HOW TO ENSURE THAT KEY ROLES HAVE THE RIGHT TRAINING PLAN

by Anne Davies

A common theme we discuss with our clients is the need to be sure that individuals know what they are expected to do. Poor, inappropriate actions, or just inactivity, can lead some people's managers and colleagues to believe that they are either incompetent or not aware of the expectations of their role. It could be that their role is not well defined or scoped. In these circumstances it is easy to see how things fall through the cracks.

Invariably, we find that education in the technical understanding of the business helps to change behavior; after all, our industry has never been better equipped with highly qualified and intelligent people. What we need is to provide context and breadth of understanding. Application will usually follow and with that appropriate behavior. To help clarify roles, I have been working with a number of clients on certifying key roles, and the results have been very positive. Feedback from the individuals has shown that they finally "get it" and working in the QA, manufacturing or QC environment is so much easier and rewarding.

ROLE DEFINITION

The GMP regulation on this subject can seem quite vague, but really finding out what is required for a role is not so complicated. There are drivers such as SOPs, company values and role responsibilities, and these can be used to prepare a training matrix for the role.

SO WHAT IS EXPECTED FOR THE INDIVIDUAL?

Each job to have a job description

- Role description
- Requirements of the job
- Some companies have targets but this is unusual

Training Matrix or Plan per individual

- Compliance training
- Education requirements to perform
- Record of performance/tracking of completion

Then we need to look at how to structure a certification or qualification process. I have found that this needs to be structured and broken down with key roles identified. Here is a typical flow of activities leading to good learning processes and ultimately individuals who understand their role and how to behave. (See figure 1.)

THE STAGES

The educational element is where you provide the context. No matter how qualified your graduates are when they enter your system, they are at best naive and at worst dangerous when let loose on pharmaceutical processes. Ensure they get the best educators and that this education is broad and all-

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WHAT IS CERTIFICATION?

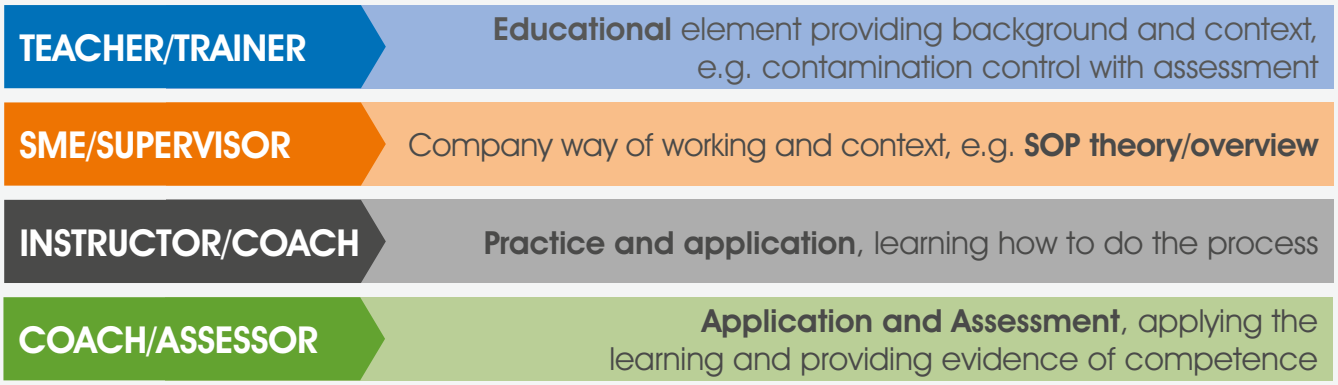

Figure 1.

encompassing for the role – it will pay dividends in the short term and compound interest in the long term as they progress through your company to become decision makers of the future.

The SOP theory is very company-based and should cover what recent recruits need for the job, focusing on the areas of real interest to their role. Do not be tempted to swamp them with everything all at once, as they will get to know the nuts and bolts of your business over time. Initially, they just need to know their role and their responsibilities. Use an experienced person to guide them through this process, who can help with the background and answer questions and queries. With the contextual element covered already, they will review this process from an enlightened point of view of logic and it could start to provide that light bulb moment.

Over time they will need to apply these two elements to their day-to-day activities and you will need a coach or instructor who has experienced these activities and who is a good practitioner as you want good habits forming. This process should not be rushed either; there is no fail, just time to get it right and learn from mistakes.

Assessment needs to be in a positive environment linked to proficient testing, feedback and coaching throughout the process.

SUGGESTED CERTIFICATION CONTENT

Batch Release/ Review	QC Microbiologist	Deviation Champions	Internal Auditor
> QMS	> QMS	> QMS	> QMS
> Pharma GMP	> Pharma GMP	> Pharma GMP	> Pharma GMP
> Applicable Product Manufacture	> Applicable Product Manufacture	> Applicable Product Manufacture	> Applicable Product Manufacture
> Analysis & Testing	> Pharma Micro	> Investigation Techniques	> Pharma Packaging
> Pharma Packaging	> RBDM	> RBDM	> Auditor skills
> RBDM			
> Pharma Law & Admin			

Figure 2.

This overall process works well for most roles, and can be adapted to allow for an individual's pre-qualification or experience. I have found that with mentoring, feedback, and experience dealing with problems, people gain confidence in taking action and are better able to defend positions and challenge and change poor situations.

WHAT ROLES?

Some of the typical roles I have recently worked with have been surprising. The figure shows an example of the roles and the content of education that has been applied, some by NSF and some by internal training. (See figure 2.)

The roles in figure 2 might not be what most people expect with certification programs, but they have all made sense. In the QC microbiologist example, our client was working with sterile products and during investigations the QC micro laboratory was called on to provide extra testing and results. They were not consulted or used in the investigation team. By increasing their breadth of knowledge in the way indicated they were able to help with contamination control in manufacturing. By joining the investigation team with a part to play in problem solving, the micro lab team members were able to add their unique knowledge to the solution finding, gaining renewed confidence and understanding of the practical challenges of the production area.

ABOUT THE AUTHOR

Anne Davies has worked in the pharmaceutical industry for over 30 years, with experience in analytical QC, QA and general QMS management. She supports client needs, working closely to ensure the service provided addresses all clients' training and compliance requirements. She has worked with a large number of companies, most recently in the development of custom training programs that provide the basis for role certification in the area of quality and production.

Ms. Davies also worked at the site level as Training and Development Manager for around 600 staff developing systems for competency training, training record systems and educational programs for QPs and professionals on the site.

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