COTS Validation – The Best Approach for Off-the-Shelf-Software

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April 27, 2016
18th Annual Computer and Software Validation
Objectives

• Discuss differences in validation of COTS versus custom or highly configurable systems.
  – Defining what COTS systems are.
  – Implementing risk based approach to COTS systems
  – Leveraging vendor documentation when validating COTS systems.
  – Examples of validation approaches for COTS systems.
COTS Systems

- What are they?
COTS

• Commercial-Off-the-Shelf
  – Software defined by a market-driven need, commercially available, and whose fitness for use has been demonstrated by a broad spectrum of commercial users\(^{(1)}\).

\(^{(1)}\) IEEE
GAMP Category 3 Software: Non-configured

- Run-time parameters may be entered and stored, but the software cannot be configured to suit the business process.
- Examples
  - Firmware
  - COTS software instruments
COTS

GAMP Category 3

• Previously called **Standard Software**
• Non-Configured refers to configuration to meet business process.
• COTS software has grown in sophistication
• Some examples may be configurable to meet the business process.
  • These could be considered Category 4.
• A Category 3 approach can be used if the software is not configured and default configuration is used.
Categories of Software

- Category 1: Infrastructure Software
  - Windows
  - Oracle
  - Excel
  - SAS

- Category 3: Commercial Off-the-Shelf Software

- Category 4: Configurable Software
  - Watson LIMS
  - Medidata
  - Werum
  - Waters

- Category 5: Custom Software
What is a COTS system?

GAMP Category 3

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  • These could be considered Category 4.
• A Category 3 approach can be used if the software is not configured and default configuration is used.

What is considered configuration?
What is a COTS system?

Example

CTMS Vendor
• Claimed COTS status
• Reason – software was commercially available
• Vendor had ~ 20 clients
• Vendor is in collaboration with CRO to develop Monitoring Report Module
• Vendor claimed module would be COTS also

COTS IEEE Definition
• Commercially available ✓
• Fitness for use has been demonstrated by a broad spectrum of commercial users.
• Over a sustainable period of time. ✗

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What is a COTS system?

Question

Is a Mobile App considered off-the-shelf software?
Mobile Apps - Definitions

Mobile Platform
- COTS computing platforms
  - Handheld in nature.
  - Smart phones, Tablets, etc.

Mobile App
- Software application run on a mobile platform
- Web-based application tailored to a mobile platform but is executed on a server
Mobile Medical App

- Any Mobile App that meets the definition of a Medical Device and
- to be used as an accessory to a regulated medical device; or
- to transform a mobile platform into a regulated medical device.

It depends on the Mobile Apps “intended use”.
Is a Mobile App considered off-the-shelf software?

COTS Criteria

- Commercially available
- Fitness for use has been demonstrated by a broad spectrum of commercial users.
- Over a sustainable period of time.

If the mobile medical app uses off-the-shelf software, manufacturers should also refer to FDA’s “Guidance for Industry, FDA Reviewers, and Compliance on Off-the-Shelf Software Use in Medical Devices

COTS – Risk based approach

• Implementing risk based approach to COTS systems

Validation approaches for COTS systems.

Leveraging vendor documentation when validating COTS systems.
COTS – Risk based approach

- Understand what a COTS system is?

Determine how it will be used.

Identify risks to patient safety, product quality, and/or data integrity.

Document the risk assessment, including mitigation.

Validate accordingly.
COTS Validation Approach

- Abbreviated Lifecycle
- User Requirements Specification (URS)
- Risk-based approach to supplier assessment
- Record version number; verify installation
- Risk based tests against requirements
  - Regular calibration may substitute for testing
- SOPs for compliance and fitness for intended use

(3) GAMP 5
Suppliers and Service Providers

• Documentation supplied with commercial off-the-shelf products should be reviewed by regulated users to check that user requirements are fulfilled.

• User Requirements Specifications are required.
• Supplier documentation needs to be reviewed.
• Risk based approach to supplier assessment.
COTS

• Leveraging Vendor Documentation

• What type of documentation should be reviewed?
• Will documentation be reviewed during an on-site audit?
• Does the documentation meet pharmaceutical “standards”? 
What would you expect to see for a COTS validation?

- User Requirements
- Risk Assessment, including vendor assessment
- Validation Plan
- Configuration Specification
- Installation Qualification
- User Testing
- Traceability Matrix
- Validation Summary Report
Summary

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Questions

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