



# CERTIFICATION LEARNING PATH TO EXCELLENCE

by Anne Davies

## CERTIFICATION OBJECTIVES

In a pharmaceutical environment the quality of the product is heavily reliant on the knowledge and understanding of the people. They must know their products, their use and the production processes. Evaluating the processes will quickly highlight the 20 percent of roles that have 80 percent impact on the quality of the environment in which the products are produced. By focusing on this 20 percent and providing good education and a learning environment, we can start to ensure the whole process of manufacture and testing.

These roles include:

- > The batch reviewer
- > The quality event investigator
- > The auditor
- > The QC microbiologist
- > The aseptic operator (including the gowning process)

## SETTING THE SCENE

The first step is **defining the job description** for each role, specific to the job, site and working environment. It must define the relationship with others, key accountability and expectations.

It should include a general competency set for the role, including **skills, knowledge and behavior/attitude** expectations that can be observed and measured in some way.

Selecting the individual is critical, as each individual must be willing to learn and grow in the role, engaging in a learning contract with the organization that will provide a win-win situation for the individual and the company.



**Tailoring the development plan** for the individual is an important start to engagement in the path of learning. This must be entered into openly by all parties, and healthy discussion of topics and methods of learning will result in a far better level of commitment and understanding of goals and expectations.

Learning and development does not happen overnight; the roles above are complex and require deep levels of knowledge and skills. Using a mentor or coach is essential. If this person is chosen early in the process, the relationship can build trust and respect from both parties, which is required for robust and open discussion throughout the development path.

## METHODOLOGY-RICH ENVIRONMENT

Choosing a good mix of learning opportunities and methodology (blended approach) is essential to ensuring that the individual will be fully challenged and will get to develop their learning tools. However the main emphasis must be on **active learning**, both in the classroom and workplace, which ultimately provides the best outcomes. For example, the classroom allows a group to work as a team to solve a problem and to learn from each other through discussion, debate, feedback and presentations.



The environment of the workplace is equally important. It can be supplemented by adding challenges to the role, spending time with colleagues doing a different role and choosing projects to stretch the competencies that need to be developed. **The allocation of a project** for the individual is a rich environment for learning. Chosen carefully and with the right business backing, it can create opportunities for individuals beyond their day-to-day roles and benefits for the organization.

## ASSESSMENT AND EVALUATION

Good evaluation practice includes using concrete measures for learning, asking What have they learned? and Do they use it? Clear guidelines for how to measure success should be established prior to commencing any activity in the learning path. These can be a mixture of learning objectives/outcomes and business objectives/outcomes. Milestones and key activities should be identified. For example, if a learning event is for the individual to spend one week in another working environment, then the expectations of this week should be laid out and could include a new way of approaching a task or a review of current practice.

## LEARNING METHODOLOGY

### 1. Inquiry-based learning

Through asking challenging questions, learners get intrinsically motivated to start delving deeper to find answers to these questions and in doing so they are exploring new avenues of knowledge and insight.

### 2. Problem-based learning

Students engage complex, challenging problems and collaboratively work toward their resolution. Problem-based learning is about students connecting disciplinary knowledge to real-world problems—the motivation to solve a problem becomes the motivation to learn.

### 3. Active learning

Students take greater control over their learning and as such the learning is open-ended and not always predictable. Active learning brings together all of the

interactions that students have in the workplace and in the classroom (e.g. case studies, group work, role play).

## EVALUATION METHODOLOGY

Variation and appropriateness of the process are key to success. Choosing the right method for measurement and the right timing will maintain a level of fairness, openness and honesty. Methods typically should include:

- > Knowledge questionnaires – either paper or electronic
- > Observation by peers and SMEs – need to be formalized and, as far as is practicable, objective
- > Feedback and discussion – generally should be recorded
- > Learning log of events and progress (per activity and/ or overall) – entered by the learner and reviewed by an agreed assessor
- > Simulations with hidden errors
- > Performance reviews for job tasks
- > Presentations

Knowledge assessments after classroom events provide hard evidence that the right knowledge is taken away. Targets are harder to set in the workplace, and must use tangible measurements such as Has the performance improved with respect to audit reporting? or Did we see a good use of decision making techniques during an event investigation? Checklists of performance or observed behavior carried out by assessors provide hard evidence. Assessments and evaluation techniques must be agreed prior to any event and aligned with the objectives of the event. It is no good trying to measure something that was never there in the first place. The people doing or setting the assessments need to understand the process, be impartial and understand the learning objectives. **Selection and education of the workplace assessors** therefore is crucial to the success of the learning path. Assessors may not be necessarily the same person as the coach or mentor; in some circumstances it will need to be a local SME.



## REACHING THE FINISH LINE

The certification process for individuals is both intrinsic to their job activities and also very emotionally linked to their personal satisfaction in the workplace. Reaching the final approval stage will need to be recognized appropriately within the culture of the organization. Records of the process need to be formalized and if the particular certification requires re-evaluation or recertification after a period, the initial document should display this.

## 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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