

EXECUTIVE SUMMARY



AstraZeneca U.S. supply sites automate learning and enhance productivity with Plateau

Challenge:

- Disseminating and logging training was a manual process making it time-consuming to manage and track
- AstraZeneca needed to automate training assignments and ensure timely access to revised procedures
- Federal regulations demand that all electronic records be as valid and secure as paper documents

Solution:

- Plateau's LMS has aligned AstraZeneca's learning to business process, enhancing productivity while reducing the time it takes to get the right information to the right people
- Implementing Plateau's LMS automated and streamlined the assignment of all regulatory and job-specific training
- Plateau enables AstraZeneca to comply with stringent federal and international regulations

THE EXPERIENCE WITH PLATEAU

Efficiency: *"Using Plateau LMS gives immediate visibility to cases where employees are overdue on their training—it's a much more efficient, accurate, and effective way to manage the learning process. Plateau Assignment Profiles allow timely assignment of core curricula, followed by a "just-in-time" approach to assignment of specific role-based curricula."*

Productivity: *"Employees can easily identify the required training for each role they perform, and are empowered to keep up to date on training for the procedures they are executing."*

Benefits: *"The use of Plateau allows a blended approach to learning. By assigning self-paced training where*

AstraZeneca, one of the leading global pharmaceutical companies, is responsible for more than making medicine. AstraZeneca operates in a customer-focused manner - its mission is to make the most meaningful difference to patient health through great medicines. Without AstraZeneca's continued focus on meaningful medicines, efficient internal manufacturing operations, and employee training, this could not be accomplished. It is important for the company to stay compliant with Food and Drug Administration (FDA) regulations, manage to Good Manufacturing Practices (GMP) and create efficient and thorough Standard Operating Procedures (SOPs). AstraZeneca relies on its employees and management to uphold the high standards that the company prides itself on and, to do this, proper training and development is key to its success. To achieve this, AstraZeneca needed a system that could automate and streamline training programs and processes to help ensure employees were always trained on new and changing regulations and progress was tracked and reported.

REGULATORY COMPLIANCE: Training in the pharmaceutical industry is truly mission-critical from a quality control and production perspective. Pharmaceutical companies must comply with stringent regulations imposed by U.S. and international regulatory bodies. The FDA demands strict adherence to GMP, a broad set of regulations created to ensure high manufacturing quality control for all FDA-regulated drugs and medical devices. Additionally, the FDA's 21 CFR Part 11 rules demand that all electronic records be as valid and secure as paper documents—no small task for companies that have dozens of different software programs to manage human resources, customer relationships, enterprise documents, and training.

QUALITY ASSURANCE: AstraZeneca continually trains all employees, contractors, and suppliers involved in the manufacturing process. At AstraZeneca's Westborough, Massachusetts and Newark, Delaware production facilities, they ensure process and quality control while maintaining an audit trail on every learning event. This includes tracking training on new procedures, revised procedures, and periodic retraining requirements. Whenever any manufacturing process is revised, from the operation of a piece of machinery to a change in drug specifications, an essential component of the quality control process requires that everyone affected by the revision is promptly identified, informed, and retrained.

AstraZeneca handled this process manually, logging training on paper and sifting through documents when Standard Operating Procedures

appropriate, time away from the job for classroom or OJT training is reduced and more value added. ”

Compliance: *“Plateau has made it much easier for us to track training compliance and auditors can be confident in the accuracy of our data.”*

(SOPs) were changed. It was a time-consuming process that made it difficult to immediately disseminate required training to people affected by the revisions. The company needed to automate the way it assigned training and managed procedural and quality control revisions. This would provide assurance that training compliance was maintained.

AUTOMATION: Plateau has allowed AstraZeneca’s US manufacturing sites to automate the business processes surrounding enterprise training to ensure that all training events are supported with bulletproof audit trails.

By interfacing Plateau LMS with its PeopleSoft Human Resources Information System (HRIS), AstraZeneca is able to automatically create comprehensive learning plans for all employees. To ensure quality control, AstraZeneca uses the Plateau LMS assignment profile capability to automatically assign the proper training profiles and curricula to every employee at the facilities. The learning plans are automatically updated if an employee’s job, role, or name changes. By interfacing Plateau LMS with its Technical Document Management System (TDMS) AstraZeneca is able to automatically update learning plans with SOP revisions, triggering the required training. This helps ensure all employees are up to date and in compliance with their assigned training. Employees can routinely access their personal learning plan to see what training they need, when it is due, complete any self-paced training within those due dates and update their own learning history through Plateau’s e-signature verification process . This feature ensures electronic records that are as valid as paper documents.

Plateaus’s audit trail capabilities helps AstraZeneca be compliant with FDA regulations for electronic records and signatures.

BUSINESS BENEFITS: For an organization focused on high quality assurance, standardized ways of working, reduction of non-value added activities, and timely flow of medicines to our customers, the ability to link training requirements directly to each manufacturing and support process has been indispensable. All in all it’s a much more efficient, accurate, and effective way of managing employee learning than our previous paper-based process. It empowers all employees to manage their own learning activities and help ensure training compliance.

Implementing Plateau LMS has had a twofold effect at the AstraZeneca US manufacturing facilities. First, it has supported compliance with federal and international regulations. Second, it has aligned learning to business processes—enhancing productivity and reducing the time it takes to get the right information to the right people.