HOTSEAT

CRITICAL COMPONENTS OF FDA-REGULATED PHARMACEUTICAL LABELING

ARDI BATMANGHELIDJ, President of Innovatum Inc., addresses challenges in pharmaceutical labeling and how the right enterprise label management system can be the solution.

Ardi is President of Innovatum Inc., a software development and IT consulting firm specializing in solutions and services for the pharmaceutical industry. Ardi has worked extensively in FDA-regulated environments for over 25 years, developing software and managing critical projects for many of the industry's most prominent companies. His company developed and implemented one of the first compliance label systems designed explicitly for the life sciences industry in 2000.

Why is labeling in the pharmaceutical industry more challenging than in other industries?

There are a number of reasons, but the overriding factor is regulatory compliance. When you work in an industry with a profound impact on public health, the necessary government regulations add significant complexities to every aspect of the business. Also, since pharmaceutical labels provide important product and dosing instructions at the point of consumption, it is vital that the information is not only accurate but traceable to the point of origin in the event of a recall. Consequently, these compliance requirements have a major impact on both the human and technical resources required for pharmaceutical labeling operations.

The human impact stems from the fact that regulated labeling requires coordinated involvement from multiple departments within a pharmaceutical company. Whereas most industries assign labeling to the purview of IT and/or packaging personnel, pharma companies must also involve manufacturing, quality assurance, quality control, regulatory affairs, legal and even marketing in their labeling systems and standard operating procedures (SOPs). As any operations manager will tell you, the goals and objectives of different departments in a corporation rarely align perfectly. Consequently, the process of merely coordinating the human resources to effectively manage regulated labeling is a challenge.

In terms of the technical impact, pharmaceutical labeling requires far more advanced and flexible interfaces to address the stringent security and data management standards of regulations like 21 CFR Part 11. After all, few other industries require multilevel security access, version control, electronic signatures and comprehensive audit trails for labeling. Consequently, most standard label software programs are not viable in regulated environments without extensive customization and manual procedures. This typically results in a collection of consumer-grade software programs knit together with custom code and manual operating procedures. Furthermore, these custom systems and manual SOPs have to be validated; requiring quality assurance and/or IT personnel to write and execute comprehensive protocols and test scripts.

How do you manage the complexities of regulatory compliance in labeling to ensure both efficient work processes and compliance?

It is essential to structure a plan that effectively addresses both the human and technical challenges of FDA-regulated pharmaceutical labeling. Until recently, this meant developing and documenting extensive SOPs to address the human element, while building custom software to address the industry-specific technical challenges.

The problem with this approach, however, is that it often relies too heavily on human involvement since IT departments rarely have the resources to develop and maintain a comprehensive label software system. The commensurate disparity in manual SOPs versus electronic automation leads to more labor intensive systems with a higher risk of error. In other words, the degree of human involvement in regulated labeling operations is directly proportionate to the risk of non-compliance, as well as the amount – and expense – of labor. Therefore, one major goal is to reduce the level of human involvement as much as possible to improve productivity and reduce risks.

The other challenge of the custom approach is standardization in multi-site environments. Custom label systems rarely have the capacity to operate in a wide area network (WAN) environment. Consequently, each location handles labeling independently – often with completely different applications and procedures. This can have a major effect on productivity since each site is operated independently. In addition, the lack of standardization can result in discrepancies between labels printed at different sites for the same product, which obviously increases the risk of non-compliance. Thus, the other major goal is to standardize and centrally manage label systems and data across any number of sites on the network.

In order to achieve these goals, one option is to devote more internal resources to developing and maintaining a comprehensive, WAN-capable compliance label system. However, the number of systems for which most pharma IT departments are responsible makes this impractical. Thus, the second option is to hire an independent contractor to build the system. While this may be an attractive option on the surface, the long-term costs of support and maintenance are exorbitant. Thus, the ideal way to manage the complexities of regulatory compliance is with a prepackaged enterprise label management system from a vendor explicitly dedicated to the pharmaceutical industry.

What do you mean when you say "enterprise label management system"? What is required for this type of system in a pharmaceutical environment?

