

## EXECUTIVE SUMMARY



### Challenge:

Create a unified global system for learning and development that supports the company's highly validated work environment and simplifies regulatory compliance.

### Solution:

Plateau Learning  
iContent

### Results:

- Consistent learning and development across 17 US and European locations  
Tighter control over SOPs as well as
- GMP and clinical compliance  
Audit-trail verification and documentation of employee training
- Integration with other electronic systems (document management, deviation and investigation, manufacturing, etc.) to support a paperless operational environment

## Plateau helps Genzyme strengthen compliance, quality and ongoing employee development

Genzyme is one of the world's leading biotechnology companies, with more than 10,000 employees, 2007 revenues of \$3.8 billion, and products serving patients in nearly 90 countries. The company is focused on rare inherited disorders, kidney disease, orthopedics, cancer, transplant and immune diseases, and diagnostic testing. About nine years ago, Genzyme implemented the Plateau learning management system to help in compliance with Manufacturing Practices (GMP) training and to help with human resources needs like scheduling and enrollment. According to David Dentino, Director of Corporate Quality Operations (CQO) Systems at Genzyme, those drivers still exist, but the scope of Plateau's contribution has grown considerably.

*"We've been able to leverage Plateau for meeting good clinical and manufacturing practices, supporting our environmental and safety teams for recurring training, and for employee development."*

## THE EXPERIENCE WITH PLATEAU

**Scalable:** *"Plateau performance is very good across the world."*

**Development:** *"We're using the learning-management system not only just to tracking training for FDA-regulation purposes and auditing, but for the continued development of employees."*

**Streamlining:** *"It used to be quite time-consuming to build curricula and assign it. Now we can group those assignments. We value the ability to integrate Plateau with other systems to get curricula information as well as notifications."*

**STAYING WITH PLATEAU OVER TIME:** Edward Armstrong, Associate Director of CQO systems at Genzyme, says that a decade after implementing Plateau it still meets the company's needs. As Genzyme has grown, the system has scaled in functionality and in scope. With the recent upgrade to 5.8, Armstrong points to how Plateau keeps them in step with the trend toward thin-client, Web-access functionality. He particularly values how 5.8 lets them look at the overall organization and see graphically what training is and is not doing." He also notes the value of built-in competencies (through Plateau Question Editor), the advent of iContent, and being able to launch iContent right from inside the system. From an IT perspective, Dentino adds that Plateau continues to meet the company's rigorous requirements. "Genzyme takes a very aggressive approach to validation," he explains. "From small patches to major upgrades, all systems go through a very rigorous validation exercise which includes the installation qualification, operational qualification and performance qualifications. There's little Plateau functionality that hasn't been challenged by our validation protocols."

**SHARING BEST PRACTICES:** As Genzyme continues to grow as a global biopharmaceutical company, Dentino views Plateau as an asset. "It helps us share best practices across all manufacturing facilities so that an eastern Massachusetts facility can benefit from what's working

**Buy-in:** *“All 10,000 employees have a login... the recurring report functionality—where you can set up a regularly scheduled report to run automatically... has all been met with positive feedback”*

**Compliance:** *“With Plateau, we can verify and ensure that employees have been trained in certain key areas related to our manufacturing and laboratory activities.”*

**Functionality:** *“Plateau has invested a lot of time and effort maintaining and updating their system. With ease of access, Web availability, and connectivity to other electronic systems, it’s definitely a tool that has evolved with the needs of the industry.”*

**Integration:** *“If an operator error spawns a deviation, it triggers process review. With learning as part of the system, a training need can also be launched to close the deviation, which would then allow the batch to be released.”*

at facilities in Belgium, France, England, Ireland -whatever it happens to be.”

**IMPROVING COMPLIANCE AND QUALITY:** The Plateau system is invaluable in assuring and documenting compliance with GMP training requirements. But Genzyme has an even bigger vision for integrating Plateau not just into the overall learning process, but into manufacturing and operations as well. “Imagine having an operator start to initiate a batch,” Armstrong explains. “When he logs into the Delta B panel, it checks against Plateau and finds out he hasn’t trained in a key SOP. He gets a pop-up screen that instructs him to train on that specific SOP. He launches iContent, then takes the test. If he passes, he can initiate the batch. If he fails, the system locks him out and notifies the supervisor.”

*“From an operations and global training perspective, Plateau’s integration capabilities help us meet our business objective of becoming more centralized and consistent”*

**BRIDGING INTERNATIONAL DIFFERENCES:** From a technology and functional standpoint, the global roll-out of Plateau was smooth. European privacy laws, however, were a challenge. Dentino explains: “We created an interface with PeopleSoft that brings over personnel or student data – name, location where they work, their supervisor. It’s pretty standard stuff here in the U.S., but in Europe it raises a privacy liability issue. It’s certainly not a major issue, we just take look at what data we pull into Plateau to make sure we’re not violating privacy laws in a particular country.”

**LEVERAGING PLATEAU’S FUNCTIONALITY:** Recently, Genzyme has started using Plateau’s scheduling function to meet recurring requirements such as annual Good Manufacturing Practices (GMP) refresher courses. Says Armstrong, “This allows people to go into Plateau and actually look at what classes are available, where, and to sign up for them.” He notes that people who are transitioning to become managers can now use Plateau to sign up for the Genzyme Management Fundamentals course and have the host or facilitator record that training directly into Plateau. But, notes Dentino, there’s even more that could be done just with the existing functionality. “From a training perspective,” he says, “we’re satisfying GMP requirements, but we can go much, much further utilizing competencies and measuring competencies of training. We’re only brushing the surface!”