

## Qualification of Employees for GXP Compliance

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### INTRODUCTION AND OBJECTIVE

This paper discusses qualification of specific categories of employees in a GXP environment. Employee categories addressed include production operators and technical subject matter experts (SMEs). These personnel are designated for specific critical tasks in an organization. Concepts discussed herein are also applicable to laboratory analysts.

This paper follows previous published work that discussed new employee orientation programs, associated GXP training, and a continuing current good manufacturing practice (CGMP) training program. The present paper is useful to anyone working in regulated industry with an interest in, and responsibility for, training programs. It also is useful to quality assurance personnel who evaluate training and its relationship to deviations, out-of-specification (OOS) findings, and associated excursions as part of investigations.

The first part of this article discusses types of employee training, including awareness training, training *per se* (which includes a paper-and-pencil assessment), employee qualification (i.e., training that includes a skill demonstration), and qualification of SMEs. The second part addresses types of qualification, including employee qualification as process and as status, as well as the use of skill demonstration assessments (SDAs) in employee qualification.

The third part focuses on the rationale for qualification, highlighting the role the qualification process plays in deviation investigations and root cause analyses. The fourth part considers the criteria for deciding what kind of training is appropriate for a specific procedure; this depends on the complexity and criticality of the procedure and the associated process. The final part delineates two other aspects of the qualification process, employee disqualification and employee requalification.

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