Objective

Manage the documents created during the drug development cycle and aid compliance with regulatory authorities.

Approach

Reviewed all records management and standard operating procedures, investigated various Electronic Document and Records Management (EDRM) systems and conducted a proof-of-concept on its preferred platform.

IT improvements

• The EDRM platform offers rapid storage, retrieval and management of documents, safeguarding mission-critical information
• Platform scalability enables use in other parts of the organisation
• Enhanced data integrity protects valuable information while strict access control ensures that only authorised users can view certain data

Business benefits

• Reduces the risk of non-compliance with regulatory authorities
• Safeguards business continuity and aids disaster recovery by securing enterprise information

Case Study

Japanese pharmaceutical giant chooses HP TRIM software to aid compliance

Safeguarding business continuity

“With HP TRIM, we have a highly adaptable and scalable document and records management system that is fully compliant with current electronic record keeping requirements.”

– Steven van der Meulen, senior manager - records management, Japanese Pharmaceutical Company
• Boosts productivity by increasing workflows and enhancing collaborative working
• Supports future business activities through increased scalability
• Improves the company’s environmental footprint and lowers document storage and retrieval costs through reduced paper usage

Developing and introducing a new drug to the market is a lengthy and very expensive process. The development process adopted by pharmaceutical companies initially involves identifying an active compound, checking effectiveness and safety, and determining the correct dosage. After clearing these hurdles, a potential drug then undergoes laboratory and clinical trials before entering the market. The world’s government-appointed medical institutions responsible for drug approval only endorse a small fraction of all the compounds investigated for human use. Therefore, to avoid risk of non-compliance with regulatory authorities, rigorous records management is essential during the development lifecycle and after a drug enters the market.

Non-compliance risk

A major Japanese pharmaceutical manufacturer with operations in Asia, Europe and North America, specialising in therapeutic areas such as anti-infectives, dermatology, transplantation and urology, has been involved with innovative drug development for a number of years. The manufacturer’s European research centre deals with several important areas including clinical pharmacology, clinical data science and research, medical science and pharmaceutical research, as well as drug safety and regulatory affairs.

Some years ago, the company became concerned about the risk of non-compliance. This was due to the ever-increasing volumes of emails and general records created during the drug development cycle and the quantity of information requiring retention following preclinical and clinical trials.

“With the regulatory authorities constantly demanding more and more information, good records management is critical to our organisation,” explains Steven van der Meulen, senior manager – records management, Japanese Pharmaceutical Company. “A few years ago, when the authorities demanded increased visibility and record systems were under constant scrutiny, we found that our system potentially lacked compliance. We therefore needed a more up-to-date system that could create a central archive. Compliance with specific international standards such as Good Clinical Practice and Good Laboratory Practice is essential to our business.”

To alleviate potential records management problems, the company reviewed all its records management and standard operating procedures. At that time, it decided to retain records in their original format, make each staff member responsible for the administration and retention of their records, and ensure the research centre would adopt new technologies as they became available. However, any Electronic Document and Records Management (EDRM) system had to be fully compliant with regulatory requirements.

“We were looking for a software tool that could deal with email archiving and records administration. Nevertheless, it had to match our current and future needs and be easily managed by all end-users; not just IT staff,” continues van der Meulen. “We looked at several possible solutions including those employed by governmental departments. However, although they could adequately handle predicted email volumes, they were only available in the local European language. As a major multinational organisation, our corporate language is English.”

HP TRIM – a comprehensive solution

After liaising with HP, who provided some reference sites, the company identified the best solution by working with the Australian Ministry of Agriculture. “This governmental body is a true archive specialist and when we saw HP TRIM in action, we knew we had found the best match,” declares van der Meulen. “It could handle our records administration, integrates paper and electronic records and lets staff create and maintain files.”

After conducting a proof-of-concept, the company rolled out HP TRIM software to 200 users at the European research centre. This reliable and adaptable application offered end-users...
effortless functions for paper records processing, email filing and the integration of paper and electronic records. Moreover, it was fully compliant with existing legislation.

More recently, the organisation has upgraded to a more advanced version of HP TRIM. This comprehensive ‘out-of-the-box’ software solution incorporates document, records, email and web- content management as well as imaging, workflow and document-centric collaboration. It offers business tight desktop integration and an ability to scale across large distributed environments. The package comprises base, Workflow and SharePoint modules; the latter interfaces directly with the company’s document management platform. From creation to disposal, users can store, retrieve and manage documents, emails, scanned paper files and images easily, securing enterprise information.

Boosting compliance and safeguarding business continuity

As the regulatory authorities inevitably demand new compliance initiatives and increased information visibility, transparent document and records management will continue to be increasingly important to the pharmaceutical company as it continues to develop more new drugs. However, after deploying HP TRIM, the organisation’s European research and development centre is no longer concerned about such issues.

“We now have no concerns whatsoever about archive inspections as we know all our mission-critical data is safe in a fully compliant records management system."

— Steven van der Meulen, senior manager records management, Japanese Pharmaceutical Company

Customer solution at a glance:

Primary applications:
• Storage, retrieval and management of enterprise information

Primary software:
• HP TRIM software
• HP TRIM Workflow module
• HP TRIM for SharePoint module

About HP Autonomy

HP Autonomy is a global leader in software that processes human information, or unstructured data, including social media, email, video, audio, text and web pages, etc. Autonomy’s powerful management and analytic tools for structured information together with its ability to extract meaning in real time from all forms of information, regardless of format, is a powerful tool for companies seeking to get the most out of their data. Autonomy’s product portfolio helps power companies through enterprise search analytics, business process management and OEM operations. Autonomy also offers information governance solutions in areas such as eDiscovery, content management and compliance, as well as marketing solutions that help companies grow revenue, such as web content management, online marketing optimization and rich media management. Please visit autonomy.com to find out more.

“Over 370 users currently employ our upgraded EDRM platform at the research centre. An ongoing roll-out across other European sites, we will increase that number to over five hundred. They are finding it easy to use and especially like the way TRIM handles different versions of email software,” reveals der Meulen.

Today, the company has a highly robust and sophisticated EDRM platform that will scale across several operational sites. The system offers rapid storage, retrieval and management of documents with excellent data integrity and strict access control. Secure enterprise information safeguards business continuity at the research centre, aiding disaster recovery. Moreover, simple-to-use functions boost workflows, increasing end-user productivity and workforce collaboration across the organisation.

“To date, we have migrated around 500,000 emails and 200,000 paper and electronic folders over to TRIM. That equates to approximately six-and-a-half linear kilometres of paper archive material or 20,000 archive boxes. We now have no concerns whatsoever about archive inspections as we know all our mission-critical data is safe in a fully compliant records management system,” concludes der Meulen.