

Using Livelink ECM™ to Enhance Collaboration and Knowledge Management

Genzyme pushes the envelope and derives business success from Open Text technology

Genzyme, a biotechnology company founded in 1981, has approximately 9,500 employees, with over 70 locations across 30 countries—including 17 manufacturing sites and 9 genetic testing labs. Its major marketed products fall into several categories including: reproductive oncology; diagnostic testing; genetic diseases; renal diseases; and orthopedic and vital surgery. The company strives to develop breakthrough therapies to aid the medical needs of patients with no other treatment options available.

Compliance is a critical part of the Life Sciences industry, and Genzyme is regulated by regulations such as the Food and Drug Administration (FDA) 21 CFR Part 11, Sarbanes Oxley and many other regulatory organizations.

“Compliance is a critical part of our business as is any company under these regulations. Failure to comply could result in financial loss due to penalties, possible recall, or worse, criminal penalties,” says Mark Wescott, Genzyme’s Senior IT Manager, ECM. “We need to ensure we have access to and the most recent versions

of business critical documents such as Standard Operating Procedures (SOPs) for our Manufacturing, Quality, and any operation that has an effect on our products. This includes the IT systems that support these functions. These SOPs need to be tracked through their entire document lifecycle including the creation, approval, revision, superseding and obsolescence of the document. Livelink ECM is Genzyme’s document management system that is used to meet these requirements.”

The Livelink ECM document repository functions allow Genzyme to store every version of the document along with the metadata. “The audit trail in Livelink gives us complete information on all transactions performed in the documents. Plus, the eSign module electronically approves documents and keeps us 21 CFR Part 11 compliant.”

Global performance: The document management challenge

With multiple worldwide locations and strict compliance regulations to adhere to, it’s no wonder that Genzyme’s biggest document and knowledge management challenges were keeping everything organized and everybody informed. “Remote sites were experiencing significant delays in document download, upload and viewing,” says Wescott. “For example, a 10 MB file that might take a few seconds in the area where our server is located here in eastern Massachusetts, could take several minutes at some of our remote sites due to three factors: bandwidth, latency, and congestion. Unfortunately, these factors play together to reduce the speed of the document transfers.”

So how did Genzyme handle tremendous growth, while adhering to strict regulations and still accommodating users on a global scale?

They rolled out Livelink ECM globally!

Genzyme supported its tremendous growth by scaling its document management system to accommodate users located around the world. “Livelink is centrally deployed,” says Wescott. “We currently have two Livelink systems at Genzyme. Our controlled system, which is our smaller

Industry

Life Sciences

Customer

Genzyme Corporation

Business Challenges

- Global productivity
- Company-wide collaboration
- Quick and easy knowledge sharing
- Document organization, location and retrieval

Business Solution

Livelink ECM – Document Management (DM)
Livelink ECM – Workflow
Remote Cache Server 3.2
Livelink ECM – eSign

Business Benefits

- Creation of a flexible, multilingual work environment
- Pioneered standards in document management
- Enhanced knowledge sharing
- Mitigated compliance risk
- Enabled quick, efficient collaboration
- Improved global performance

validated instance of Livelink, has Workflow, Electronic Signature, Adlib, Forms, and it has an interface to our Learning Management System (LMS). This is where our SOPs, validation documents and other controlled documents are kept. And we also have our production instance, or our much larger, more collaborative instance, which stores other corporate information. This instance has Livelink Explorer, and serves as our back end storage for the content on our portal intranet.”

Genzyme first deployed a single department roll-out of Livelink ECM to their Regulatory Affairs organization in 1997. Gradually, they built upon this document management infrastructure—adding Livelink ECM – Document Management (DM), Workflow, Remote Cache Server, and Livelink eSign, the first solution to give regulated industries an electronic process for managing legally binding e-signatures to key documents across a large enterprise.

“We use Livelink forms as a front end for many of our workflows. This allows users to perform the necessary transaction using a form-based interface that they are already familiar with,” says Wescott. “For instance, previously we used a paper DCR form. With Livelink, we can mimic the electronic one to look like the paper form, so it reduces the learning curve.”

Sharing critical business information across borders

Today, Genzyme depends on Livelink ECM to enhance company-wide collaboration, knowledge management and to stay compliant. Because of the global infrastructure that Genzyme has built, based on Livelink ECM, employees can access critical documents securely from a central library from anywhere in the world.

“Livelink provides a great way to share information across many business units, across different geographical boundaries...anything from meeting agendas, minutes to detailed project plans,” says Wescott. “And Livelink notification is a crucial part of that collaboration. Project teams or individuals can be notified by email when something of interest changes. For example, documents have been added or deleted or versions have been added or deleted, or tasks or workflow steps are due or require their attention.”

Many of the Genzyme sites have adopted Livelink ECM Workflow for their document approval process. “We have workflows in place for SOP approval, routine change control, product label control, and lab systems change control, as well as periodic review of documents. These workflows vary from very simple to very complex, depending on the business process that they are automating. The nice thing about Livelink ECM is that you don’t have to mold the business process to fit the tool, you can mold the tool to fit the business process,” adds Wescott.

Genzyme: 2007 GlobalStar Enterprise Awards Winner

Genzyme was recognized as the winner of the GlobalStar Enterprise Awards program in 2007. This annual awards program recognizes outstanding efforts in delivering business value from an innovative and successful ECM deployment, something that Genzyme—through their implementation and deployment of Livelink—has excelled at.

According to Wescott, Genzyme uses their Livelink remote cache servers for what he refers to as “pseudo replication servers,” which means instead of quick storage and deletion of the documents, they maintain hundreds of gigabytes worth of information on the cache server and set the expiry to the longest available, allowing users to have almost all of the content immediately.

According to Therese Harris, Program Manager for Life Sciences at Open Text, the way Genzyme is using Livelink ECM and the document management/knowledge management tool, clearly illustrates what the trend is in the life sciences industry and that is a holistic view of content. A single business process can no longer sit in a siloed environment and work independent of all the other business processes in the organization.

“It’s an interesting perspective for a life sciences organization who is typically first and foremost concerned with their regulated content. Genzyme’s continual exploration of how they can push the envelope by building processes onto Open Text technology is something that other organizations need to realize they can do,” says Harris. “The resulting underlying enterprise content management technology or document and knowledge management technology, allows for business processes to link together. It allows cross functional teams to share and collaborate on content and information and it allows external systems to be integrated into the content management environment.”

In addition, the IT ECM Team at Genzyme has used Livelink to build their own internal knowledge base. For example threaded discussions have been organized into folders for the major areas of Livelink—such as general issues, discussion topics, trouble tickets, and replies from Open Text support on ticket resolutions. “So we actually attach the email sent from the Open Text folks where an issue is resolved into the threaded discussion as an attachment,” says Wescott, “so when we encounter the same issue months later, we don’t have to wade through six months worth of email to find out how it was resolved last time. We can simply do a search on it and get the information we need, saving a lot of time. Livelink has really become a common word at Genzyme—as common as Outlook or Word. I’m often at meetings and I hear, ‘OK, well you can find this document in Livelink...and I let out a little smile.’”



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