The Essential Building Blocks of Effective Training

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The US Food and Drug Administration (FDA) has escalated its scrutiny of Indian pharmaceuticals and medical products. Beyond FDA, the same scrutiny is reflected in recent decisions by the Indian Supreme Court, regulations by agencies including the Central Drugs Standard Control Organisation, and heightened cooperation among international regulators regarding site inspections and compliance enforcement.

The growing demand for India's medical products has put significant stress on Indian companies to meet that demand while also complying with the quality standards of global regulators and customers. Recent experiences of well-known Indian companies illustrate the quality risks associated with rapidly expanding international markets, complex supply chains, global compliance requirements and often-limited corporate resources.

Understanding and implementing programmes that address global compliance demands will enable companies to improve their reputations and avoid unnecessary costs. As the global market opportunity for Indian medical products increases, all companies large and small, generic and brand, domestic and global – will be held to strict standards of compliance and quality or face enforcement actions that have recently included Warning Letters, closed facilities, massive fines and product bans.

Management Commitment

Every company's culture is defined at the top, by senior executives. Underlying that culture are the corporate philosophy, mission, expectations and standards that flow through middle managers to production employees, subcontractors and vendors. Yet, while "tone at the top" is essential, it is not enough to ensure compliance. Both inside and outside the Life Science industry, companies have failed to follow through on the public statements of their senior executives, often with damaging results.

Global regulation is clear on the subject of "management commitment." It is a strict liability law and cannot be delegated. Unfortunately, middle managers may overlook quality problems because they are being pushed to increase production, no matter what. Documentation may be shortchanged because it "takes too much time" and provides no direct profit. When the message from the top is not supported with resources, reinforcement through training and consistent adherence throughout the organisation, quality always suffers.

Walking the Talk

Both ISO 9001 and ICH Q10 require executive management to provide evidence of its commitment to establishing and maintaining a company-wide culture of quality. This requires an ongoing training and communications programme that provides equal focus on the company's financial (including product throughput) goals and quality topics. Leading topics identified in the UL annual 2013/2014 benchmarking study for "Critical to Quality" training and measurement are: CAPA, inspection and internal audit findings, adverse events, customer complaints and non-conforming products. Correlating this data, we have seen an increasing commitment to quality

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through the distribution of the UL-FDA library of courses on these topics. The most popular courses used in 2013 were "Handling an FDA Inspection," Introduction to GMPs" and "Principles of Good Documentation."

Effective SOP Management

The purpose of an SOP is straightforward: to ensure that essential job tasks are performed correctly, consistently and in conformance with internally approved procedures. Clearly, employees' correct, consistent performance of essential job tasks is as much a business and quality issue as it is a regulatory requirement. Yet, regulators routinely cite Pharmaceutical and Medical Device companies because of inadequate Standard Operating Procedures (SOPs) management. Common observations during inspections include non-existent SOPs or those that are not understandable, regularly updated and easily accessible to employees and inspectors. In addition, a company with inadequate SOP management procedures at one facility is likely to face regulatory scrutiny for similar problems at its other facilities and those of its suppliers.

Risk versus Training Method

Since SOPs form the basis of effective compliance; they also serve as the essential foundation for personnel performance and product quality. UL EduNeering's SOP Management Suite is the most widely used feature available via our ComplianceWire® Learning Management System, having recorded approximately 15 million training completions in 2013 alone. Best practices gleaned from this Suite include developing SOPs for each job task written in conjunction with users (and translated into native language); providing a documented distribution programme to ensure that only current SOPs are being employed; confirming employee comprehension on key SOPs via testing; risk ranking SOPs and aligning that risk to training approach, and maintaining a corrective and preventive action programme to identify, rectify and prevent quality failures. ComplianceWire offers the added benefit of documenting distribution of required SOPs as well as the ability to incorporate testing on an individual or group of SOPs, providing defensible records for inspectors and regulatory agents.

Who is Qualified?

Highly publicised quality issues have triggered public distrust and governmental anger, putting Life Science companies under the spotlight more than ever. A

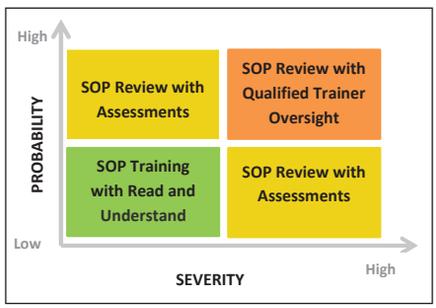

Figure 1: We recommend aligning training approach to match the risk and importance of each SOP

common complaint by FDA, for example, is a company's failure to have "sufficient personnel with the necessary education, background, training and experience to assure that all activities are correctly performed." Regulators from other countries make similar complaints, asking, "Are employees qualified to perform their assigned duties accurately, effectively and in compliance?" There are a number of factors that complicate a company's ability to ensure appropriate qualifications of its employees. Among those factors are high turnover rates, rapid facility expansions, new production processes and reduced training budgets. Although each of these factors may complicate the employee qualification process, the single most common flaw is the lack of a cohesive programme that incorporates initial assessments of knowledge, targeted role-based training, testing to ensure comprehension, and automated delivery of remedial training when required test scores have not been achieved.

