

# Biopharmaceutical Manufacturing



## **Analytics As a Key Differentiator in Contract Biopharmaceutical Manufacturing**

*STATISTICA Enterprise GMP Analytics Platform Provides Process Understanding, Process Optimization, Process Monitoring, Compliance Reporting, and a Customer Self-Service Portal*

“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

### Analytics Addresses Challenges in Biopharmaceutical Contract Manufacturing

StatSoft’s client is a global leader in the contract manufacturing of active pharmaceutical ingredients, intermediates, and biopharmaceuticals. With sites all around the world, multiple processes running at each site, and many customers, each customer with their own commitments to regulatory agencies and specifications for the manufacturer of their specific products, this contract manufacturer has a complex set of challenges:

- Customers want to review the latest information about the manufacturer of their respective products
- Data is in disparate data bases requiring data connections, aggregation and alignment

across data historians, LIMS, SAP, etc. At each manufacturing site, a complex assortment of products are being manufactured for a wide variety of customers

- Each customer has high demands about the manufacture of its products, reviewing the yields and quality with a high degree of scrutiny
- Engineers need access to the latest continuous and discrete data to identify and troubleshoot any issues
- The contract manufacturer needs to keep close scrutiny on raw materials, yields, and other costs impacting bottom line and the supply chain of customers
- Variability in the sourcing of ingredients and media sourced by the contract manufacturer’s customers impact the processes

This contract manufacturer relies on *STATISTICA Enterprise* software as its global, standard GMP analytics platform which empowers its engineers and analysts with role-based access to data, standard analyses, and reports to support process understanding, process monitoring, and regulatory compliance. *STATISTICA Enterprise* is a key component for the contract manufacturer’s customers as they can self-service the data and reports about the manufacturing and quality of their respective products.

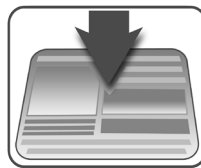
### Immediate ROI

The *STATISTICA Enterprise* software platform was deployed and integrated with this contract manufacturer’s other systems in only a few weeks. Engineers configured a set of automated statistical monitors on key process parameters and immediately had a different level of insight and awareness about the status of the manufacturing processes.

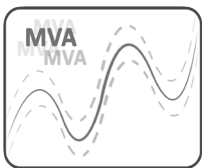
## Featured StatSoft Products



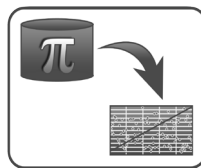
**STATISTICA Enterprise** – is the server platform for delivering analytic and business intelligence applications to departments and divisions within the enterprise via centrally managed queries, analysis templates, report templates, and dashboards.



**STATISTICA Web Data Entry** – enables Pharmaceutical companies to configure data entry scenarios for each unit operation of their processes, with integrated workflow/approvals and analytics.



**STATISTICA MSPC** – is a complete solution for multivariate analytics, designed for applications in process monitoring and predicting quality outcomes using multivariate predictive analytics (including data mining) methods.



**STATISTICA PI Connector** – allows for direct integration to data stored in the PI data historian, used for streamlined and automated analyses for applications such as Process Analytical Technology (PAT).

Within the first 12 weeks of the use of *STATISTICA Enterprise*, an engineer monitoring the maturity of a batch noticed that a key parameter deviated from the expected pattern. The engineer acted and found that a valve was stuck. The batch was saved and the savings from avoiding lost materials, lost processing time, lost engineering resources, and the impact to their customer's supply chain meant that the software had delivered its return-on-investment within 12 weeks of installation. Since then, the contract manufacturer reports that dozens of batches have been saved through the use of *STATISTICA Enterprise*.

## Using *STATISTICA Enterprise*

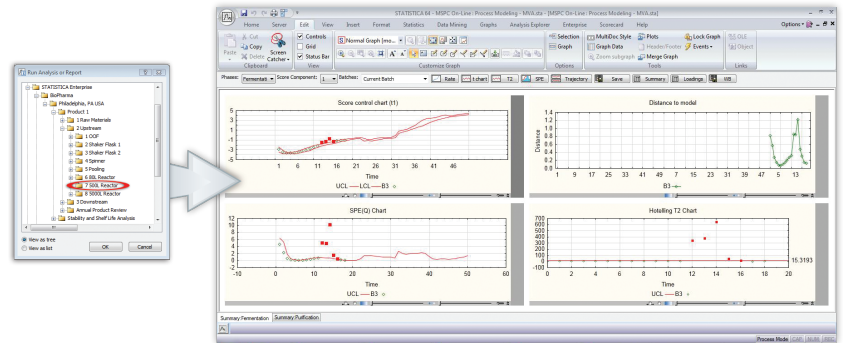
At the heart of its analytics, this contract manufacturer utilizes the *STATISTICA Enterprise* server-based analytics platform. Engineers and analysts at multiple sites log on to *STATISTICA Enterprise* and are provided with configured queries, analysis templates, and reports specific to their role, making it easy to support their work and decision making. The contract manufacturer's customers also log on to *STATISTICA Enterprise* to view a customer-specific portal in which each customer has access to the latest data and reports about their respective products.

