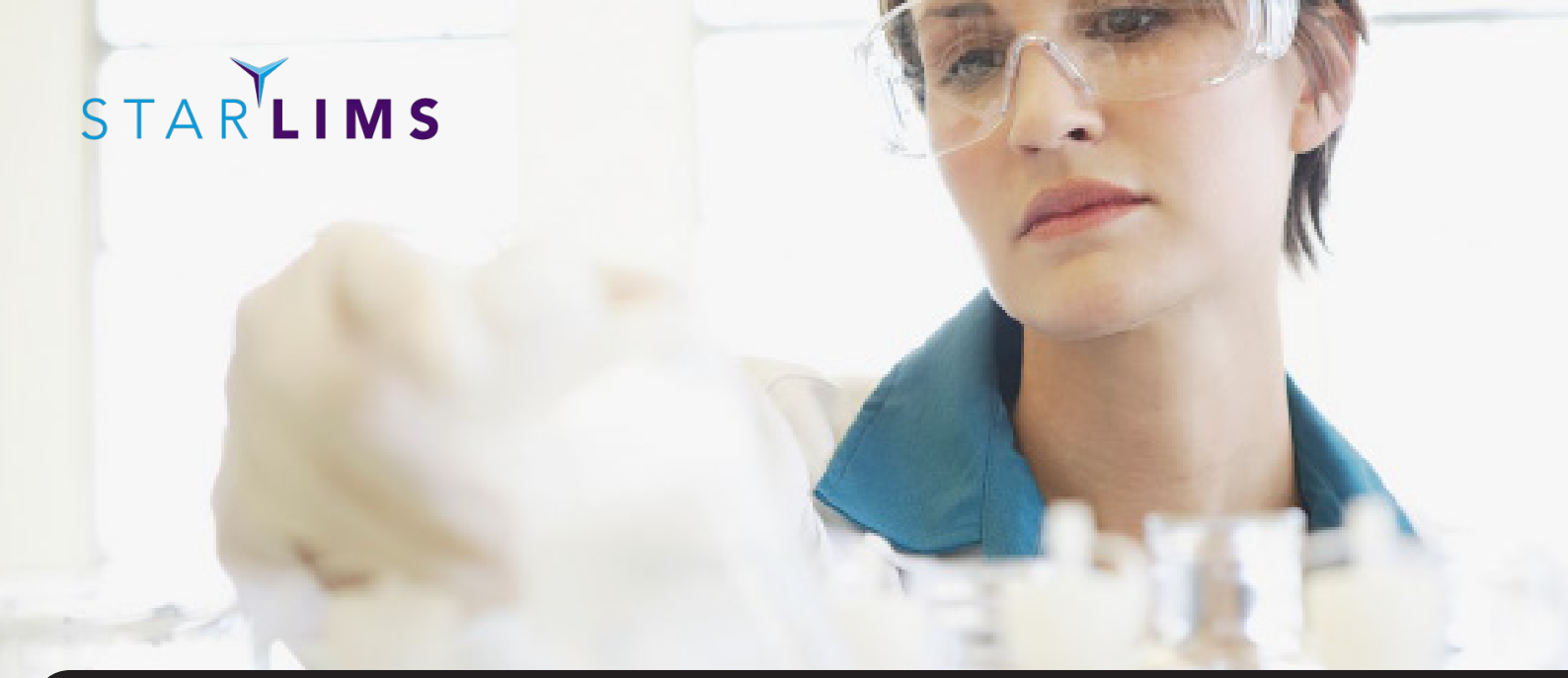

HOW STARLIMS SDMS HELPED IMCLONE CUT COSTS AND BOOST PRODUCTIVITY

"With STARLIMS SDMS, our reviewers no longer have to be on-site to review samples and data packages. Instead, STARLIMS SDMS allows us to have all instrument files and reports attached electronically to the sample submission and available for reviewers to review and approve on weekends and off-hours. This allows samples to be processed much faster." Richard Caron, Associate Director, ImClone Systems

