The Qualification or Validation of Laboratory COTS Computerized Systems

By Adnan Wasim May 30, 2018 8:14 am PDT

Introduction

Advances in testing technologies have significantly increased the functionalities and controls of laboratory instruments through dedicated software over the two last decades. Regulatory emphasis for data security and safety has led to these software to be more compliant with current regulations. The vast majority of software used in a laboratory are Commercial-off-the-shelf (COTS) applications that load onto local computers. The validation for a new system, or a remediation, approach for a Laboratory COTS application that normally resides within a company's computerize system validation program can be cumbersome if the implementation is not planned.

Computerize System Validation Approach

A common approach that is widely used is a System Life Cycle program with five or six phases (initiation, design or requirements, installation/testing/validation, pperation, and retirement). Each phase has multiple deliverables which include:

- Planning Documents
- Lengthy Risk Assessments (GxP/Regulatory/Risk)
- Design, Functional, User and Configuration Requirements Document(s)
- Vendor Testing Protocols
- User Acceptance Protocols
- Traceability Matrices
- Summary Reports
- Release to Service Notices
- Validation Documents or Deliverables Trackers

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