

INTRODUCTION

A myriad of exciting, but often frustrating challenges face today's pharmaceutical, biotechnology and medical device companies. Individuals working in these industries contribute, commonly without much recognition, to the discovery and manufacture of major advancements in human health. These employees have to navigate through a complex set of regulations set up by the watchful government or governments of the markets into which the company sells. They must know, understand, and follow all the regulatory requirements while controlling costs and remaining prepared for the next audit. Keeping up with the latest regulations and tools to maximize productivity and compliance poses a unique challenge on its own. Recently, in addition, they've had to do much more with less, given the rapid expansion of many companies and the consolidations and acquisitions of others.

Well-trained and resourceful employees are a well-known key to success for any company. Additionally, as demonstrated by some recent consent decrees, the FDA and other regulatory bodies have certain expectations about the level of training and demonstrated ability of key personnel at life science companies. Attention to employees, including their quality of performance skills and their diligence to compliance issues should warrant a place of importance in the company culture.

EMPLOYEE COMPLIANCE

The FDA administration has sent a strong signal that they will take action against drugs and devices that fail to meet quality standards. "As the nation's top enforcer of manufacturing standards, the FDA will continue to ensure that drugs being sold in this country meet those crucial requirements," said former FDA Commissioner Dr. Lester Crawford.¹ Companies found not meeting current good manufacturing practice (cGMP) standards have been ordered to stop manufacturing and distributing their products until they become compliant with cGMP standards to the satisfaction of FDA.

"Most every time that you see a 483 item, it can be directly related to training."
- FDA National Expert Investigator

Since the implementation of the Quality Systems Inspection Technique approach (QSIT) by the FDA, FDA-483 inspection reports have increasingly referenced the quality system regulation (QSR) stating that employees must have the appropriate "background, training, and experience" to perform their function within the organization. Personnel training issues are therefore becoming a standard FDA-483 issue under the FDA's QSIT.

For companies that sell or wish to sell in the United States, specific regulations on training include:

- 21 CFR Part 58: Good Laboratory Practices (GLP)
 - 58.29(a) Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

- 21 CFR Part 211: Good Manufacturing Practices (GMP) for pharmaceuticals
 - 211.25(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs in cGMP as they relate to the employee's functions.
 - 211.25(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.
 - 211.25(c) Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained.
- 21 CFR Part 606: Good Manufacturing Practices (GMP) for biologics
 - 606.20(a) The personnel responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components shall be adequate in number, educational background, training and experience, including professional training as necessary, or combination thereof, to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess.
- 21 CFR Part 820: Quality Systems Regulations
 - 820.25(b) Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.²

A company's quality systems are often the focus of FDA inspections. Without a quality approach to personnel training a firm can face regulatory enforcement actions from FDA including product approval delays, FDA-483s, Warning Letters and consent decrees, in addition to valuable time and money losses. Ensuring that a company has a training program in place that addresses features and recommendations by FDA will alleviate regulatory backlash. Under FDA's Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations draft guidance, management is expected to define appropriate qualifications for each position to ensure that employees are assigned suitable responsibilities. Within a quality system personnel should have the skills and knowledge necessary to perform quality work, understand the impact of their activities on the quality of the product, and be encouraged to supply suggestions regarding process efficiency and improvements. These components can be guaranteed and fostered with training.

IMPROVING PERFORMANCE & COMPLIANCE

Compliance and performance are the goals of every food, drug, cosmetic, blood, and medical device manufacturer. To achieve these goals in today's environment it is critical that companies have a well-trained workforce to successfully implement emerging new technologies. Technical training, training in theory and design, and specific system training are requirements to ensure that employees stay ahead of the latest regulations and possess the skills to get the most from software systems, sophisticated processing equipment and analytical instrumentation.