SUMMARY

- Reduced turnaround time by 53%
- Resulted in a 25% increase in testing volume without increasing headcount
- Eliminated a projected 65% cost increase in paper printing, managing, and storage
- Reduced errors by providing all relevant sample data in one spot
- Increased efficiency by converting assays to be completely paperless
- Boosted laboratory productivity by allowing reviewers to work remotely to approve results

COMPANY BACKGROUND

ImClone, a wholly-owned subsidiary of Eli Lilly, is a leader in the research, development and manufacturing of oncology drugs. The manufacture of pharmaceutical products is a complex process requiring multiple validation checks necessary 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

Prior to implementing STARLIMS and STARLIMS SDMS in 2010, the ImClone testing laboratory utilized an entirely paper based system to track and manage test results. Samples would come into a lab and a paper requisition would capture what the sample was, how many vials were involved, and what testing was required, among other things. The paper requisition form would be passed along throughout the process documenting the chain of custody. Test results would be printed and attached to the sample submission as it went through the lab.

ImClone was forecasting tremendous growth in manufacturing, which would result in increasing demand on the testing department. The volume of paper based submissions was projected to increase 64%, while the lab would need to increase headcount by a projected 40% to handle the increased volume. The paper based process

was difficult to scale to accommodate the increased volume and presented several challenges. First, processing paper is resource intensive and slows down turnaround time. In addition, paper makes it difficult for the lab to continue scaling up in response to the increased volume of manufacturing, without adding additional headcount. Finally, a paper process increases the risk of samples not getting tested properly, or being unnecessarily retested.

SOLUTION

ImClone initiated a process to select a new automated Laboratory Information Management System (LIMS). After a thorough decision review process, ImClone selected STARLIMS and the STARLIMS Scientific Data Management System (SDMS) as best meeting its needs. STARLIMS offered a web based LIMS solution which would allow the automation of sample receipt and tracking throughout the laboratory process. In addition, the tight, seamless integration between STARLIMS and STARLIMS SDMS allows the centrally administered LIMS solution to process all types of data generated by instruments.

BENEFITS

ImClone resources and STARLIMS Professional Services worked together to implement the new automated process. The project successfully went live in January 2010. The new STARLIMS solution allowed ImClone to completely automate sample receipt and tracking throughout the testing department, and the SDMS component provided several additional benefits including reducing errors, increasing efficiency and boosting laboratory productivity.

STARLIMS SDMS reduces errors by providing all relevant sample data in one spot

STARLIMS SDMS pulls together paper and instrument data for each sample and makes it available to whoever needs it as the sample moves through the laboratory. All kinds of sample data, including raw instrument files, PDF files, csv files, and so on can be parsed via SDMS and attached to the sample submission in STARLIMS. This is a significant improvement because the data no longer needs to be attached by paper to the sample and tracked manually. Now data is easily accessible using a web based system with full traceability and is retrievable later as needed. The right data is available for each sample, and there is no longer an opportunity for reports to be mismatched to samples.

STARLIMS SDMS increases efficiency through paperless assays

ImClone was able to convert assays to be completely paperless. Not only did this cut down on paper costs, but the data is stored within the STARLIMS database, which means it can be retrieved at a later date if needed. STARLIMS SDMS provides full traceability and through powerful search features, technicians can find any information they need from the sample and files.

STARLIMS SDMS boosts laboratory productivity

Previously, reviewers had to be physically in the office to review the paperwork and sign off on sample submissions. But now, reviewers are able to review results remotely, during weekends, and off-hours because the test results are available via secure web browsing. Critical sample submissions can be reviewed and approved even if the reviewer is working from home or the review needs to happen on the weekend. The increased access significantly increases laboratory productivity.

RESULTS

By implementing STARLIMS LIMS and SDMS solutions, ImClone was able to scale up volume by 25% without increasing headcount. A projected cost increase of 65% in printing, management, and storage was eliminated due to the automated data capture within STARLIMS SDMS which would store all data electronically. ImClone was able to save on paper and printing costs, archiving costs, additional time spent on managing paper forms, and storage space for storing the forms. And ImClone was able to reduce the average turnaround time for an Active Pharmaceutical Ingredient (API) test from 60 days to 28 days, a decrease of 53% so that the patients ImClone serves can get the drugs they need faster.

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