



# What Keeps Regulatory Professionals Up at Night?

Jim Nichols at Liquent, Thomson Scientific looks at how investment in record management technology and skills outsourcing is the best way to register pharmaceutical products and ensure that they gain market penetration – two ways to make the regulatory professional's life easier and ensure a better night's sleep



As Vice President of product strategy and marketing for Liquent, Thomson Scientific, Jim Nichols is responsible for product strategy and overseeing the delivery of the complete line of products and services. During Jim's five year tenure, he has driven a number of significant milestones in the company history; namely, defining the market and corporate propositions behind many of its leading publishing and regulatory products, spearheading the company launch into Japan and managing the company market transition from ESPS to Liquent. Jim garnered much of his management expertise during his time at Intracorp, where he directed project management and software operations for this disability management company. He is a well-known and much respected figure in the document and information publishing field, where he is a regular contributor and speaker on both the US and European conference circuits. Jim was awarded his degree in Mathematics from the Pennsylvania State University.

Managing the product registration process on paper alone can present many problems for life sciences companies already weighed down by extensive paper-trails. Companies that persist in developing procedures around paper-based processes and submissions can suffer from duplication and have the headache of the storage and retrieval of multiple copies of the paper document to deal with. These factors can create a significant and unnecessary burden and regulatory risk. By the same token, too many organisations fail to consider the other factors that go into making product registration work – that is, people and systems. Paper-based or manual processes are poor foundations for a successful product registration; staff not trained on the latest published rules and regulations is another concern.

## PAPER-ONLY COLLECTION

When paper-based processes are working well, the organisation feels secure in the knowledge that its submission is available and stored securely in a physical location. But even with the best run physical filing systems, inefficiencies are inherent. If many copies of the same document are needed by the regulatory authorities, care must be given to version control and access. These problems are exacerbated if the regulatory departments are spread over multiple sites, introducing unnecessary time lags in approvals as staff track down time-sensitive information. Paper-based processes and submissions generally take longer to be compiled and dispatched to the regulatory authorities.

There is also the issue of overheads created by hiring additional staff to meet submission targets. It is estimated that managing documents to be included in a submission can end up requiring as many as nine full-time employees for a period of nine months. And an



organisation that does hire the extra resource to meet the demands of the submission process is prey to being overstaffed once a submission is complete.

## WHY GET COMPLIANT?

At a time when regulatory standards are growing in number and importance, it is critical that a company knows and understands the requirements for product registrations in the countries in which it wants to market its products. The problem is that keeping abreast of the untold number of regulatory standards and new initiatives that most pharmaceutical companies are working with today can be an overwhelming task for staff members.

Indeed, when a new standard emerges, such as the electronic Common Technical Document (eCTD), the structured product labeling (SPL) requirement of the FDA, and the emerging product information management (PIM) initiative in Europe – it's going to be a lot more effective for your business to be able to use a system or an outsourced team of consultants that can immediately grasp the changing rules and the resulting processes, without introducing unnecessary time lags, as staff try to brush up on the new standards.

Take a situation where a pharmaceutical organisation wants to market its products and as yet has no effective staffing strategy in place to keep tabs on the relevant country-based registration requirements. How do you, the regulatory professional, know what the local requirements for your products are, and whether they are being interpreted correctly? The cost of getting it wrong could be missing a launch target or facing a product recall. Nothing is more costly – financially or competitively. Fines as high as tens of



millions of dollars can be levied as a result of audits that uncover non-compliance. In some cases, the end result could be lasting damage to a company and its reputation, rather than to one discrete product set.

Now imagine that same organisation with a simple outsourcing strategy in harness. Use of a team of highly-skilled regulatory professionals will help to identify the relevant regulatory requirements imposed by authorities in the countries where products are to be registered. They can also establish what new systems and processes are needed to better comply with these standards. All of this helps to better manage the peaks and valleys in workload. Furthermore, database tools now exist to support staff in their jobs by providing easy online access to regulatory information in the right format and when it is needed.

### ELECTRONIC DOCUMENT MANAGEMENT DELIVERS

If paper management becomes an issue for an organisation, the traditional solution is electronic document management (EDM) – the electronic capture of a snapshot of the document as it enters the organisation's doors. The idea is to store that product form in the equivalent of a central electronic filing cabinet, accessible to all relevant users throughout the organisation's information systems. While many of these systems have provided tremendous value to their organisations, perceptions have arisen that they are difficult to use, expensive to buy into and maintain, and are often tied in to large business software systems.

There is also some scepticism about the ambition to create the paperless office – a misunderstood notion of how a business environment should operate. It seems that electronic document management systems could have some value, but only for companies processing thousands of documents and not for handling the appropriate licensing, marketing and legal compliance of pharmaceutical and medical products.

The software supplier market has been undergoing many changes, while at the same time technology in both storage and functionality has continued to develop. The end result is that today's market features highly functional and affordable systems that can provide great value to pharmaceutical organisations. EDM systems have extended their usefulness in this marketplace, with excellent registration and planning and eCTD publishing facilities, meaning documents can easily be made compliant. As a result, organisations that recognised the need for central capture and secure access to the information

stored on documents – not the physical documents themselves – have considered how they need to work with a range of different regulation and document formats, and how they can better route that around their business processes.

These companies are now achieving increased value through the reduced use of resources to manage paper-based submissions. This has had a number of benefits; a key point being that staff can feel more useful, clued up and confident about the content and construction of their submissions. Modern submission management systems can greatly ease the approval process and improve compliance observance by simplifying the secure collection of information and by making key information instantly accessible to reviewers.

Indeed, many product registration guidelines – 21 CFR part 11 and Annex 11 for instance – now insist that organisations store all of their submission documents within an electronic records system so that regulators can have quick and easy access to the relevant paperwork.

### GETTING THE BEST FROM YOUR EFFORTS

This is just one of many examples of how EDM could work across all levels of a pharmaceutical company. However, a holistic approach – incorporating skills outsourcing – is needed. EDM can radically improve your ability to approve products quickly for distribution in the marketplace. But by ensuring you have the right skills and appreciate the requirements of the desired market, along with access to the latest regulatory intelligence, real long-term success is possible.

Pharmaceutical companies need to be aware that by ignoring the issue of better document management, they risk an invisible cost, an item not on the P&L, which is the time staff spend preparing and researching the ever-changing rules that surround compliance observance – most often slow and error-prone – when they could be spending their time much more valuably. There is much greater job satisfaction in being able to answer a query immediately by having instant access to relevant documentation, as opposed to spending a daunting amount of time being nothing more than a glorified filing clerk.

Optimum running of the product approval process means more than just cutting down on waste and slack time. As the technology and skills come on stream, the two can start to work together, thereby making your whole product marketing operation run at a higher level of efficiency, almost invisibly, resulting in tens or even hundreds of thousands of dollars in daily savings. ♦

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