An enterprise label management system (ELMS) is an application with the capacity to electronically handle all labeling requirements and processes for an entire corporation in a centralized network environment. In the pharmaceutical industry, it means the system should address all label design, review, approval, printing and reconciliation requirements in a secure manner with extensive audit trails and reporting capabilities. It should also enable seamless integration with other enterprise systems like enterprise resource planning (ERP) and product lifecycle management (PLM) to share and update critical data like lot numbers and expiration dates that must be printed on labels. Since business requirements and operating procedures vary from company to company, a modular architecture with a variety of flexible licensing and configuration options is a necessity. In addition, the pharmaceutical ELMS should be a commercial, off-the-shelf (COTS) product with an existing base of validated installations. This is vital with regards to ongoing support and maintenance since it indicates the vendor is committed to updating and improving the system over the long term.

In terms of specific functionality, the system should minimally provide: a "what you see is what you get" (WYSIWYG) label design interface, support for all barcode symbologies and RFID standards; international language support, function-level security, electronic approval workflows, integrated Windows printing support for industrial-grade label printers, version control, comprehensive audit logs and all relevant validation documents (e.g. URS/FRS, IQ, OQ, test scripts, etc). While there are literally hundreds of other features, these should be considered non-negotiable by any pharmaceutical company looking to maximize productivity and minimize risks associated with labeling operations.

What should a pharmaceutical manufacturer look for in a vendor when implementing an ELMS?

First and foremost, the vendor should have an explicit focus on the needs and challenges of FDA-regulated manufacturers in the life sciences industry; the vendor should have a documented history of successful implementations in the pharmaceutical industry. They should also be able to demonstrate that the majority of their business comes from the life science industry. In other words, anyone can claim to focus on the pharmaceutical industry in a brochure or on a Web site, but it is essential they be able to back it up with real-world evidence and impeccable references. Unfortunately, the prominence of regulations like 21 CFR Part 11 has attracted a virtual hoard of opportunistic vendors claiming compliance expertise. Thus, the ideal vendor not only has extensive, verifiable experience in the pharmaceutical space, but also has an explicit long-term commitment to the needs of the industry. This ensures they can handle the initial implementation and validation, as well as the long-term support and maintenance of the system. It also helps guarantee that the client will not outgrow the system since a truly dedicated vendor is constantly improving their product, addressing new compliance requirements and incorporating best practices from other industry leaders.

Given the mission-critical nature of labeling in pharmaceutical production environments, the vendor should also offer 24-hour staffed technical support, 7 days a week, 365 days per year. Any company for whom this is out of the ordinary should be eliminated from consideration since it is a clear indication that they are not focused on life science. Finally, the vendor should have the consulting resources to manage an entire project if necessary – from installation and training to validation and go-live. After all, an experienced vendor in this industry should know that pharmaceutical companies regularly need to augment their internal resources with contract personnel on large projects.

What are some the key benefits a pharmaceutical company can expect by implementing a dedicated ELMS?

While eliminating regulatory exposure is probably the most important benefit of a pharmaceutical ELMS, a sharp increase in productivity is probably the most visible. In other words, the compliance benefit is more akin to insurance; it protects the company from the dangerous and costly risks of non-compliance, but it doesn't necessarily put money in the bank. However, saving hundreds of staff-hours by streamlining and automating labeling processes has an immediate and profound impact on a company's bottom line. The biggest productivity increases are typically seen in IT. For instance, they no longer have to support and maintain custom systems individually at each location since they can administer the system from a central location. In addition, they deal with a fraction of overall user support if the vendor offers 24/7/365 technical support. In short, a pharmaceutical ELMS frees up a considerable amount of IT resources to focus on other priorities.

However, quality and regulatory departments are not far behind with regard to increased productivity. Prior to implementing an ELMS, most pharma companies handle label reviews and approvals manually; they print and attach hard copies of labels under review to a paper routing sheet, which is then physically taken to each approver for his or her review until all personnel have signed off and the label is released to production. This is an extremely cumbersome process under ideal circumstances, let alone when an exception or rejection occurs mid-stream. Furthermore, the near-glacial turnaround times imposed by these manual processes can delay critical events and production schedules, hurting the company as well as its suppliers and clients. However, after implementing an ELMS with electronic workflow capabilities, we've seen many companies cut their label approval turnaround from weeks – or even months – to mere days.

In addition to these obvious advantages, the right pharmaceutical ELMS from the right vendor can have a number of ancillary benefits in terms of improved corporate image from the uniform appearance of all labels; better responsiveness to vendors and clients from streamlined SOPs; and better quality of life for production personnel from easier interfaces and processes. In short, an ELMS designed explicitly for the needs of FDA-regulated manufacturers can have an incredibly positive impact on a wide range of departments, people and processes in a pharmaceutical company.