



ImClone Systems, Incorporated Improves Environmental and Utility Monitoring Efficiency and Accuracy with MODA-EM™

Solution Summary

Challenge

ImClone Systems Incorporated, (ImClone Systems) recently expanded its bulk manufacturing facility in Branchburg, NJ. Scaling up current environmental and utility monitoring operations would require the addition of many new technical personnel.

Solution

ImClone Systems implemented MODA-EM™, a mobile computing platform to automate the collection, management, and reporting of environmental and quality control monitoring information, which increased the productivity of its current staff.

The new workflow reduced, and in most cases, eliminated paper and prevented documentation errors.

Business Value

By improving the productivity of its QC Analysts, ImClone Systems reduced the hiring requirements to support the expanded facility – a significant cost savings. In addition, the improved accuracy of the new workflow gives ImClone Systems a more robust QC operation.

Product Demand Drives Growth

ImClone Systems Incorporated (Nasdaq: IMCL), was founded in 1984, with its first laboratory opening in 1986 in New York City. The company originally focused on immunology-based diagnostics and infectious disease vaccines. In the early nineties, the company shifted its focus to the development of innovative, biologic compounds in the area of oncology.

Case Study

Leveraging the advances made in the fields of molecular biology, oncology, genomics and antibody engineering, ImClone Systems has since built a novel pipeline of product candidates to address specific genetic mechanisms involved in cancer growth and development.

ERBITUX®, ImClone Systems' flagship product, was approved in 2004 for treatment of colorectal cancer and in 2006 for treatment of head and neck cancer. ERBITUX is a monoclonal antibody designed to inhibit the function of a molecular structure expressed on the surface of normal and tumor cells called the epidermal growth factor receptor. This receptor is part of a signaling pathway that is linked to the growth and development of many human cancers, including those of the head and neck, colon, and rectum.

ImClone Systems' Branchburg, NJ site is the primary bulk manufacturing facility for ERBITUX. Commissioned in 2001, the Branchburg site has since grown from two to seven buildings to meet the increased demand for the product.

Business Impact

ERBITUX is classified as a parenteral drug – one that is administered by injecting it into the patient. Like many parenterals, ERBITUX can not be terminally sterilized – a process that kills potentially contaminating microorganisms using heat or radiation. Instead, ERBITUX is manufactured aseptically – a highly controlled process that minimizes exposure of the product to potential contaminants. Aseptic manufacturing requires constant monitoring of the environment to ensure that potential contaminants are kept below prescribed levels. Routine sampling and testing of the environment (air, surfaces, equipment, personnel, water, and compressed gases) for potential contaminants is required by the Federal regulations that govern the manufacture of products like ERBITUX.

When the Branchburg facility expanded, the existing QC staff was required to work overtime and additional hiring was planned to handle the increased workload. In addition, the paperwork involved with the environmental and utility monitoring regimen was consuming too much of the analysts' time. "The process required a lot of coordination," stated Kimberly McFarland, ImClone Systems' Associate Director of Quality Control Microbiology. "Critical information was recorded on paper by the QC Analysts for all sampling, incubation and testing activities. Supervisors reviewed the paper records for accuracy and if necessary, corrected the information. Once that was completed, the information was entered into a database system which also required a review and approval step. We were basically managing the same information on paper and in the computer."

The time, effort and cost required to compile and manage this critical information had become very labor intensive for the QC Microbiology organization.

Improving the Process

ImClone Systems recognized that eliminating paper-based record keeping was the key to improving the efficiency of its environmental monitoring and quality control program. By streamlining the process and eliminating redundant and error-prone activities, ImClone Systems felt it could manage the increased sampling and testing volume with their existing personnel without overtime. “We had outgrown the old system,” continued McFarland. “Each analyst spent significant time each day managing paperwork which took time away from more important activities. We needed to get rid of the paper, simplify the process and generally increase the overall efficiency of the program.”

To go paperless, ImClone Systems needed an automation platform that would collect, manage and report environmental and utility monitoring information. The product had to be mobile to visit the many sampling sites in its facilities while meeting the strict requirements of an aseptic environment. ImClone Systems chose MODA-EM to meet these needs.

A Phased Implementation

ImClone Systems’ implementation of MODA-EM was divided into two phases: first, automate data collection and then manage the environmental and utility monitoring operation. The initial phase focused on automating the workflow for collecting environmental monitoring and utility samples using MODA’s Field Data Capture (MODA-FDC™) platform. MODA-FDC leverages wireless computing technology to provide a mobile platform for collecting, labeling (via barcode) and tracking environmental and utility monitoring samples. The automated workflow engine that drives the location-based sampling regimens improved productivity and ensured compliance with ImClone Systems’ standard operating procedures.

Prior to the implementation of MODA-FDC, paper worklists and sample labels were printed from ImClone Systems’ legacy system and were used by the QC Analysts to direct their sampling activities. After each shift, the collected samples had to be reconciled with each worklist and any errors or missed samples had to be addressed. As a result of implementing MODA-FDC, ImClone Systems not only significantly reduced sampling paperwork but also increased the efficiency of the sample collection process while reducing errors and the incidence of missed samples.

The second phase of the project involved replacing the entire legacy system with MODA’s Administration (MODA-Admin™) and MODA-EM Server products. Using MODA-Admin, ImClone Systems could easily define and maintain the parameters that govern their environmental and utility monitoring program and express the sampling, incubation and testing regimens that are used by the MODA workflow engine.

MODA-EM Server, a 21 CFR Part 11 compliant data repository, became ImClone Systems’ complete data management platform and system of record for their environmental and utility monitoring information. MODA-EM Server also provided ImClone Systems with improved decision support and process intelligence functionality through its comprehensive event notification, data reporting and trending capabilities.



Tangible Business Benefits

ImClone Systems' justification for implementing MODA-EM was straightforward; eliminate the need to hire additional QC Analysts and reduce or eliminate mandatory overtime for the existing staff while meeting the increased environmental monitoring workload that resulted from the Branchburg expansion. Following the implementation, ImClone Systems recognized immediate improvements. The MODA-EM system generated excitement among the QC Microbiology group and the staff adapted quickly to it. With the elimination of paperwork, QC Analysts not only were able to manage the increased sampling and testing volumes but also were able to spend more time on higher value activities within the microbiology lab.

In addition to improving the acquisition and management of environmental and utility monitoring data, the reporting and trending of ImClone Systems' EM and QC data improved dramatically as well. "The elimination of paperwork had a tremendous impact on the operation," concluded McFarland. "We gained back the time that we had previously spent compiling, routing, reviewing, and filing paper forms. Because all of the information originates from within the system the need for batch data entry at the end of the shift is also eliminated. With fewer mistakes and less time spent on reconciliation, the overall efficiency and effectiveness of our operation has increased. Our environmental monitoring information is now available real-time which significantly improves our ability to monitor and manage our growing facility."



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