

Overview

The client is among the world's leading biotech companies, with multiple products on the market and in the development pipeline to diagnose and treat patients with serious or life-threatening medical conditions.

Background

Before the merger, each company relied on a different legacy registration tracking system to manage regulatory submission related documents and their status. The differences between the systems each company used were formidable. One organization used a custom Oracle 10g application to manage metadata with content on file share, while the other relied on a customized Documentum 5.x application to manage regulatory submissions. The new system was to combine the best features of each legacy application. As a result, Oracle 11 was selected to manage the structured data, while Documentum 6.5 was chosen to manage the content.

Migration Challenges

Despite having a solid foundation in place for the new system, the company quickly realized that it faced several technical, time-sensitive and geographical challenges with the project.

Upon initial analysis, the client team found several technical challenges with the migration scope. First, they determined that there was little documentation available on the custom components of either legacy system. Secondly, after selecting an Agile methodology for development, the group consequently faced continuous design changes during critical testing and validation phases. In addition, the data model itself changed during migration testing phases and the gap between the new system design and the source system's requirements for the migrated data became a moving target. Lastly, a large number of data problems resided in the source systems including duplicate records, missing required data field values and content files present in multiple locations for the same record.

The new registration tracking system was also designed to build and maintain relationships between global and local regulatory submissions; however, these assets were managed and maintained separately in the legacy systems. This resulted in the need for the migration team to build a link between global and local submissions as part of the overall migration project.

Time constraints were also a concern, as terabytes of content from the Documentum 5.x and Oracle 10 systems needed to be migrated to the new system quickly and accurately prior to go-live, with no more than a weekend of downtime. As such, there was a need to fully understand the intricacies of both the legacy systems and the new system in a very brief time frame.

Lastly, unit geographies proved to be another roadblock for the company, as there were two separate business groups involved in the migration effort – one located on the West Coast, and the other dispersed between the East Coast and Basel, Switzerland. The business processes varied greatly between the two, compounding the geographical challenges further. The new system was to be consolidated in Switzerland, so moving large amounts of data from the two distinct U.S.-based facilities proved to be another complication.

Valiance Solution

From the start, EMC recommended Valiance Partners. EMC's endorsement was based on successful past engagements between its team of highly skilled migration specialists and its data migration software, TRUmigrate. In addition, Valiance's experience with controlled document management allowed the company to understand and ensure that all business and compliance requirements were considered.

Working with the client, Valiance guided the company's team through their options using audit trails and its specialized validation process. As a result, Valiance and the client decided to create an audit record capturing the conversion to controlled documents, as well as all of the essential document attributes including class, status, lifecycle, policy, and so on.

Valiance's TRUmigrate technology was the first off-the-shelf solution that migrated DCM controlled documents. This feature was the perfect foundation on which to build a supported application for the client, as the user community could convert documents in place automatically. Using TRUmigrate, the upgrade was completed with ongoing support and maintenance for the client's continuing conversion requirements.

Results

In the end, the client was able to not only overcome complex migration project challenges, but was also able to reach its desired outcome in a timely manner with help from Valiance's team of migration specialists. Valiance was able to identify data issues well in advance, allowing the client team to correct the issues early in the migration process, before they had the chance to impact results in the final migration. This provided a predictable and clean end result.

TRUmigrate and TRUcompare's configuration evolved throughout the Agile development process, without any need for customization. TRUcompare was also used to verify the migration of 100% of data and content, which would not have been possible using a traditional sampling approach, saving the client significant time and related expense associated with Agile test iterations. To the client's delight, Valiance was able to complete and test 100% of the migrated data and documents in just 72 hours.

Global Pharma Creates Custom Registration System with Oracle and Documentum



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About Valiance Partners

Valiance Partners is a leading vendor for high-risk data and content migrations when compliance and business risk demand "getting it right."

For more information: www.valiancepartners.com, or call
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