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Validation of ERP software and system architectures in a GxP controlled environment

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Abstract

ERP (Enterprise Resource Planning) is a software system which integrates all the business processes to run a company successfully. These software systems are widely used across all the industries like Manufacturing, Retail, Life Sciences, Banking and Finance etc. However, for pharmaceutical companies, the ERP systems must comply with GxP regulations which poses unique challenges. This whitepaper explores how to design and implement the software architecture of an ERP system in a GxP controlled environment.

Keywords: ERP Software; GxP Validation; ALCOA+

1. Introduction

GxP is a set of regulations and standards established by FDA (Food and Drug Administration) to ensure the safety, quality and efficacy of life science products such as medical devices, biotechnological equipment, and medicines. These standards are recognized as:

- **G:** Good
- **X:** It's a variable which can be **M** (Manufacturing), **L** (Laboratory), **C** (Clinical), **S** (Storage), **D** (Distribution), **R** (Review) etc.
- **P:** Practices

While at a high-level, it may look unrelated to the ERP systems or other technology systems, but the GxP validation process equally applies here which poses unique challenges due to FDA's focus on following areas:

- Traceability
- Accountability
- Data Integrity

2. Importance of GxP regulations

The GxP guidelines are global, therefore these regulations apply to regulated industries such as food, pharma, medical devices etc. however these guidelines might vary slightly depending on the country. Some of the major regulators include FDA in the United States, TGA in Australia and HS-SC in Canada.

Therefore, it's essential that regulated organizations prioritize GxP considerations in their day-to-day operations and continuously strive for excellence in maintaining the quality of the product, thus ensuring patient's safety.

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3. Validation process of ERP Software and systems

Validation of ERP systems and software falls under the **CSV** (Computer System Validation) guidelines which is a documented process to demonstrate that it meets a defined set of applicable regulatory requirements. Below are the most relevant guidelines for CSV:

- ISO 27001: 2022 - Information Security, Cybersecurity and Privacy Protection (Security Techniques)
- ISO/IEC 27002: 2022 - Information Security, Cybersecurity and Privacy Protection (Code of Practice)
- USFDA CFR - Code of Federal Regulations Title 21 Part 11 – Electronic Records and Electronic Signatures
- USFDA – Software Validation Guidelines – General Principles of Software Validation
- EU GMP guide Annex 11 – Computerized Systems
- Japanese ERES Guideline Notification No 0401022 – Use of Electronics records and electronic signatures for approval or licensing of drugs
- GAMP 5 (Good Automated Manufacturing Practice) - A Risk-Based Approach to Compliant GxP Computerized Systems
- ICH QSEM – The International council for harmonization of technical requirements for pharmaceuticals for Human use (Q: Quality, S: Safety, E: Efficacy, M: Multidisciplinary)

4. Importance of CSV Validation

The health and safety of patients are of utmost importance and therefore it's vital that a computer system consistently does exactly what it's supposed to do. *Nothing more, Nothing Less*.

The periodic CSV (Computer System Validation) can help organizations demonstrate their commitment to risk mitigation thus boosting the stakeholder's confidence. Please note that from the guideline's perspective, the 'Verification' and 'Validation' are separate and distinct terms. Both FDA and regulated industries define the ERP software validation within the context of process validation terminology.

5. FDA Part 11 Compliance Guidelines for ERP System validation

The FDA validation guidance describes the user site software validation in terms of:

5.1. IQ : Installation Qualification

This stage ensures the correct installation of the ERP software (e.g. SAP, Oracle etc.) in alignment with the hardware and other operating conditions. All the steps must be documented in validated tools such as Microfocus ALM, Tricentis qTest, OpenText ALM Octane etc. and evidence must be attached to it. It's important to capture the evidence (e.g. screenshots) in real-time with the help of these tools. A business audit in collaboration with the QA team must be done to cross-check the installation with manufacture's specifications.

Important documents resulting out of IQ step are IQ Protocol (Criteria), IQ Checklist (series of checks) and IQ Report (findings and results).

