

Manufacturer - Combination Product

Sample Tracking & Workflow Management Redesign

Client Situation

- Cumbersome and redundant system for tracking samples and reporting test results.
- Poor traceability of samples received in QC Lab.
- Lack of ownership for QC samples chain of custody.
- Considerable redundancy in QC test results reporting.
- Inconsistent instructions in Master Batch Records (MBRs) on identifying and handling in-process samples sent to QC.

Client Strategic Objectives

- Simplify the sample tracking and workflow system to prepare for commercial production.
- Improve traceability and control of routine, environmental and purified water QC samples.
- Define responsibilities, improve timely submission, and chain of custody for QC samples.
- Redesign documentation and workflow to reduce redundancy.
- Standardize instructions for QC sampling in MBRs to eliminate inconsistent requirements.

Key Issues and Internal Barriers

- Past efforts to redesign and streamline the sample management system added more complexity to the process.
- Lack of methodology, resource, workload, time constraints, and priorities of other initiatives.
- Inability of Production and QC to agree on what constitutes “best practice” for sample handling and tracking.

Key Program Components

- Develop a “smart” ID numbering system for all QC samples.
- Develop a sample management and tracking system that is “user friendly”, efficient, and GMP compliant.
- Redesign and integrate documents to eliminate redundancy unnecessary data entries and reduce errors.
- Address internal communication gaps between Production and QC.
- Challenge and explore technology and/or techniques to improve sample initiation, tracking and test results reporting.
- Develop MBR instructions for QC samples that are consistent, ensures proper identification, handling and submission to QC Lab.

Results and Improvements

- Developed a “smart” QC ID numbering system that allows for quick and easy recognition of sample identity, lot number, and test to be performed.
- Integrated forms to allow for sample submission and test results reporting in one document.
- Developed pre-printed sample submission form developed for all routine samples to reduce data entries, error rates and cycle times for sample submission, tracking and results reporting by QC.
- Defined chain of custody ownership and tracking process for all QC samples.
- Standardized instructions in the MBRs that include how samples are collected, identified, temporarily stored (if applicable) and submitted to QC. The applicable QC ID numbers are now pre-printed to ensure proper identification for tracking of the samples.

As a result of Malcom’s redesign program, the client now can identify and track the QC samples and report test results more effectively and efficiently.

Client Quotes

“I believe the changes performed will allow us to significantly improve consistency and efficiency in our sample management practices.”

Quality Operations Director

“I like the fact that everything is now preprinted. This will reduce cycle time for receiving the sample, will reduce data entry errors, and therefore will reduce the review cycle time, allowing me more time to concentrate on other projects.”

Quality Control Manager

“I like that all information is now preprinted in the sample submission form. I also like the revised instructions for QC samples. They are simple, consistent and easy to follow.”

Production Manager

“I like that now we will only have to record the results once. This will allow me more time for other tasks.”

QC Analyst