Training that Works

The purpose of training is compliant behavior – not the number of hours or courses provided. Training should be based on the role and responsibilities of the learners. It should be relevant to their jobs and tailored by language, literacy, experience and culture. According to regulations, employees must be able to demonstrate their documented qualification to perform their specific job functions. "Qualification" could be represented by a collection of "role-based" training items or tasks that must be completed to satisfy the defined expectations for that role. Those tasks could include prior education, a series of SOPS, demonstrated proficiency via on-the-job-training, attendance in instructor-led classes, and computer-based learning. As a role changes, so do the training requirements for that individual.

Metrics and Technology

FDA and its counterparts in other countries are adopting a risk-based approach to inspections and enforcement actions. As part of that approach, companies are encouraged to use metrics to improve their performance and quality. In fact, 67 per cent of respondents in our customer benchmarking study cited "collecting training data to support the organisation's quality or compliance metrics" as a top priority.

Although companies may agree about the value of "metrics," there are key challenges in collecting relevant data and making effective use of the information. Critical records are often "lost" in a web of inefficient processes and conflicting technologies, forcing quality managers to grab vital information "on the fly." Training metrics, including the status of each employee's training completions, remedial requirements, distribution patterns and testing scores can enable managers to identify knowledge gaps before they result in serious quality issues. The reverse is also true.

Figure 2: Training content should be aligned to each individual's role to demonstrate qualification

Documentation about quality issues from specific facilities, production lines, product types, employees or departments can be used to target relevant training that reinforces the knowledge needed to perform well.

Metrics for Visibility

Companies that effectively use metrics to improve their training, compliance and operational performance typically turn to a technology-based management system that links data from across the entire organisation. By consolidating the data into a coherent system, managers are able to identify trends and respond quickly. There are key considerations in choosing a technology system capable of delivering the desired functions and results. Among those considerations: interoperability of the new system with established corporate infrastructure; presentation of data in real time; scalability to allow the seamless extension of existing programmes and systems to new facilities; flexibility to allow customisation for company-defined formats; data security and compliance with mandated documentation requirements; and robust capacity to handle additional company programmes and initiatives for the distribution of training, communications, competency testing, qualification certification, programme management and oversight.

Document, Document, Document!

There's a saying in the compliance profession: "If it isn't documented, it doesn't exist." Documentation has always been important; now, with the implementation of new laws including the US Food and Drug Administration Safety and Innovation Act (FDASIA), documentation has taken on even greater significance.

Life Science companies face several issues in achieving effective documentation management. Many companies have several, often unconnected collections of documents. Conflicting policies among different facilities or even departments within the company increase the risk of inconsistency even further. In addition, some companies continue to rely on paper records that are easily lost, damaged or cannot be validated for accuracy. Increasingly, the consequence of poor documentation is a serious violation of Good Manufacturing Practices (GMPs), with the resulting enforcement actions by regulatory agencies and law enforcement groups.

Documents Demonstrate Compliance

Effective document management has several components. Documents must be properly designed and distributed; they must be approved, signed and dated by the appropriate personnel; they must be regularly reviewed for accuracy and completeness; they must be stored in secure locations; and they must be available to regulators, investigators and compliance managers. Effective documentation procedures must ensure not only the quality of the recorded data but also the security of the records, and the validity of the signature (electronic records must comply with 21 CFR Part 11). Access should be limited to authorised personnel only and any corrections must be signed and dated. Recent FDA inspections have uncovered instances of falsified, nonexistent or destroyed records. For several companies, the cost of those "simple" documentation issues was a Warning Letter from FDA or a ban on the facility's products.

Conclusion

The market for Indian Pharmaceuticals is expected to more than double in the next seven years. Along with that expanding market comes increased regulatory and consumer scrutiny, particularly regarding product quality and related quality training. Quality and compliance training is a challenge for companies at every sector of the Life Sciences industry. Even companies with well-established compliance programmes want to know why their training programmes aren't working. Why are they still receiving complaints from regulators about inadequate knowledge and performance by employees – despite the company's substantial investment in its compliance programme? For smaller companies or for those new to the emerging quality demands of global markets, the challenge of developing and implementing quality training programmes can seem overwhelming in complexity. Although companies may have different budgets, workforces, compliance requirements, product lines and facility locations, they can all benefit from these five building blocks of effective quality training, which have been gleaned over many years from our work supporting global companies and the US FDA's training programme. ■

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