

Partners in Pharmaceutical Manufacturing

HOW STARLIMS HELPED IMCLONE REDUCE CYCLE TIMES AND CAPTURE METHOD DATA IN A FLEXIBLE ELECTRONIC CANVAS

“We were impressed by the flexibility of the STARLIMS ELN, which allowed us to configure the system to fit our processes, rather than being forced into a set path. In addition, our people loved the fact that the STARLIMS ELN looks like an Excel spreadsheet, and we could set it up to mirror the way the paper forms looked.” Eric Natchman, Supervisor, ImClone Systems

SUMMARY

- Reduced turnaround time for the SDS assay by 50% on average
- Reduced turnaround time for the Endotoxin assay by 29% on average
- Reduced cycle times and errors during review & testing
- Provided powerful flexibility through an Excel-like interface

COMPANY BACKGROUND

In 2010, ImClone, a wholly-owned subsidiary of Eli Lilly implemented a fully automated LIMS process from STARLIMS Corporation to replace the paper based process used in their quality testing labs. The automated LIMS system enabled ImClone to accommodate a 25% increase in testing volume while holding headcount steady. The manufacturing of pharmaceutical drugs is a complex process requiring multiple validation checks to ensure patients get a safe and efficacious product. ImClone has implemented rigorous testing processes to ensure manufactured lots meet stringent quality control standards. The quality control process takes samples off manufacturing lines and tests them against defined test processes to ensure all quality standards are met.

CHALLENGE

Scientists in the laboratory were capturing results and ancillary data associated with the test method in log books or other forms. The results were then transcribed manually into the STARLIMS LIMS application. The manual component introduces delays and the potential for errors due to human transcription. In addition, the process required manually tracking a lot of data.

SOLUTION

The ImClone team considered several solutions for Electronic Lab Notebooks (ELN). The team selected STARLIMS ELN primarily due to the tight, seamless integration with STARLIMS and STARLIMS SDMS.

BENEFITS

Reduced cycle times and errors for review & testing

By eliminating the use of paper to capture ancillary method data, ImClone was able to reduce cycle times for testing and review. This was especially true for assays which extended over several days. In addition, errors due to transcription could be eliminated as the data would be automatically fed into the STARLIMS LIMS system. The tight integration with STARLIMS SDMS ensured instrument and other kinds of data were automatically parsed and available for use without the need for transcription. Scientists could get the instrument report, upload it to STARLIMS ELN where it is parsed and added to the sample submission, and then the calculation would be completed automatically. Finally, scientists were able to reduce the risk of having to repeat tests because they could make sure all the data was matched correctly to the sample submission within an electronic system.

Powerful flexibility through an Excel-like interface

ImClone scientists were impressed by the interface to STARLIMS ELN which looked just like Excel. Many of ImClone's current paper based forms were built in Microsoft Word or Excel. These forms could be easily mirrored in STARLIMS ELN, easing the transition to the electronic notebook process. STARLIMS ELN provided a familiar layout for them. In addition, the flexible ELN canvas in STARLIMS ELN allowed scientists to capture unstructured data, such as charts and graphs, and to annotate pictures. The flexibility of STARLIMS ELN enabled ImClone to configure the ELN based on their processes rather than forcing ImClone to follow a pre-defined process.

RESULTS

STARLIMS ELN was very well received by the lab scientists. Implementing ELN on the SDS assay has reduced turnaround time by two hours on average (50%). Implementing ELN on the endotoxin assay has reduced turnaround time by one hour on average (29%). And even labs which were previously reluctant to embrace the electronic format now wanted to use ELN for other assays.

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