COMPETENCY-BASED ASEPTIC TRAINING PROGRAMS IMPROVE LEARNING, ENGAGEMENT, AND PERFORMANCE

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In a perfect world of quality assurance and quality control, it would seem unimaginable for these events to happen in your cleanroom:

- Operators on all fours crawling on the floor under the filling line during routine aseptic filling operations adjusting or removing vials from the line wearing gloved hands rather than restricted access barrier system gloves

- Poor facility and equipment design inadequately protected the sterile product during manual manipulations, posing a substantial hazard to product sterility and an unreasonable risk to patient safety

- Failure to follow appropriate written procedures specifically designed to prevent microbiological contamination of drug products purporting to be sterile, and that require validation of all aseptic and sterilization processes

The events listed on the left represent US FDA investigator citations typical of what pharmaceutical companies operating in a sterile manufacturing environment would see as 483 observations during a routine FDA inspection.

The FDA expects sterile drug manufacturers to maintain a keen awareness of the public health implications of distributing non-sterile products. Poor and lax current Good Manufacturing Practice (cGMP) conditions at a manufacturing facility can ultimately pose a life-threatening health risk to patients. As a result, the Agency provides guidance to help companies meet the requirements in its cGMP regulations (21 CFR parts 210 and 211) when producing sterile drug and biological products using aseptic processing.

It's no coincidence that aseptic processing, along with environmental monitoring and sterilization represent three of the FDA's top 10 areas of ongoing scrutiny for organizations operating cleanrooms. Training ranks a close fourth. Yet, despite its relative importance for building and

sustaining the competencies that support regulatory compliance and risk mitigation, training is often a topic that suffers from a low priority among the executive team and the resource allocation pecking order.

This could be attributed to perceptual and operational hesitancy in the sterile manufacturing space, since developing an effective skills training program takes time, funding, and:

- Requires indirect human capital to develop the course curriculum and analytics

- Can be more complicated than originally projected

- Suffers from a misperception about the value of the skill sets needed

- Is impacted by an institutionalized "re-train" mentality that offsets investing in a long-term development solution that elevates learning, engagement, and performance

MAKING A CASE FOR EFFECTIVE TRAINING #1: ASEPTIC GOWNING

CHALLENGE

An unacceptable rate of gowning monitoring failures resulted in deviation reports, additional testing, and retraining. This caused the employee to be restricted from the aseptic production area and product lots placed on hold.

SOLUTION

The sterile plant team developed a best practices training regimen and behavior classes with a focus on aseptic gowning.

OUTCOME

• Resulted in development of basics of microbiology, aseptic gowning, and aseptic behavior training modules that focused on how product quality was impacted by the employee, their behavior, and interaction with their environment

• Learner comprehension was tested before, during, and after training

• KPIs were used to evaluate success: incidence rate of personnel monitoring and production line environmental monitoring failures, deviation reports, and lot rejection rates

• Operators who were physically unable to successfully gown and maintain acceptable levels of asepsis were reassigned to other areas

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With regulatory enforcement becoming more stringent, the days of cleanroom operators performing tasks by rote, or executing them incorrectly because that's how their predecessors did it, are over. More organizations are concluding that it's time to drill down deeper – beyond SOPs and OJT checklists – and raise their training profile. Studies show that competency and skills training can deliver long-term benefits that:

• Empower employees with the underlying knowledge to perform their jobs at the highest level of proficiency

• Enable employees to understand why competencies are required for the jobs they are doing, and why what they do is important

Competency training is as critical to an organization's success as maintaining a high level of audit readiness.

Specifically designed to measure technical skills, competency programs serve as foundational elements of "critical to quality" initiatives. In addition to helping organizations remain compliant with the FDA and other regulatory agencies, a well-designed competency-based aseptic training program addresses these business performance issues:

• Reduce work stoppages, compromised product sterility and other failures

• Mitigate risk exposure from FDA observations

• Minimize allocation of time, money, and human resources for CAPAs

• Improve performance, productivity, and quality for competitive advantage

• Raise workforce morale and motivate the pursuit of excellence

• Simplify life for everyone from the shop floor to the executive floor

Managing a cGMP-compliant cleanroom operation is predicated on your ability to select and train personnel that have both specific technical skills and a quality culture mindset. This calls for a comprehensive competency mapping strategy that can identify the requisite skills your team needs to perform aseptic processes on a reliable basis.

As a skills development exercise, competency mapping is one of the most accurate means of identifying the job and behavioral competencies of an individual in an organization.

Forward facing pharmaceutical companies engaged in aseptic processing operations should consider a skills development framework similar to the "Seven Steps" example that follows.

These steps map relevant, competency-based actions that need to be conducted for each job function, so that an organization can achieve compliance, and at the same time improve business performance.

SEVEN STEPS FOR BUILDING A SUCCESSFUL SKILLS DEVELOPMENT FRAMEWORK

STEP 1 Assess each role within the area, and walk through the processes that each role interacts with.