A survey of pharmaceutical workers found a majority reporting that increasing pressure from regulators and evolving regulations made them feel that additional training was necessary to keep current. In a survey conducted by PTi-international 74% answered that they would need re-training as a result of FDA's "Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach" initiative.³

Beyond the regulatory compliance issues and its significant implications, the optimal utilization of employees can also be a significant competitive advantage for a company. Likewise, if employees aren't performing to the best of their abilities or they are hindered in performing their tasks the company will ultimately suffer. However, given the nature of the burgeoning pharmaceutical, biotechnology and medical device industries, achieving maximum employee efficiency is not always straightforward. The Process Analytical Technologies (PAT) initiative, Risk-Based initiative, recent revised guidance from the FDA and increasing external pressures on organizations all combine and filter down to affect employees in various ways.

The ultimate objective of training must be to enhance performance in the workplace.

Training should be carried out to meet specific needs that have been identified. The need for training may arise from job specifications; process specifications; plans for new products or technologies; new regulations, and more. After the initial initiative to train an entire staff, additional training is often necessary for new employees, when employees change departments or roles, when significant process changes are made such as when new products are being produced, when new regulations change what is required of the employees, and when new technology comes available that improves productivity or reduces costs and risks.

Most employees will embrace the opportunity to attend training courses, particularly if they feel training will help them achieve their own personal objectives. Surveys have shown that employees' motivation for additional training is to seek professional advancement and increased compensation. If the proper culture is established, employees themselves can play an important role in researching and recommending valuable training opportunities.

Another practical strategy for improving employee productivity is the outsourcing of non-repeating, discrete jobs that are not associated with core strengths and objectives of the company. When done with internal resources, these tasks shift the focus of employees off their areas of greatest

competence and contribution to the organization, sap energy, and are generally not performed as well as could be done by a company with strengths and experience in that area. For example, a software implementation effort may be best outsourced to a vendor with expertise in that specialty. By outsourcing appropriate activities, life science companies can ensure that staff and resources concentrate on and achieve their key tasks and responsibilities.

CHOOSING THE RIGHT TRAINING

Training programs do not need to be complex. Introductory level and broad based training courses present overviews and provide a framework of knowledge for further advancement ideally suited for employees assigned to new responsibilities, those new to the life science fields, or supervisors whose tasks involve oversight of various departments.

Focused training topics are ideal for veteran employees or key personnel who need specialized technical training on specific aspects of their job. Regulatory compliance training ensures that workers in the industry are adequately trained in the area in which they work. For example, it is estimated that 70% of lab resources are devoted to compliance activities. Laboratory controls encompass everything from specifications, sampling plans, test procedures, investigations, calibration, equipment qualification, stability testing, documentation maintenance, and other important areas. Each of these areas includes a gamut of techniques and procedures to establish and implement GxP controls. Seeking out and attending focused, in-depth training on any one of these areas would be a critical requirement for employees appointed these specific tasks.

Training is an essential component of quality.

Training designed for specific hardware or software systems can be offered directly by the vendor or OEM or by a third-party trainer. Generally speaking, the greatest value is received directly from the vendor as they have the greatest familiarity with the software and its applications, particularly if they are also directly involved with on-site implementations and optimizations. There may be different training for administrators of the system versus regular users. For example, the administrators need to be familiar with all the different configuration options and how to optimize the system for the company's specific needs. In some cases it may be possible to have a single individual attend the formal training and then come back to train the rest of the employees, referred to as "train the trainer". However this requires significant time investment and a unique skill set from the designated internal trainer.

Relying on or expecting veteran workers to informally train newcomers on-the-job is not an adequate training method in a regulated environment. Many veteran workers either are not very good trainers – or do not want to be. Commonly, the time to train and oversee new employees is not factored into veteran's daily schedule and they resent the additional burden placed upon them. As a result, incomplete and poor information invariably gets passed along. Structured on-the-job training conducted by qualified individuals requires advanced planning and a method to evaluate the newly trained employees ability to perform tasks with minimal supervision.

