



Connecting the Dots

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Jim Nichols at Thomson Scientific explains how to address challenges and achieve success in the management of regulatory information

Jim Nichols has been at the forefront of the technology industry for over 15 years. As VP of Product Strategy and Marketing of Thomson Scientific's Lipient Regulatory Solutions business, Jim is responsible for product strategy and overseeing the delivery of the complete line of products and services. During his seven-year tenure, Jim has driven a number of significant campaigns including spearheading the company launch into Japan and managing the company market transition from ESPS to Lipient.

French intellectual, novelist and essayist Marcel Proust once said: "The real voyage of discovery consists not in seeking new landscapes but in having new eyes." Life sciences companies around the world are having to find 'new eyes' in response to evolving regulatory requirements. As they start on new voyages of discovery, opportunities for operational excellence are emerging within the area of regulatory affairs. What novel concepts have these companies identified that are leading to regulatory innovations? This article describes a few of the many key areas that have recently been explored.

IDENTIFYING INFORMATION ALREADY DISTRIBUTED

Companies are looking to simplify the process of preparing and reviewing content for regulatory submissions and updates; using official document versions means information can be identified with confidence, and reused without extensive review cycles. In an electronic document management system (DMS) environment, it is typically easy to identify which documents are internally approved. However, it is not easy to identify which are externally approved for a given market. Even when the relationship of the submission to the source component is tracked, it remains difficult to know if a particular component, once it was submitted to an authority, was ever approved, or if that component was made obsolete by the submission of a replacement. As a result, some authors recreate or reuse content that is inappropriate in reference to a particular region. This current risk in the DMS environment means that extra review and approval cycles often need to be provided, wasting time and reducing efficiency. There is also a more serious risk that incorrect manufacturing information may be supplied to an authority, which inevitably delays the drug approval process.

Companies should look for ways to help authors find and verify the correct document components by connecting the submission and registration management function with the DMS. This provides an author access to information about which document components are considered 'current' for a particular country. The benefits of this system include:

- ◆ The ability to see where each document in the DMS was submitted and approved, and if that approval is still current (if not still current, the ability to see what document has replaced it)
- ◆ The ability to see all submitted and currently approved source document versions still in effect for a given country
- ◆ Specific search capacity to identify a particular kind of document that is approved for a given country and date (for example, an approved stability document for France)

Typically, the improved efficiency associated with finding the desired document from which to start authoring represents a time saving of two to three hours per document, and there are between five and 100 updated documents in a variation. The time delays currently incurred by added content reviews, fact verification or rewriting are between two and four months for a submission or update.

KEEPING TRACK OF PRODUCT DETAILS

Companies are aiming to reduce their resource effort in identifying the regulatory impact of manufacturing and labelling changes and responding to agency inquiries, while also needing to decrease compliance risk and improve safety by ensuring registered product details are accessible both interdepartmentally and globally.

They need solutions for the tracking of registered product details such as shelf-life and indications. They also require manufacturers that will provide targeted reporting to evaluate

which products, markets and registrations are affected by a proposed alteration (such as a change in supplier). Such investigation requests can occur up to hundreds of times per year for an active product. Moreover, when these solutions can be made available via a web client, companies can also encourage a more proactive approach to the verification of operational data. By leveraging good design practices, focusing on end-user training and holistically implementing their approach, a product detail management solution can be associated with a two-week reduction in research effort for each request.

INCORPORATING SUBMISSION PLANNING AND TRACKING

Another requirement for managing information is the reduction of effort in preparing and reviewing dossiers. Enabling increased automation in the creation of the regulatory submission would result in less user time spent on repetitive manual activities such as adding folders and assigning files, and more time available to focus on quality and management activities. In addition, because the document assignment process itself can be automated to be based on standard approaches, users are less likely to make errors in document assignment within the submission. Such errors result in increased cycle time during internal review, or even, potentially, a longer agency review period. More efficient dossier assembly can be achieved through initiating a new collection using a cumulative or virtual view of what has already been submitted in another region. For example, an Australian filing could be based on a European equivalent after many updates were applied to the original submission. Rather than requiring the user to manually determine and replicate these changes, a virtual submitted or approved view can form the basis of the new submission document. Compared to starting a submission from scratch, this procedure can save 10 days in assembly time and potentially up to 25 days in research and compilation time.

INTEGRATED SUBMISSION AND REGISTRATION PLANNING AND TRACKING

This strategy can accelerate drug approval timelines and streamline the resources of registration support activities through improving the co-ordination of planning and tracking activities while also reducing the effort required to research and report on submission status.

Ultimately, operational efficiency can be improved by ensuring that the key functional areas and their associated information management needs are supported in an integrated fashion. In operating on this model, companies can support executive summary reporting to manage risk in completing dossiers on time and identify remaining components for the submission which are complete and ready for review and approval. In companies where this information and the related processes are not truly integrated, the typical methods of reporting via manual submission are likely to require one day per week for a submission over a three-month period. Where the identification of late documents may be

associated with two to three weeks' reduction in the required duration for a submission, integration provides management techniques for communication of document due dates.

In addition, integration planning can improve coordination of submission tasks, global communication and resource management by providing a central portal for all product activity, product milestones, interdepartmental tasks and best practice documents. Poorly understood milestones and non-coordinated activities can cost months in unnecessary resource expenditure submission activity. One example is two global regulatory groups producing the same or conflicting submission requests. Poorly managed resources can result in weeks or months of consulting requiring staff supplementation. In comparison, well-coordinated communication between affiliates, partners and regulatory groups typically reduces the preparation of product changes by one to four months.

For most life sciences companies, the information available to regulatory affairs areas departments is likely to be sparse and managed across a host of disparate applications and locations. Companies who have approached this challenge by seeking ways that integrate information by providing systems to several different functional areas are seeing new benefits.

Operational Efficiency

Reducing cost can be achieved through greater operational efficiency. Companies are realising the value of entering information once and using it multiple times. They are also finding that by consolidating multiple point-solution systems, they have a lower IT burden for maintenance and validation activities.

Working in Partnership

Strengthened partner communication and collaboration capabilities have yielded better working relationships with internal and external affiliates and across global locations.

Speed and Accuracy

Improved speed and accuracy in decision-making has resulted from the ability to locate, aggregate and analyse key information leading to the potential avoidance of missed business opportunities.

Compliance

Increased capacity for compliance since information can now be quickly and completely delivered, enabling both manufacturing and labelling compliance, and the ability to stay on track with product registration renewals and mandatory reporting requirements.

CONCLUSION

What do companies realising integration strategies all have in common? Essentially, they have realised that by 'connecting the dots' that represent what have historically been isolated data points, they can achieve new success in their operations and excel at what is now being called 'regulatory information management.' ♦

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