Writing Pharmaceutical Equipment Qualification Protocols

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ABSTRACT

Development and construction of validation protocols is a critical activity in the validation process. Writing protocols is a comprehensive activity that should involve the entire validation process. This discussion adds important considerations for protocol writing in addition to activities in the general validation "V" model. These considerations are consistent with the evolving lifecycle approach to validation. Earlier involvement of site groups in the validation process, post validation monitoring and maintenance, testing planning, and comprehensive documentation prior to and following qualification testing are discussed. This discussion also provides practical hands-on suggestions and examples to facilitate the protocol-writing process for equipment and other applicable qualifications.

INTRODUCTION

Every validation professional has been tasked with writing technical protocols as part of their job. Having the responsibility to write a protocol for a piece of equipment or process that may never have been seen before is extremely challenging; it sets an expectation to essentially become a subject matter expert (SME) on the assigned project within a very limited timeframe. Some organizations provide standard templates for use in writing protocols. A standard template is ideal in theory, but is not always easy to utilize and is not applicable in all situations. The writer must understand the need for equipment and operation of equipment so that appropriate protocol tests may be designed. Attention must be given to the attributes, functions, and parameters that are going to affect the required performance of the qualified equipment. The protocol must be approved by SMEs, quality assurance, engineering, validation, and other departments; their perspectives must also be considered in development of protocols.

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