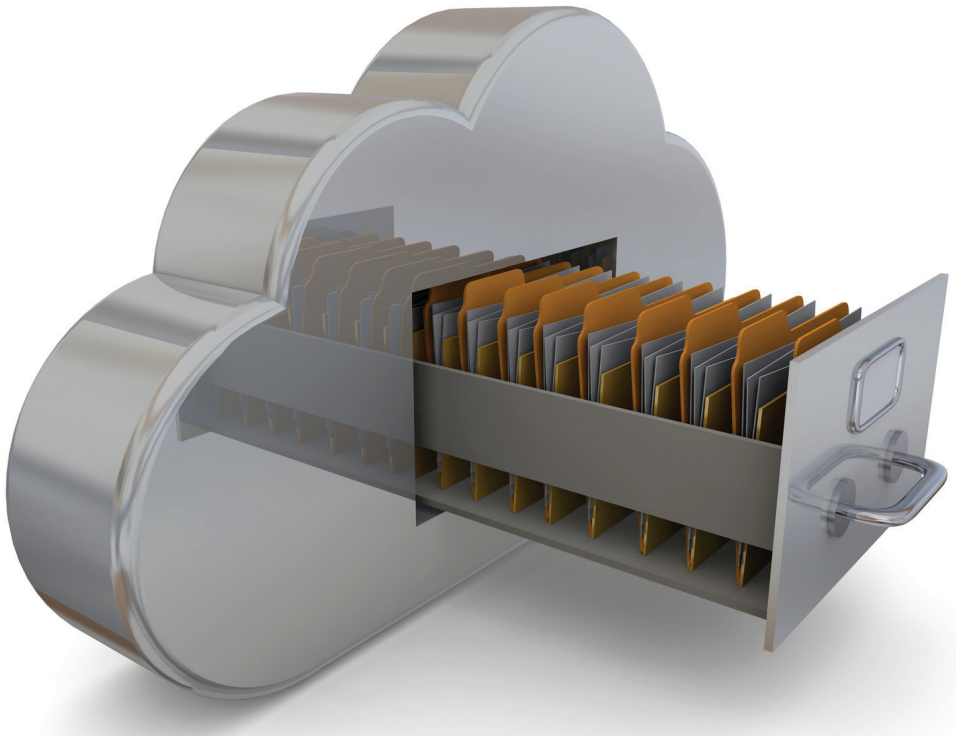

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In the Cloud

Globally disperse submissions, together with 21st century pharma's increased collaborative needs, mean that cloud-based platforms are fast emerging as an advanced alternative to outdated electronic document management systems

Rik van Mol at Veeva Systems

The pharmaceutical industry deals with a complex and intense drug submission process to regulatory agencies that continues throughout the life of a drug or biologic – from patent to death. In this environment, it is becoming clear that existing server-based document management systems can no longer keep up with the requirements of global biopharma companies, and can even lengthen the document and submission creation processes.

In response, the industry is increasingly turning to cloud-based multitenant systems to improve document authoring and submission preparation, speed up application submission, and keep companies in sync with global health authorities for the life of the drug.

Global Portfolios

Historically, the submissions dossier for a new drug or biologic often included enough paper documentation to fill multiple 18-wheeler-sized cargo containers from floor to ceiling. In the 1990s, electronic document management systems (EDMs) came to the rescue, enabling pharma companies to gather submissions paperwork into a neat, searchable electronic filing system where accompanying metadata made documents easier to track.

These systems initially proved a godsend, sparing many trees and increasing the efficiency of drug submission preparation. The only problem was the high cost of developing and maintaining these highly customised client/server solutions, but the costs were offset by the era's blockbuster successes.

However, the marvel of EDMs was relatively short-lived. Today, the life sciences landscape has shifted dramatically, with the highly centralised business model of yesterday replaced by one that is globally disperse. According to the report on a Gens and Associates survey of life sciences companies in 2013, "Global submission management is predicted to be the top area of change over the next two years as companies are trying to effectively manage a global portfolio" (1). Furthermore, life sciences companies must now operate in a more tightly regulated environment, with smaller pipelines making it imperative to reduce operational costs and outsource more functional aspects of the business.