5.2. OQ: Operations Qualification

This phase tests the system's recoverability, security attributes, alert mechanisms, audit trails and all other system functions. Important steps are:

- Test Plan – Comprehensive set of steps to test all system and ERP software functions.
- Test Run – Execution of test plan in a varying condition with all the evidence captured in real-time.
- Defect – Any deviation from the intended functionality must be tracked as a defect linked to the corresponding test run.
- Test Results – Evidence to validate if the test run was successful or not and any corrective actions taken thereof.
- Validation Plan – Comprehensive set of guidelines to be followed for validating the outcome.
- Data Integrity Assessment – Guidelines for tracking any authorized or un-authorized changes for critical data sets. Most of the modern ERP software such SAP etc. have this functionality in-built.

Some essential documentations are OQ Protocol (Scope, Methodology and Acceptance Criteria), OQ Test Scripts, OQ Reports, Calibration records (e.g. any Addendums during OQ cycle), SOPs, RTMs, and user training documents.

5.3. SOP (Standard Operating Procedure)

It's very important that the ERP system is used correctly and consistently for OQ testing. Any deviation to the SOP would result in a deviation of OQ protocol.

5.4. RTM (Requirement Traceability Matrix)

It connects the User Requirements Specification (URS) and Design Qualification document to the test sets conducted during OQ.

The entire test cycle must be managed using GxP validated software such as Microfocus ALM etc. and any documentation must be stored in an e-signature supportive platform such a Veeva Vault etc.

5.5. PQ: Performance Qualification

This is the most critical step because the ERP system is validated against the real-world performance, simulated in real-world conditions, closely mirroring the intended working conditions. Continuous monitoring is needed to ensure the ERP system is performing consistently.

6. Computer System Validation process for ERP

The validation process can be represented with a V-model as bellow:

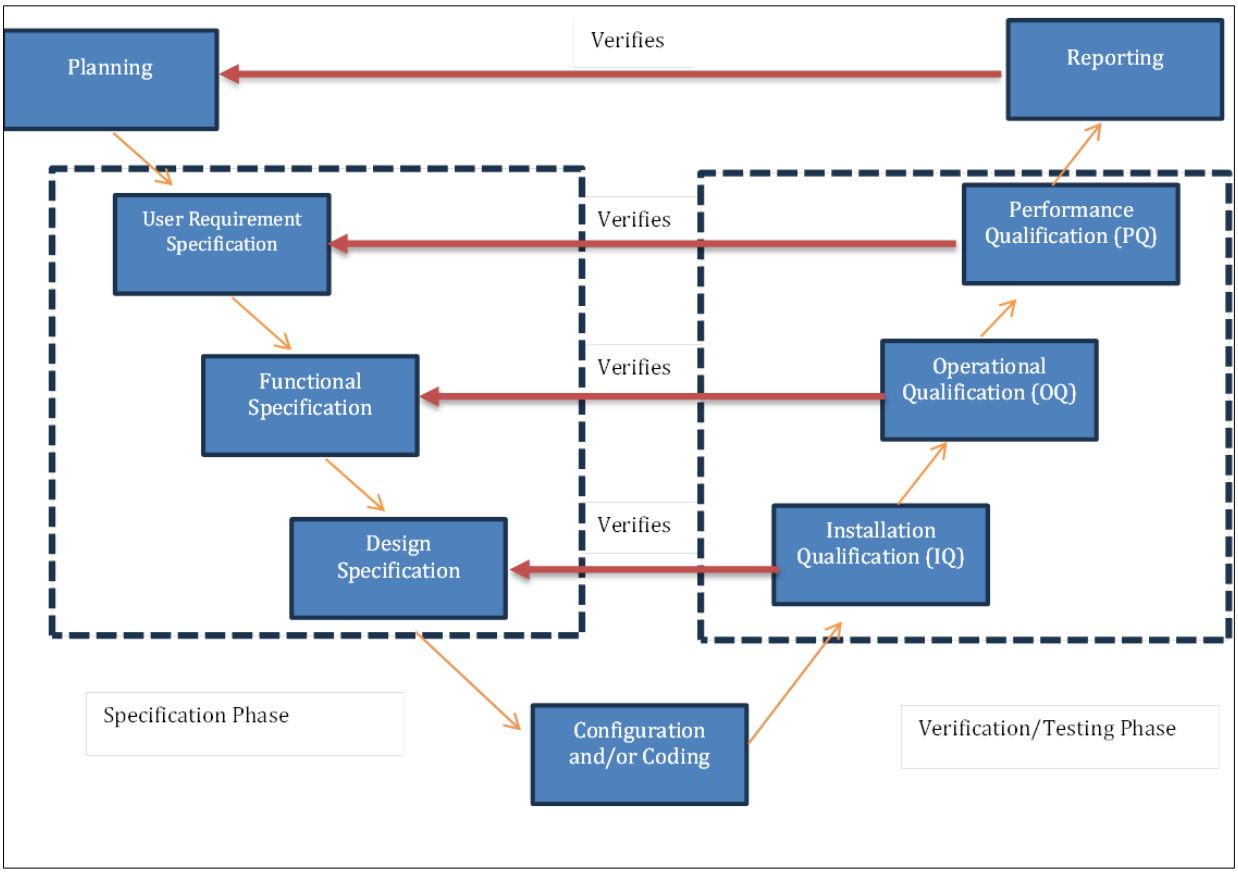

Figure 1 V-Model representation of CSV (Computer System Validation)

- Functional Specification: This document describes in detail how the system will meet the requirements in URS.
- Design Specification / Technical Specification: It's a follow-on document to the Functional Specification and more technical in nature. It contains detailed tech design as well as the code snippets.
- Configuration and/or Coding: This step represents the steps of custom configurations or custom coding (e.g. in case of SAP ERP, the configurations are done using T Code SPRO and the coding is done using SAP ABAP i.e. Advanced Business Applications Programming).

- Risk Assessment: This is typically performed at each step of the V Model to ensure that the required controls are in place, should a situation arise.

6.1. SDLC (Software Development Lifecycle in GxP Environment)

GxP regulations can be leveraged to work with Agile Methodology, but the regulations are rigid and the flexibility for ERP development teams is often limited.

6.2. ALCOA+ Principles

The data should be Attributable, Legible, Contemporaneous, Original and Accurate. In addition to these guidelines, it's recommended that the data is also Complete, Consistent, Enduring and Available.

- Attributable – The Source of the data should be traceable whether it's an individual or a system. Any changes must be signed and dated.
- Legible – The data must be readable, and signatures should be identifiable during any time of data retention period.
- Contemporaneous – The data must be documented in real-time or during the time of the activity.
- Original – The 'Source' or 'Raw' data must be preserved, irrespective of the success or failure.
- Accurate - The data record should correctly reflect the action and any amendments must be explained.
- +Complete – All the relevant raw data and metadata must be collected and stored.
- +Consistent – The data elements must be timestamped in correct sequence.
- +Enduring – The data should be stored for longevity using electronic media.
- +Available – The data must be available and readable by the auditors during the retention period.

7. Conclusion

The Validation of ERP Software and System Architecture in GxP environment is a complex yet essential process that requires careful planning, execution, and comprehensive documentation. With continuous trend of new innovative drugs being in trial phases, the pharmaceutical companies can't miss any of the GxP regulations as it may result into delays to the market launch.

The ERP systems play a vital role in the overall manufacturing operations for pharmaceutical companies. Companies like SAP, Oracle and Microsoft are launching new cloud-based products which are already GxP compliant. With so many options available, the pharmaceutical companies must choose the ERP systems and software which can help with successful FDA audits and faster turnaround to the market.

Compliance with ethical standards

Disclosure of conflict of interest

No Conflict of Interest to be disclosed.

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