

## **ImClone Builds World Class Lean Manufacturing System**

Insightful's S-PLUS® is providing ImClone with insights into its manufacturing process that allows the biopharmaceutical company to produce products more quickly, efficiently and reproducibly.

S-PLUS provides a core analytical tool which supports the detailed understanding of the manufacturing process), ImClone is also achieving cost efficiencies by being able to do more with less money.

### **Company Overview:**

ImClone Systems Incorporated is a fully integrated biopharmaceutical company committed to advancing oncology care by developing and commercializing a portfolio of targeted biologic treatments designed to address the medical needs of patients with a variety of cancers.

ImClone currently markets ERBITUX for the treatment of metastatic colorectal and head and neck cancers. The Company's research and development programs include growth factor blockers and angiogenesis inhibitors. ImClone Systems' headquarters and research operations are located in New York City, with additional administration and manufacturing facilities in Branchburg, New Jersey.

### **Situation:**

For more than 50 years the pharmaceutical industry and the FDA have been working together to ensure the safety of the drug products manufactured for consumers. Several years ago, the FDA undertook a new initiative to address "Current Good Manufacturing Practices" (CGMPs) for the 21<sup>st</sup> century. As a result, the initiative found the need for a number of changes in both the regulator's and the industry's approach to ensure the highest drug quality.

### **Solution Overview**

#### **Profile:**

ImClone Systems Incorporated (NASDAQ: IMCL) is a fully integrated biopharmaceutical company committed to advancing oncology care by developing and commercializing a portfolio of targeted biologic treatments designed to address the medical needs of patients with a variety of cancers. ImClone currently markets ERBITUX for the treatment of metastatic colorectal and head and neck cancers. The Company's research and development programs include growth factor blockers and angiogenesis inhibitors. ImClone Systems' headquarters and research operations are located in New York City, with additional administration and manufacturing facilities in Branchburg, New Jersey.

#### **Business Need:**

ImClone needed to build a world class lean manufacturing facility in parallel with all of its data systems development. ImClone needed a manufacturing system that would provide insights into the manufacturing process allowing the Company to produce products quickly, efficiently and safely.

#### **Insightful Products Used:**

Insightful S-PLUS Enterprise Server

#### **Benefits:**

- End-to-End System and Variable Monitoring
- Real Time Access to Data Provides The Knowledge to Act
- Rich Visualization Capabilities Enhance Communication

ImClone, a rapidly growing biopharmaceutical company, wanted to concurrently build both a second manufacturing facility and a cost effective world class data and information system. The Company was interested in utilizing statistical tools in its manufacturing system to ensure the system followed QbD (Quality by Design) principles and met CFR Part 11 requirements.

### **Solution:**

ImClone wanted the solution platform to utilize rapid, flexible and scalable systems with intuitive human interfaces for quick training and implementation. ImClone selected Insightful's S-PLUS® Enterprise Server for integrating multiple data streams including manufacturing, quality, and ERP systems because S-PLUS met all of the Company's requirements.

"We had to build and plan systems not in a serial fashion with the analytics at the end, but in parallel with the analytics ready to deploy when the data systems were complete," said Anthony Lonardo, Senior Director of Statistics and Quantitative Sciences for ImClone.

S-PLUS Enterprise Server delivers custom analytics to business users, giving timely information to decision makers and freeing up valuable time for the analytic development and IT teams. By combining its pipeline architecture for out-of-memory data processing with the elegance and power of the S programming language, S-PLUS Enterprise Server offers a rapid-development environment together with the power to scale to extremely large data sets.

"Since I led both the data system and analytic development teams and was familiar with the strengths of S-PLUS, I could ensure the data systems fit. Rapid development was possible because of the flexibility and development speed the S-PLUS Enterprise Server offers," explained Lonardo.

### **Benefits:**

#### **End-to-End System and Variable Monitoring**

One of the first benefits the company achieved by implementing its manufacturing system is the ability to see their manufacturing process and all its variables end-to-end. Seamless integration between the multiple data streams and S-PLUS Enterprise Server allowed ImClone to create an intuitive system that tracks all of their production metrics. ImClone has more than 11,000 individual pieces of data for each production batch.

#### **Real Time Access to Data Provides the Knowledge to Act**

S-PLUS Enterprise Server provides more than 100 users including management, quality control personnel and staff throughout the company with real-time access to production information and statistical analysis. This real-time access to the manufacturing process information provides ImClone with the opportunity to monitor progress to ensure things are progressing appropriately and make changes or adjustments if needed. If a change is made, it also provides real-time feedback on the effect of the change. The insight the system provides into ImClone's manufacturing process gives production management the knowledge needed to identify bottlenecks for any particular batch of drug and closely monitor the costs involved in production.

## Rich Visualization Capabilities Enhance Communication

ImClone has also found that the superior graphic reporting capabilities of S-PLUS Enterprise Server enhance communication across the entire company. "The simple, intuitive and information-rich reporting features make results obvious and easy to digest by management, quality personnel, and subject matter experts throughout the development process," said Lonardo.

S-PLUS Graphlets® allow users to create interactive web-based charts. Graphlets also provide users the ability to "drill-down" to and extract additional information or perform new computations remotely on the S-PLUS Enterprise Server.

## Standardization of Investigation and Regulatory reports

Useful analysis developed on the desktop are easily transferred, automated and linked using the S-PLUS Enterprise Server and a web interface. Standard reports required by regulatory agencies have also been standardized and automated.

"This manufacturing system has been well received by the organization and has generated many great ideas by our users," said Lonardo. "We have seen improvements in nearly every area of quality measures. As a result, we are moving the system upstream and integrating it with the development groups such as formulations, pre-clinical, quality control, process development and engineering."

Insightful Life Sciences Solutions: S-PLUS and Insightful products have been delivering flexible, validated and streamlined data analysis results to the pharmaceutical industry for more than 18 years. The S-PLUS product family provides a Rapid Development and Deployment Platform for Analytic Solutions. More information about Insightful Life Sciences Solutions can be found at [www.insightful.com/industry/pharm/default.asp](http://www.insightful.com/industry/pharm/default.asp).

S-PLUS 8 – Delivering the Power of Predictive Analytics Across the Enterprise: Designed with an open architecture and flexible interfaces, S-PLUS 8 provides the scalability to handle gigabyte-size data sets and the flexibility needed to integrate advanced analytics into the business processes that decisions makers and researchers interact with every day. With S-PLUS 8, statisticians and developers can quickly develop prototypes and deliver targeted applications that automate analytical processes and enable non-statisticians to conduct their own analyses. More information about S-PLUS 8 can be found at [www.insightful.com/products/splus/default.asp](http://www.insightful.com/products/splus/default.asp).

## For More Information

For more information about ImClone products and services, call 212.645.1405, or visit the Web site at <http://www.imclone.com/>. For more information about Insightful products and services, call us at (206) 283-8802, or visit our Web site at [www.insightful.com](http://www.insightful.com).

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