These factors have caused the formation of an industry that – at its core – requires external collaboration, which means that all stakeholders must be able to access documentation, wherever it resides, quickly and easily. Traditional client/server EDMs arguably do not provide the accessibility or

flexibility that are required to support today's high level of collaboration. Cloud technology, however, does.

Great Enabler

When it comes to documentation in original investigational and marketing applications, plus the ongoing repeat submissions throughout a drug's lifecycle, the cloud is a great enabler. "The cloud technology model supports the key drivers in today's life sciences industry – global collaboration, efficiency, speed, harmonisation of processes – and it provides the flexibility to scale when utilising contract research organisations (CROs) or in the case of mergers and acquisitions," comments Rainer Debus, Head of Client Services for global publishing software provider, LORENZ Life Sciences Group.

In addition, as the Gens and Associates survey revealed, pharma companies are showing growing interest in adopting cloud solutions for submission-related content. "We have seen a 3X increase in overall investigation of cloud solutions (as measured by product plus pilot plus investigating) since 2011," states the report (1).

Positive Outcomes

No longer does the patent-to-death submissions process require rooms of paper and the constant risk inherent in document version control with multiple participants. A multitenant, cloud-based submissions EDM integrated with key regulatory information management technologies, such as submission publishing applications, can shave significant time off the filing process.

Not only does the drug or biologic get to market sooner, providing an opportunity to recoup investments faster, but it can also extend the precious exclusivity period, leading to substantial incremental revenues. Revenue estimates go as high as $1 million per region for each extra day a blockbuster remains unchallenged on the market. These numbers compound when considering the companies striving for simultaneous global launches at the earliest time, including growing markets. Cloud-based submissions EDMs yield such positive outcomes by enabling global collaboration, visibility into the process, and simplified affiliate submissions.

Filing Complexity

Today's pharma organisations operate in a complex global environment, with teams scattered throughout the world as a result of mergers and acquisitions and marketing opportunities in growth markets that include Brazil, Russia, India, China, Mexico, South Korea and Turkey (2).

Local market submission content and format requirements can vary from country to country. While the electronic common technical document (eCTD) global submission format has become standard for some countries, highly specific local requirements still exist. These can be as simple as the need for translations, or as complex as the structure of the entire clinical trial.

Further complicating the submissions process, many countries do not follow the eCTD format at all. Brazil, India and China have their own formats, while non-eCTD formats are also still fairly prevalent in Europe. Worse still, the submission process does not cease once licences are obtained – quite the contrary. Every change to the drug's recipe or manufacturing process, any new data on patient use – these all require a new submission to the dossier for each country where the drug or biologic is licensed.

Compound this filing complexity with internal teams in multiple locations working more often with external parties such as CROs worldwide, and it is easy to understand how access to a central document repository in the cloud can vastly improve the submission process.

Real-Time Collaboration

"Today's teams have to collaborate in real time on global and regional requirements, which can be supported by cloud-based solutions in a very efficient way," explains Christian Bohrmann, Vice-President Global Marketing and Alliances at software and service provider, Extedo. "Cloud systems integrated with resident publishing tools help make these complex processes more efficient from end to end. A good example is in supporting the European mutual recognition and decentralised procedures by allowing creation and maintenance of many 'child' dossiers, based on one central 'parent' dossier, and giving all parties access to the same documents to maintain integrity of the dossier."

Cloud-based EDMs provide a single source for reliably sharing documents. Searching for documents, sharing and collaborating with internal and external users, and then drawing upon the requisite publishing tools for submissions, moves the entire submissions process along efficiently and with less chance of error worldwide.