Role and Importance: Enables companies to focus on specific skill sets, improves audit results when companies are asked for qualifications by role, and allows HR and department heads to identify potential recruits.

STEP 2 Define the skill levels and competency levels for each job function.

Role and Importance: Provides employees with the skill sets to advance along the "basic to expert path," and delivers more objective results for performance management.

STEP 3 Align similar roles, similar competencies, roles to competencies, and other relevant company scales.

Role and Importance: Allows for more targeted training, improves retention, and reduces over-training.

STEP 4 Develop role-based training programs, curricula, and technical competency models.

Role and Importance: Builds a competency management database that standardizes job functions and skill sets, while ensuring consistency and efficiencies across the organization.

STEP 5 Implement and deliver both training programs and technical competency programs.

Role and Importance: Ensures objective evaluation by integrating data from multiple sources. Results can be used for "pay for performance" and provide advancement opportunities. Metrics may include a cohesive system of self-assessments, coaching/feedback, testing, performance demonstration, process metrics, e.g., manufacturing waste and rejections, and ongoing match-up of job descriptions with employee performance and training assignments.

STEP 6 Track and report qualifications to these programs, identify skill and competency gaps, and drive training that closes these gaps.

Role and Importance: Puts predefined skill performance programs in place to improve manager coordination and consistency.

STEP 7 Monitor skill and competency development, evaluate if progress is on track, and adjust accordingly for each employee, team, unit, department, and physical location.

Role and Importance: Provide managers with ongoing progress reporting to ensure continuous discussions between managers and their direct reports.

Applying this disciplined framework can help design and integrate the competencies and training elements required to operate an effective and compliant cleanroom. The tasks incorporated range from FDA aseptic processing expectations, aseptic and microbiology basics, and aseptic gowning to aseptic technique and cleanroom behavior, cleaning and sanitization, and environmental monitoring.

MAKING A CASE FOR EFFECTIVE TRAINING #2: FREEZE DRY PRODUCT DEVIATIONS

CHALLENGE

Human performance deviations were above desired levels resulting in product lots being quarantined and at times, rejected, causing critical supply issues. As a result, lengthy time-consuming investigations were required to determine corrective actions or to test product quality.

SOLUTION

Goal was set by the Freeze Dry team to reduce human performance deviations by at least 50 percent. All Freeze Dry team personnel were trained in incident investigations and root cause analysis, resulting in effective CAPA implementation.

OUTCOME

The training effort focused on teamwork and communication across shifts, and not solely on the technical aspects of the freeze dry operation.

As a result, the unit was able to reduce human performance deviations by half, from 10-12 per month to 5-6 per month along with several months where no incidents were recorded

"PAY FOR PERFORMANCE" AS A STRATEGY

A global leader in pharmaceutical manufacturing saw the long-term value and benefits of implementing a pay-for-skills competency and training initiative with clearly defined goals. The program was designed to streamline training across its manufacturing division, and to create a skills-based training platform that placed each role and career path onto levels that synced up with their HR-administered and approved pay scale ranges.

Grounded in a foundation of assessment, alignment, and development functionality, The company's program methodology includes the following activities:

• Review job descriptions and training plans for each role in each department; list each core competency required for each role; create a master file for the plant; consolidate the master list and review for commonalities

• Rate each competency based on relative skill level (basic, intermediate, advanced); do the same for equipment-related job functions and responsibilities

• Combine roles with common titles where major similarities exist; identify common training courses, SOPs and OJT checklists required across the various roles; develop a training plan for each new role

• Leverage synergies by identifying opportunities to consolidate training across roles and departments; group roles into dedicated career path stages where each stage has corresponding competencies; align each role and career path with levels that correspond to the HR approved pay scale

With an eye on results, the company put tools in place to identify and close training gaps, and added metrics for ongoing measurement and analysis of competency.

EMPOWERING YOUR WORKFORCE FOR COMPETITIVE ADVANTAGE

The 21st century sterile manufacturing environment continues to grow more knowledge intensive increasing the demand for Life Science companies to recruit, train, and retain top talent. "Sustained competitive advantage is no longer rooted in physical assets and financial capital, but in effective channelling of intellectual capital."

Competency-based aseptic training initiatives are designed to help leverage your organization's intellectual capital so they can operate effectively in a cGMP-compliant cleanroom environment.

The framework you put in place will help build a culture of quality, and add value to your organization by:

• Increasing its audit and compliance readiness

• Reducing the incidence of failures

• Enabling staff to understand the importance of competencies to their jobs

• Improving personnel mastery of skill sets

• Recording and documenting all training so it becomes part of the curriculum

• Protecting your brand reputation and balance sheet

This is an exerpt from a UL webinar held on September 14, 2016, on "Developing a Competency-Based Aseptic Training Program", featuring GMP consultant Ann Early. A recording of this webinar is available at http://www.ulcompliancetoperformance.com.