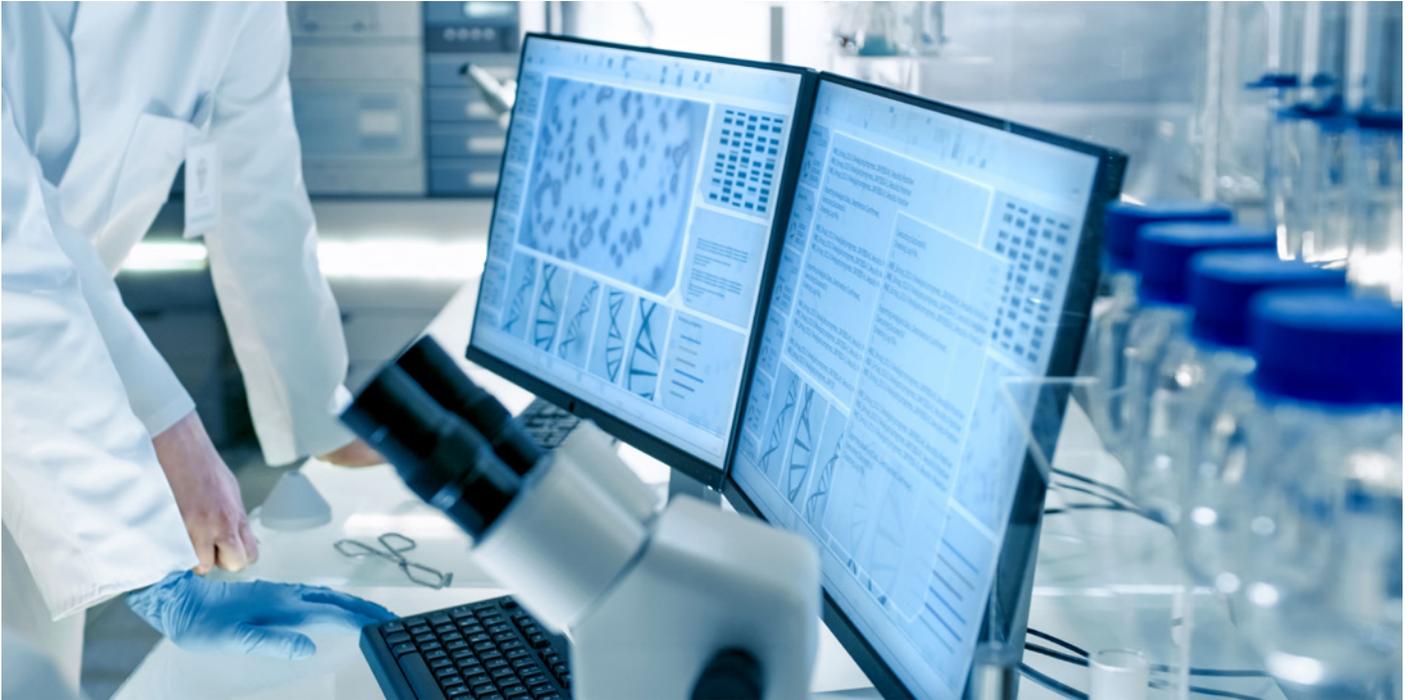


CASE STUDY: LabWare Centralized Data Review



OVERVIEW:

A global biopharmaceutical company specializing in discovery, development, and commercialization of innovative medicines was using a manual process for the oversight of commercial release lots. The company manufactures approximately 3-4 thousand commercial lots each year, many with the help of contract manufacturing organizations. The quality data for these lots was entered into LabWare LIMS for review.

In order to ensure the quality of manufactured products and maintain performance metrics for the manufacturing locations, certain lots were selected for a higher level of review. Unfortunately, not all

of the selection criteria were available in LabWare. The company decided to hire Astrix Technology Group to help customize LabWare for automated selection of commercial lots for review.

BUSINESS CHALLENGE:

The main issue that the company was facing was an inefficient lot selection process for the higher-level review. Selecting the relevant lots could only be accomplished through a time-consuming, manual process that involved compiling lot data from multiple sources. This tedious selection process resulted in slow overall review throughput for the company.

'Selecting the relevant lots could only be accomplished through a time-consuming, manual process that involved compiling lot data from multiple sources.'

SERVICES PROVIDED:

The Astrix Team began the project by conducting interviews with key stakeholders in order to gather and develop the requirements for the LabWare customization. After several rounds of interviews, the project team finalized the key requirements for the necessary LabWare enhancement. LabWare needed to:



- provide a dashboard of identified lots for review, their current review status, reviewer, data reviewed, and comments.
- provide a configurable rules engine to identify lots for review based on the current commercial oversight business rules.
- allow manual selection of lots to review that were not flagged by the business rules.
- allow the updating of the lot status once the second level review had been completed.
- send an email notification when a new lot is flagged for review.

With these requirements in hand, the project team went to work designing and building the enhancement. In order to ensure a successful implementation that would allow for the configuration of lot selection rules and an automatic selection of commercial lots for review, the project team applied the following solutions:

- Visual workflows were utilized to view and configure the lot selection business rules and to view and manage lots that were selected for review.
- User defined tables were defined to store the lot selection rules configuration.
- Automation scripts and database events were configured to process system events to determine if lots needed to be flagged for review based on the defined business rules.
- Email notifications were configured to notify administrators when a lot was flagged for review.
- New user roles were created to manage the lot selection business rules and to process lots that were identified.

RESULTS DELIVERED:

The customer was very pleased with the implementation. The project was completed in 3 months. Some of the results from the project include:

- The commercial oversight lot selection process was dramatically improved. The manual selection process was completely eliminated.
- The risk for missing a necessary review was greatly reduced since the new system is automated.
- The review process was centralized by making use of LabWare's visual workflows. The review team could easily track and manage lots for review in one place.
- The review process was made more flexible and traceable since the lot selection rules can be configured by the business on the fly and support auditing.