This contract manufacturer is typical in that there are many disparate data repositories with the relevant data from its processes and product testing. *STATISTICA Enterprise* streamlines access to data because it is configured once to know how to import data from the relevant LIMS systems, data historians (the PIT<sup>™</sup> data historian from OSI Soft<sup>™</sup>), and other systems. When an engineer needs immediate information about the latest batches, *STATISTICA Enterprise* is ready, already "knowing" how to retrieve the relevant data. For many analysis types such as process monitoring and automated trending, *STATISTICA* connects to the relevant data repositories with auto-updating connections for real-time status.

## Self-Service Customer Portal

At this contract manufacturer, *STATISTICA Enterprise* is configured with specific user accounts for each customer. Customers log onto the system through their Web browsers. Once logged on, each customer sees a portal with links to data and reports about their respective processes. These customer portals allow this contract manufacturer's customers to self-serve as needs arise, day or night, eliminating the manual efforts utilized in the past to keep customers updated with the latest status reports. In addition, the customer portals are configured to allow the customers to download any data about

Engineers and analysts at each site are presented with a user interface that matches what they know: the processes! On the *STATISTICA Enterprise* screen, they see and interact with the respective unit operations and parameters from the processes.



their products in Microsoft Excel<sup>™</sup> format so that they have immediate access to their data to perform follow-up analyses. For this contract manufacturer, these customer portals are a major differentiator compared with other contract manufacturers; for example, the contract manufacturer shows prospective customers how they can self-serve to gain up-to-the-minute status updates.

## Regulatory Agencies

When representatives from regulatory agencies pay a visit, this contract manufacturer sits them down with an engineer who delivers a brief tutorial of the *STATISTICA Enterprise* analytics system. Once the agency representatives understand how the system works, they are allowed to self-serve any data or reports of interest. The contract manufacturer has found this approach reduces the amount of inquiry and scrutiny during a visit.

## Computer Systems Validation

*STATISTICA Enterprise* is a validated analytics system in use around the world for GxP applications. StatSoft is an exemplary vendor of commercial off-the-shelf analytics software, with many of the largest Pharmaceutical, Biopharmaceutical, and Medical Device companies using *STATISTICA* for analytic applications that improve product efficacy, product reliability, and consumer safety. StatSoft's customers using *STATISTICA Enterprise* have been audited numerous times over the years, receiving praise from agency auditors for their approach to analytics.

## Key Benefits Summary

- Central Configuration and Management
- Data Connections, Aggregation and Alignment across Data Historians, LIMS, SAP, etc.
- Streamlined Computer Systems Validation
- Comprehensiveness with Trending, Multivariate Analyses, Graphical Data Analysis, Data Mining, and Compliance Reporting in One Integrated System
- User Experience and Ease of Use
- Automated, Proactive Alerts

## Types of Applications

### Batch Data Entry

Configurable data entry screens for simple Web browser-based data entry, configured with drop-down lists to minimize data entry errors and workflows for second-person data review and verification.

### Automated Trending

Real-time, auto-updating connections to data repositories with standard analysis templates that allow operators, engineers and analysts to monitor batches at the click of a button; detect shifts and trends in the process when they can be addressed.

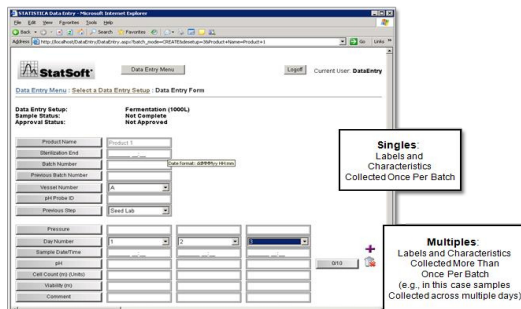
### Multivariate Analyses (MVA)

Server-based, centrally-managed platform for understanding which parameters affect product quality and their patterns resulting in good batches versus bad batches.

### Annual Product Review Reports

Aggregate all of the relevant parameters and data to automate the analyses and reporting for Annual Product Reviews. Saves time and money, and reduces the potential for errors by automating Annual Product Review reports.

## Configurable Web Forms for Batch Data Entry from Any Unit Operation: With user permissions, audit trails, and optional second person verification workflows



### Column Integrity

Employ multivariate analyses to monitor column transitions during purification steps to detect when a column needs to be re-packed.

### Ad Hoc Analyses

But what about the things that are unexpected? On a day-to-day basis, engineers need to perform ad hoc analyses and investigations. The configured connections to the data sources (LIMS, data historian, etc.) enable the engineers to quickly and easily select the relevant data and then perform ad hoc analyses from the comprehensive list of traditional statistics, multivariate analysis, root cause analysis, data mining, and others.

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## About **STATISTICA** and StatSoft

StatSoft is one of the world's largest providers of analytics software, with 27 offices around the globe and 1 million+ users of **STATISTICA** software. StatSoft provides Enterprise Manufacturing Process Intelligence software solutions to help Pharmaceutical companies better meet the high standards of control, monitoring, and documentation mandated by the industry's strict regulatory framework and to improve product and process outcomes. With its **STATISTICA** suite of quality control and analytics tools, StatSoft is a trusted partner of the world's largest pharmaceutical companies, helping them reduce the time and cost of analyses, improve accuracy, reduce risk, and streamline workflows.

