

# The Mix

Strategies, tactics, insights and opportunities

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# Operation: Optimization

In response to new requirements, life sciences companies around the world are rethinking their regulatory activities, creating new opportunities for operational excellence. Jim Nichols explores some of the new concepts that are making a difference.

"You are the embodiment of the information you choose to accept and act upon. To change your circumstances you need to change your thinking and subsequent actions." — Adlin Sinclair, businessman, motivational speaker and humanitarian.

Due to new and emerging regulatory requirements, companies are looking to streamline regulatory affairs and operations, improving in areas such as reducing time spent in preparing and reviewing content for submissions and updates. This is because official document versions can be identified with confidence and then re-used without extensive or additional review cycles.

### Understanding document usage

Typically in a document management system (DMS) environment, it is easy to identify which documents are internally approved. However, it is not so easy to identify which are also externally approved for any given market. Even when the relationship of the submission to the source component is tracked, it remains difficult to determine if a particular component, once submitted to an authority, was ever approved, or if that component was ever made obsolete by the submittal of a replacement. As a result, authors

often recreate or re-use content that is actually the wrong starting point for a particular region.

Because of this risk in the DMS environment, extra review and approval cycles are needed; this wastes both time and resources. There is also the bigger risk that incorrect information, such as manufacturing information, for example, could be provided to a regulatory authority; this would delay drug approval dates.

Companies should be looking for ways to help authors and publishers find and verify correct document components. They can do this by connecting the submission and registration management function with the DMS, thereby giving authors access to information about which document components are considered 'current' for a particular country. Examples of the benefits of this include

- The ability to see where any and every document in the DMS was submitted and approved. The ability to see if that approval is still current and, if not, the ability to see which document replaced it.
- The ability to see all in-effect submitted and currently approved source document versions for any given country.
- The ability to find a specific kind of document that is approved for a specific country as of a specific

date (for example, "show me the approved stability document for France").

Typically, the time savings associated with finding the desired document from which an author should start are two-to-three hours per document — and there can be anything from five to 100 updated documents in an individual variation. Typically, two-to-four months can be shaved from the duration of creating a submission or an update by reducing or eliminating delays such as added content reviews, fact verification, or rewrite of content.

### Keeping track of product details

Companies want to reduce the resources needed to identify the regulatory impact of manufacturing and labelling changes, and to respond to agency inquiries. But they also need to decrease the non-compliance risk and improve safety by ensuring registered product details are accessible both interdepartmentally and globally.

With these objectives in mind, companies should seek solutions for the tracking of registered product details (such as shelf life, indications and manufacturers) that also provide targeted reporting to evaluate which products, markets and registrations are affected by a

proposed change, such as a change in supplier. 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. These investigation requests can occur dozens to hundreds of times a year for an active product. Well-designed product detail management solutions can be associated with a two-week reduction in research effort for each request.

### **Incorporating submission planning and tracking**

As submission standards continue to evolve into increasingly complex technical structures, companies must reduce the time and effort spent preparing and reviewing dossiers.

Enabling increased automation in the creation of regulatory submissions results in less user time spent on repetitive manual activities, such as adding folders and assigning files; this leaves more time available to focus on quality and management activities. In addition, because the document assignment process itself is more automated based on standard approaches, users are less likely to make errors in document assignment to the submission. These errors result in increased cycle time during internal review, and can even potentially lead to a longer agency review period.

Capabilities to enable more efficient dossier assembly can include initiating a new assembly using a cumulative or virtual view of a document already submitted in another region. For example, even after many updates were applied to the original submission, an Australian filing could be based on the European filing. Rather than requiring the user to determine and replicate this need manually, personnel can use this method as the basis for the new submission structure. Compared to starting a submission from scratch, starting with the virtual submitted or approved view can save ten days in assembly time, and potentially up to 25 days in research and compilation time.

### **Integrating submission and registration planning/tracking**

Through talking to clients, Thomson Scientific has observed that companies can require fewer resources and improve submission delivery execution and registration support activities via

improved co-ordination, planning and tracking. This also reduces the time required to research and report on submission status.

Ultimately, operational efficiencies can be gained by ensuring that the key functional areas and their associated information management needs are supported in an integrated fashion. In doing so, these companies can support executive summary reporting to manage risk, complete dossiers on time and identify remaining components for the submission that 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 manual submission reporting are associated with one day per week for a submission over a three-month duration.

Through an integrated approach, more efficient management processes for communication of document due dates and identification of late documents can be associated with a two-to-three week reduction in duration for a submission.

Companies can improve co-ordination of submission tasks, global communication and resource management by providing a central portal to all product activity, product milestones, interdepartmental tasks, and best practice documents. Poorly understood milestones and non-co-ordinated activities can cost months in unnecessary resource expenditure on submission activity — for example, if two global regulatory groups produce the same or conflicting submission requests. Such poorly managed resources can result in weeks or months of additional staff supplementation consulting needs. By comparison, well co-ordinated communication with affiliates, partners, and regulatory groups typically reduce preparation of product changes by one to four months.

### **Business benefits**

For most life sciences companies, the information available to their regulatory affairs areas is likely to be sparse and managed across a host of disparate applications and locations. Companies that have integrated much of this information in systems available to several different functional areas are realizing new benefits. These benefits include

- Reducing costs by achieving operational efficiencies. Entering information once and using it many times provides more value than

different functional areas entering the same information repeatedly. Consolidating multiple point-solution systems also lowers the IT burden for maintenance and validation activities.

- Strengthening partner communication and collaboration capabilities. This also yields better working relationships with internal and external affiliates and across their global locations.
- Improving speed and accuracy of decision-making, resulting from the ability of these companies to locate, aggregate and analyze key information — leading to the potential avoidance of missed business opportunities.
- Increasing abilities for their organization's compliance, since they can now quickly and completely deliver information that enables manufacturing and labelling compliance and also stay on track with product registration renewals and mandatory reporting requirements.

What do the companies taking these steps and enjoying these benefits all have in common? Essentially, they have realized that by 'connecting the dots' of what have historically been isolated data points, they can streamline their operations and excel at what is now being called 'regulatory information management'.

And, with a strong platform of regulatory information, these companies can begin to realize important new benefits and synergies by integrating this information into other key business processes while also ensuring the highest levels of data integrity and regulatory compliance.



### **About the Author**

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