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FDA SPL Submission Regulations

How to minimize the effects of a new and constantly changing standard on your existing business process

Environment

Introduced in 2003, the Food and Drug Administration ([FDA](#)) requires pharmaceutical companies to electronically submit the content of labeling required for marketing applications. In October 2005 the FDA expanded the existing labeling regulations to include the submission of the content of labeling in XML (SPL) format. The SPL format replaced the existing requirement for a PDF version of the label.

Business Challenges

To meet the SPL requirement, some Pharmaceutical companies have purchased tools to assist in the creation and management of their product labels. These tools, though capable, are not without fault in real-life labeling processes.

Since the introduction of the SPL requirement the FDA has made changes to the acceptance and data criteria. With every change, no matter how minor, updates to the tool(s) purchased by the sponsor organization are required. These updates have caused, in some cases, sponsors to wait months for the latest release of the tool, introduction submission risk. In some cases, delays have caused invalid SPL to be submitted to the FDA.

In addition to managing tool updates, these tools have proven to be immature. While the tools have succeeded in meeting most of the technical requirements, they do not provide a user friendly experience and often require costly business process modifications that end up frustrating users and introduce additional risk associated with lifecycle errors. The tools require non-technical pharmaceutical label authors to become SPL (XML) experts and entails that they use tools that are restrictive and counter intuitive to the way authors do their jobs. In addition, the tools require employees to manage codes and data that are not displayed easily for the user. This approach inundates the user with the responsibility of knowing all of the implementation rules of SPL as well as having to know how the tool has been configured to meet those rules. The tools require all of this in addition to having to maintain their role as product manager and author.

Over and above its management complexity, tools introduce additional business and information technology organization costs. If one assumes an employee's blended cost to be ninety dollars an hour, the time spent introducing an application to the end users (design, development, deployment, and training), deciphering and recovering from tool errors, managing the challenges introduced by lifecycle management, challenges managing and deploying tool updates (regression testing, package building,



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and training) and the overall cost of modifying and maintaining business processes, some companies have seen costs quadruple.

The End Result

The adoption of a tool will introduce business process risks and impacts unique to each pharmaceutical company. Sponsor organizations should take into account the complexity inherently associated with these tools when applied to an immature implementation that has already resulted in numerous guidance updates. Some of the risks and additional costs associated with a tool are:

1. Numerous product updates
2. Lengthy vendor deployment
3. Extensive sponsor regression testing
4. Protracted package building and deployment
5. Supplementary user training
6. Reoccurring maintenance costs
7. Additional functionality costs
8. Internal IT costs (training and support)
9. Forces non-technical users to perform technical tasks
10. Increased risk associated with non-compliant SPL submissions
11. Efficiency costs due to application errors, training, and employee turnover

The Solution

Intagras firmly believes that ***a change in your business process is a change to what has made and sustained the success of the company.*** We employ proven methodologies that have little to no impact on your organization's current labeling process. Our solution works with your existing practice so that your employees can remain focused within their skill sets using tools they are already familiar with. We allow you to continue to manage your existing labels in Microsoft Word by converting those documents to the latest FDAs XML standard. Our SPL management approach keeps the registration process as is, and your staff unchanged and unaffected.



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The Result

Utilizing Intagras as an SPL management partner is a low impact, low cost, and long term solution to a rapidly changing set of standards.

- Our strategy...
 - allows your staff to utilize their expertise appropriately
 - allows your business processes to remain intact
 - allows your company to focus on your products
 - allows you to leverage the SPL knowledge base that we have acquired

We are committed to developing a long lasting relationship with our clients. By partnering with Intagras, you leverage the highest level of SPL expertise and involvement without impacting the efficiency within your organization. SPL is an evolving standard. Managing the continuous updates is what we do, and we do it better than anyone else. The industry's biggest name depend on us, why shouldn't you?