There are various training delivery options all with their respective features and benefits. Public training sessions allow for networking and interacting with peers working with similar challenges and responsibilities at other organizations. It can be reassuring to learn that others in the industry struggle with similar problems and issues. Often they are held in another city, an attractive destination, and therefore can be used as a reward for good performance or as a clear demonstration that the company values the employee's professional development.

If a company has multiple employees that need to be trained on a topic, then it is often more cost efficient to arrange on-site training. The per student costs are usually much less, particularly taking into account travel time and costs, and the content can often be tailored to a company's exact needs. Sensitive proprietary issues, corporate initiatives and/or departmental strategies can even be discussed among attendees.

There are very few disciplines in the life science industries that do not have significant regulatory concerns connected with decisions and procedures. Therefore, in most cases, regardless of the type of training selected it is a good policy to ensure that the training emphasizes the unique requirements and decisions associated with regulated life science industries.

RECRUITING QUALIFIED, HIGH PERFORMING EMPLOYEES

Another factor that contributes to employee performance is the loss of talent during company mergers or downsizing during periods of slow growth. Losing skilled and talented employees in these situations places adverse strains on any remaining or evolving critical projects and depletes already stressed organizational resources. When the time arises to hire again, hiring unskilled but disciplined and energetic individuals can alleviate the labor shortage but these new employees require intensive training. After making the investment, it is possible to keep new employees motivated by creating a working environment that offers a sense of belonging and encourages growth through professional training and development experiences.

A performance issue that arises when hiring employees that have worked at other life science companies is the inherent gaps in their knowledge due to differences in company-to-company procedures and SOPs or experience. Quality systems in the life science industries typically include a multitude of standard operating procedures (SOPs). SOPs are the documents that detail the routine and non-routine tasks that must be performed at each step in a manufacturing process. SOPs describe how procedures and situations are supposed to be handled, even emergency situations that the company has never experienced before. A majority of inspection observations relate to a lack of proper training when employees covered by a SOP are not trained on the contents of that document. It is important to ensure that these employees are competent at the specific skills and talents they will be responsible to perform at their new place of employment.

It has been well documented that the number of jobs in the rapidly expanding biotechnology sector far exceeds the number of skilled and qualified individuals to fill these jobs. The US Labor Department has recognized the shortage of knowledgeable labor and the need for increased training

in the life sciences to meet labor demands from the biotechnology sector. Recruiting and selecting employees with the necessary and appropriate skills is an ongoing exercise for many life science companies.

Industry and discipline specific web sites offer affordable job posting services, often free. Calibration resource sites such as eCalibration.com, callabmag.com, and professional organization sites such as ncsli.org for example, visited by thousands of calibration professionals, can be a valuable way to advertise open positions to a very targeted and skilled audience. These and other web resources are generally well known by the professionals they serve and it benefits human resource departments to become familiar with them and utilize services the web sites have to offer.

With the challenges and costs of recruiting new qualified employees, maintaining proactive employee training and professional development initiatives that enhance the proficiencies and contribute to the growth of current employees will help in retaining talent that might otherwise leave the organization.

TRAINING IN REGULATORY ASSET MANAGEMENT

With recent changes, one area where training offers a clear value is in regulatory asset management. Specifically, new regulatory and financial pressures and new technologies have encouraged a greater emphasis on an integrated strategy for asset management and have therefore increased the requirements for new depths of understanding in each discipline and additionally broader inter-disciplinary familiarity.

The Quality System Inspection Technique advocated in the 1999 "Guide to Inspections of Quality Systems" formally introduced the FDA's theory of a company's complete "quality system" containing seven sub-systems:

- Management Controls
- Design Controls
- Corrective Actions & Preventive Actions (CAPA)
- Production & Process Controls
- Material Controls, Records, Documents, & Change Controls
- Equipment & Facility Controls

Not going unnoticed by the industry is the grouping of maintenance, calibration, and validation into a single sub-category: Equipment & Facility Controls. This categorization is clearly encouraging companies to take a broader look at how these disciplines interact and support each other.