Among the companies taking advantage is Ipsen Pharmaceuticals, which recently adopted a cloud-based submissions content management across 20 countries. Its multitenant system provides easy yet secure access by internal and external stakeholders and affiliates worldwide. Bohrmann adds: "More and more companies are starting to outsource parts of their publishing services to external partners, so it is very important for them to be able to seamlessly and securely share information at different levels and stages."

Ongoing Visibility

A cloud-based submissions EDM also provides much-needed insight into the actual process of submissions content preparation. Validated collaboration and accountability occur in real time within a controlled environment where complete reports and easy-to-use dashboards are available for quick updates on how the submissions process is coming together.

Such functionality provides regulatory departments with ongoing visibility on filings or document updates, highlighting problem-areas and bottlenecks as they arise. The organisation can quickly pinpoint areas for improvement, and head-off problems to potentially shorten timelines.

To further improve oversight, submission content plans can be built into a cloud system at the start of the process and shared with internal and external parties for constant visibility. When changes are made within the system, the application can automatically populate the content plan and keep everyone in the loop as updates occur.

This is a superior approach to the static spreadsheets traditionally used for submissions document management. Because any updates made to spreadsheets need to be shared with all parties involved – and since these regulatory tracking tools are often not connected to electronic submission systems – it becomes easy to lose track, make errors and thereby slow down the approval process. In addition, although the eCTD might define what the submission should look like for the major markets, local market needs often vary – something virtually impossible to track efficiently via a spreadsheet, but which can be well-handled by publishing tools within the cloud.

"There is a clear trend in the global life sciences industry toward using cloud-based solutions to manage regulated processes and content, especially for smaller companies or large companies with affiliates in emerging markets that want to become more flexible in their submission process to decrease time to market," says Bohrmann.

Affiliate Submissions

The industry's global reach has undeniably created a licensing situation within affiliate countries and regions that has been exhaustive and fraught with risk. Local affiliates of the corporation rarely have the budget or IT infrastructure of their parent company, yet are tasked with the similarly complicated submissions for licensing within their respective countries.

In most instances, corporate headquarters sends the core eCTD to each regional affiliate via email or physical media and, in turn, the affiliate repurposes the content to meet the requirements of the health authorities in its respective country. Without the cloud, the local affiliate makes the changes to a copy of content, places the updated documents on the company's file share or sends them to headquarters (also via email or physical media), and submits the revised documents to the local authorities. There is no feedback mechanism and corporate headquarters has no immediate visibility into what has been changed and submitted. This is a process inherent with risk, further exasperated by any future changes in the drug's dossier, as there is no way to easily communicate such issues throughout all the affiliates.

Bird's Eye View

The industry has a long history of siloed, purpose-built systems and processes. Each system was designed to manage information for a specific regulatory activity or region, and frequently did not use an enterprise set of data and process standards, except at the most elementary level. Consequently, companies often dealt with submissions preparation 'blind spots' across the globe.

A cloud-based submissions solution, on the other hand, allows for a single, centralised, enterprise-wide platform. Headquarters gets a 'bird's eye view' of all changes made before and after the core submission dossier is handed-off to affiliates, preventing any potential filing errors, and keeping all parties informed of any submissions changes needed throughout the lifecycle of the drug or biologic.

Such insight is particularly critical because submissions management does not end once the drug gets to market. If there is a change in labelling in the drug's country of origin, for instance, this needs to be propagated to all affected markets to enable the required local market update submissions. The cloud allows for constant visibility into a universal dossier, while also allowing for seamless information flow across functions, including regulatory, clinical, preclinical, safety, manufacturing and commercial.

Cloud solutions are also inherently quick to implement, providing fast relief to organisations struggling with expensive client/server-based technologies, long implementation periods and ongoing IT maintenance. "Instead of the many months required to install and set-up traditional on-premise software systems, best-of-breed cloud applications can be implemented in a fraction of the time," remarks Debus.

Furthermore, multitenant cloud systems offer the flexibility to scale up or down with the organisation, making them accessible and cost-effective for even the smallest organisation. Collectively, these advantages dramatically and efficiently speed time to submissions and, ultimately, time to market.

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About the author

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