

STATISTICA™ Case Study

STATISTICA Enterprise™ Helps Enhance the Operational Process Flow at a Medical Device Manufacturer



SUMMARY

STATISTICA Enterprise provides Instrumentation Laboratory, a global medical diagnostics company, with a multi-user analytics platform to simplify and ensure quality in the manufacturing process while strengthening collaboration across departments to achieve these goals.

ABOUT INSTRUMENTATION LABORATORY

Instrumentation Laboratory, founded in 1959, is a worldwide developer, manufacturer, and distributor of *in vitro* diagnostic instruments, related reagents, and controls for use primarily in hospitals and independent clinical laboratories. The company's product lines include critical care systems, hemostasis systems, and information management systems. Instrumentation Laboratory's products include the GEM Premier™ 4000 analyzer with Intelligent Quality Management (iQM®), GEMweb® Plus Custom Connectivity, the ACL TOP® Family of Hemostasis Testing Systems, and the HemosIL line of hemostasis reagents. Instrumentation Laboratory employs more than 1750 employees worldwide and is a wholly-owned subsidiary of the global healthcare corporation Werfen Group.

CHALLENGES OF DATA ANALYSIS

Instrumentation Laboratory faced challenges integrating and accessing data from various systems for quality control of its manufacturing process. "Medical device manufacturing and testing is complicated, with large amounts of data from suppliers, manufacturing processes, product testing, and field performance," says Rob Eames, Director of StatSoft's Life Sciences Practice. Because the relevant data are stored in different file formats and even use different terminology, the task of accessing and analyzing the data was difficult and time consuming for both engineers and management. To address these challenges, Instrumentation Laboratory investigated the utility of a Web browser-based reporting tool and portal with links to static and interactive reports analyzing data from disparate databases.

THE SOLUTION:

STATISTICA ENTERPRISE

STATISTICA Enterprise streamlines collaboration so that engineers and managers work from a common platform, file format, and terminology. Consequently, they can now answer questions immediately, perform interactive investigations, and explore processes and product testing regardless of where the data are stored. These benefits translate to tangible savings for Instrumentation Laboratory.

"... automated analyses and reports enable the engineers to focus on analyzing results, collaborating, and problem solving instead of hunting down data."

**– John Young,
Business Analyst at
Instrumentation Laboratory**



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“We have incorporated *STATISTICA Enterprise* into our manufacturing process for standard data access and as our analytics server platform,” says John Young, Business Analyst at Instrumentation Laboratory. “A standard set of connections to our data sources and the automated analyses and reports enable the engineers to focus on analyzing results, collaborating, and problem solving instead of hunting down data.”

In the past, engineers and analysts invested a considerable amount of time simply obtaining the relevant data and then determining how to analyze it. *STATISTICA Enterprise* streamlines the data analysis components of process validation and automates common reports and analyses. Leveraging *STATISTICA*'s set of standard analysis templates and report templates, Instrumentation Laboratory now has a common set of “views” of their processes, tests, and product performance results.

Instrumentation Laboratory's utilization of the *STATISTICA Enterprise Server* software platform is a foundation component for its adherence to the process control and statistical analysis guidance aspects of the FDA's 21 CFR Part 820 for medical device manufacturers. The Solution: *STATISTICA Enterprise*.

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ABOUT *STATISTICA* AND STATSOFT

StatSoft is one of the world's largest providers of analytics software, with 30 offices around the globe and 1 million+ users of *STATISTICA* software. StatSoft provides Enterprise Manufacturing Process Intelligence software solutions to help companies in a variety of industries better meet the high standards of control, monitoring, and documentation mandated by strict regulatory frameworks 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 Life Sciences companies, helping them reduce the time and cost of analyses, improve accuracy, reduce risk, and streamline workflows.