enterprise Workspaces, also helped expedite the implementation. This modular environment facilitates rapid configuration of sequences of analytics steps, delivering the greatest flexibility for users to build highly targeted analytic flows without programming. In addition, analytic flows can be validated and placed under Statistica Enterprise version control.

Installation occurred in two phases:

- **Phase I:** Development and roll out of a Good Manufacturing Practices (GMP) system to replace the custom-made data collection and reporting system
- **Phase II:** Replication of historical batch record data, enabling a seamless, retrospective view of the process history

RESULTS

Phase I was rolled out in March 2014 when the new Statistica GMP system officially went live with data entry, analysis, reporting and the availability of LIMS data (historical and new). Immediately, end business users were able to publish charts, graphs and reports to a web portal via their company intranet. In fact, within a few moments of going live, one engineer was already sending real-time LIMS data summaries and analyses that were needed urgently for an ongoing project. Prior to implementing Statistica, such real-time tasks would have been

labor-intensive and time-consuming, if not impossible. Business users can now intuitively generate and configure data analyses efficiently without the need for specialists, programming or IT involvement.

Statistica provides a validated single point of entry for data capture across processes and locations, eliminating training on multiple systems, reducing data entry errors and making data accessible to users faster. The solution enables teams to close process investigations with more efficient root cause analysis, reducing operational risk and costs.



Verified data and reports are visible across sites, which increases efficiency, reduces cost and improves communication. The system publishes reports automatically, freeing up staff time and providing immediate and broader access and transparency.

Statistica also supports proactive interventions to stop negative trends from becoming excursions. The solution increases predictability of production by reducing process variability and decreasing defects and lost batches.

Gloria Gadea-Lopez, Director of Manufacturing Systems, noted that other functional areas, upon witnessing the success of Phase I, have already requested support for additional features,

including installation of Statistica Shelf Life and Analysis.

The value in this particular area is highly anticipated following delivery of a successful prototype.

Phase II is already underway, delivering successful milestones such as the implementation of additional product lines for data generated at external manufacturing sites (CMOs). With the addition of stability operations and CMO fill/finish processes, Shire will have access to end-to-end process information for its Rare Diseases products that, prior to the implementation of Statistica, would have been a monumental task.

Future anticipated phases include the addition of Statistica's Product Traceability module.

ABOUT STATISTICA

Statistica's advanced analytics, big data and IoT offerings provide you endless possibilities to innovate your enterprise. Whether it's uncovering the genetic basis of a disease, reducing hospital readmissions, mitigating financial risk, or ensuring procedural validation, Statistica enables organizations to transform in new and exciting ways. By embedding analytics everywhere and empowering a wider community of citizen data scientists, you'll accelerate innovation, improve customer experiences, and streamline your enterprise for the future. <http://statistica.io>

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