ONE QUALITY LAB INDUSTRY PROCESS EXPERIENCE

DATASHEET

Quality Testing in Pharmaceutical and Biological manufacturing consists of many areas within the corresponding enterprise. However, you can define Quality Testing as being comprised of Quality Planning, Quality Control, Quality Assurance and Quality Improvement.

All of these areas are equally important and work together to provide the level of compliance, efficiency and cost savings all Pharmaceutical and Biological manufacturers need to be competitive today. The biggest hurdle for Quality Testing to overcome is the stigma of being a major bottleneck within the product release process. Time is money and the longer Quality Testing takes, the more time passes before the product can ship and revenue can finally be recognized. ONE Quality Lab helps alleviate the bottleneck by replacing error-prone, paper-based systems with a solution that integrates directly with instruments and other systems, dramatically decreasing compliance risks and shortening release cycle times.

CHALLENGES

Quality Testing is often seen as a bottleneck in the product release process. At the same time, it is highly visible and heavily scrutinized both internally and externally by the FDA. Companies are looking for a better Quality Testing strategy. Unfortunately, current systems do not promote a robust Quality Testing solution that meets an organization's needs as it continues to grow. Most systems are paper-based, time-consuming and error-prone due to transcription issues, missing data points, erroneous entries, missing samples and test methods not being up to date or followed. Paper-based systems can be compliant according to the FDA; however, not following test methods is one of the major issues cited in FDA 483 warning letters, and paper-based systems cannot enforce procedures to be followed. Current Quality Testing inefficiencies stem from the non-value add reviews of quality data captured in paper-based systems, which significantly increases Quality Testing costs and cycle times. Rework loops, investigations and the inherent cost of paper handling and storage also increase overall costs.

Figure 1 shows that QC testing is a major component of the overall time required by the pharmaceutical manufacturing process. Reducing QC testing times is a function of the level of technology used. The ONE Quality Lab provides a level of automation proven to reduce QC cycle times by up to 50% at pharmaceutical manufacturing sites that have deployed the solution.

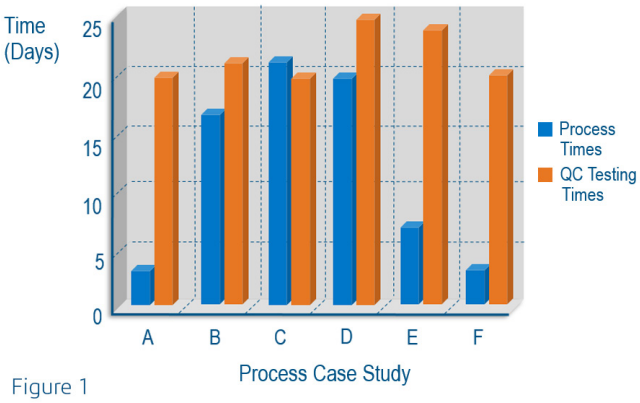


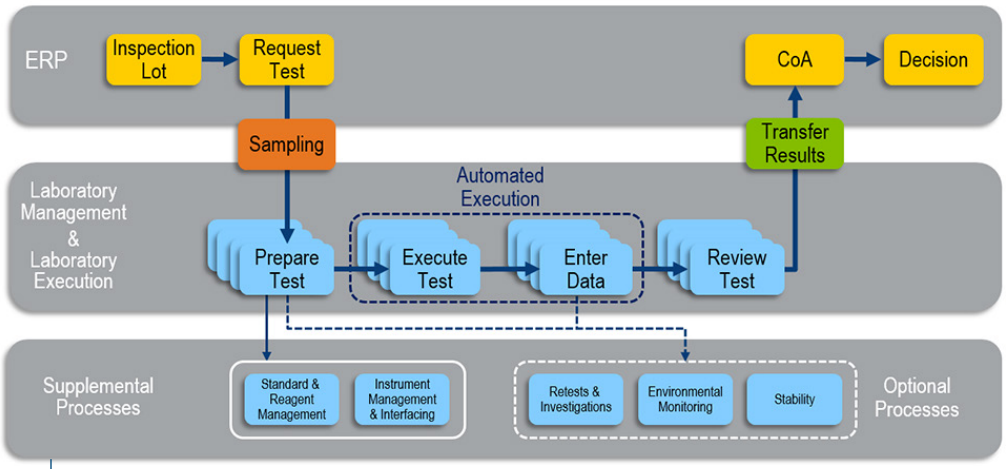
Figure 1

Reference: Raju, G.K., New Opportunities for Pharmaceutical Manufacturing, a 2001 presentation to FDA's Science Board

Typical paper-based Quality Testing systems are not only inefficient and extend process times, they are also one overarching cause of high compliance risk. The inherently error-prone, paper-based Quality Testing systems deployed at many Pharmaceutical and Biological manufacturing sites can become serious issues during FDA Quality Testing inspections. FDA-issued 483 warning letters are only the beginning of a significant remediation and 'corrective and preventive action' (CAPA) process that takes additional time and money away from what the Quality Testing system should be focused on—the release of product.

SOLUTION

The ONE Quality Lab begins—like most Quality systems—in an ERP (Enterprise Resource Planning) or a LIMS (Laboratory Information Management System) software package where the inspection lot is created. With ONE Quality Lab, this lot can automatically be directly released and submitted into the ONE Quality Lab, which can automatically assign any necessary experimentation for the lot while verifying that all required inventory items are available in the quantities needed. Therefore, once the testing starts, the analysts do not have to stop their work and order more inventory items or, worse, wait for an inventory item to be shipped from the manufacturer. ONE Quality Lab integrates "correct and current" test procedures with the user interface, ensuring that the analyst is executing the procedure "as it is written" and avoiding one of the major compliance errors listed in FDA 483 warning letters. Instruments needed to execute the test procedure are interfaced directly with the BIOVIA



Example workflow for Quality Testing

Quality Testing solution, providing accurate, automated data collection and eliminating tedious and error-prone manual data collection and transcription often encountered in paper-based or disconnected software Quality Testing systems. The ONE Quality Labexecutes the test procedure "right the first time," while also providing real-time limit checking ensuring that no Out of Limit (OOL) data values will be included in the completed test procedure. All calculations can be automated, eliminating the potential introduction of an incorrect data result that could have a dramatic impact on the overall result of the test procedure.

When the analyst completes the test procedure, he or she will need to review their work which must also be reviewed by the Quality Assurance team. To aid this process, the ONE Quality Lab solution features "review by exception" functionality. Analysts and QA personnel can use a built-in Data Review dashboard to:

- See all of the data collected
- Identify any OOL values that may need to be remediated
- View all audit trail events
- Review any supporting data with a single button click
- Ensure all of the instruments used to capture data were calibrated
- Review/approve the data collected

Capabilities	Benefits
• Enforced (up-to-date) procedures and sequences • Automated data transfer with meta data and audit trails	Increased compliance with regulations and guidelines
• Eliminated reworks and investigations by automation • Less paper	Reduced Cost
• Integration of all related functions to Quality Testing with automated data transfer	Improved productivity by >25%
• Fully integrated paperless process for Quality Testing • Total electronic review process, Approve-at-a-Glance	Improved efficiency
• Removal of manual non-value added process steps • Faster Data Review, Approvals in QA	Reduced QC cycle times by up to 50%

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