Meanwhile, the FDA is recruiting and training inspectors with more diverse backgrounds, exposing new areas of a company's business to increased depth of scrutiny.

Also changing the landscape for asset management is the increased financial pressure being placed on life science companies. Leaner staffs mean that more people have to be trained in multiple areas to provide the redundancies required to cover vacations and natural turnover. Meanwhile, more

sophisticated technologies and procedures being introduced to improve productivity in all areas mean employees are having to learn new ways and ideas quickly, such as:

- Increased automation and paperless systems for calibration management
- Sophisticated analytical techniques
- Streamlined and more strategic master plans

Managers too are finding themselves either responsible for additional disciplines or charged with finding ways to improve synergies across departments. In both cases, a broader understanding across disciplines is becoming an important prerequisite for a manager's success.

To maintain compliance and maximize productivity, employees will need to master these and other new technologies and techniques, developing a greater depth of understanding of not only the changes in the science and art of their own discipline, but also the regulatory changes that require changes to behavior, including enhanced documentation of changes and reasons for changes. In short, they will need to acquire knowledge that does not currently exist within most life science organizations.

At the same time, management will be challenged to find new ways to reduce operating costs through synergies between departments. A calibration technician may uncover a need for maintenance on a piece of equipment. Likewise, the actions of the maintenance technicians can often spawn a need to recalibrate or even re-validate a piece of equipment. What procedures and systems can be put in place that reduce redundancies and facilitate collaboration between calibration, maintenance and validation while maintaining secure control over changes to a validated process?

Individuals involved in decisions that involve multiple disciplines should take it upon themselves to understand the regulatory and productivity implications in the balance between the needs of different departments. Increasingly decisions made for one department can have a significant impact on the productivity of another department, completely reversing the anticipated gains. Regulatory asset management training courses that view asset management in the life sciences as an integration of maintenance, calibration, validation and change control into a single strategic plan and vision are a good choice for companies trying to minimize risk and maximize productivity.

In most cases, the best way to gain this inter-disciplinary insight is through external training, which has the advantage of being more objective than internal resources, being securely isolated from the natural interdepartmental politics common within most organizations. Additional benefits of these external training courses include:

- Sharing of experiences and knowledge between other professionals in the industry
- Gaining broader perspectives on current topics and trends in the industry
- Instructors have extensive experience and greater access to best practices

ABOUT BLUE MOUNTAIN QUALITY RESOURCES

Blue Mountain Quality Resources is a leader in providing calibration management solutions for regulated life science manufacturing companies. Blue Mountain's Calibration Manager, the Best in Class calibration management software designed for life science companies, allows companies to improve their operating efficiency, maintain requirements for compliance and maximize their return on investment.

With over 15 years of experience Blue Mountain offers a complete set of solutions for any size company from set-up and installation to training and validation. Blue Mountain's regional Calibration Manager training courses are designed to provide the tools and skills needed by Calibration Manager users to obtain optimal performance and compliance. Regional training classes are scheduled throughout the United States at state-of-the-art computer training facilities and utilize a small group format that fosters interaction between the instructor and other students. On site training can be arranged and tailored to meet the facility's unique needs and requirements.

Blue Mountain Quality Resources, Inc. and eCalibration.com have teamed up to offer informative and professional training seminars focused on unique aspects of regulatory asset management including both introductory and advanced GMP calibration and maintenance topics. Courses are designed and instructed by independent, professionally recognized training consultants who are leading industry experts in issues particularly relating to calibration, maintenance, metrology, and qualification applications in the pharmaceutical, biotech, laboratory, R&D, and production environments. Training courses are offered throughout the year in public sessions located across the country and also are available for customized on-site facility presentations.

For more information about how Blue Mountain Quality Resources can help improve employee performance and compliance visit www.coolblue.com, email us at training@coolblue or call 800-982-2388.

REFERENCES

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