Kevin TECHNOLOGIES

www.kevintech.com

VALIDATION

of Vision Inspection Systems Including Track and Trace

Kevin CONNECT

ISSUE .2/2017

CONNECT INSIDE

- Introduction to Validation for Track and Trace system
- Type of Validation Approach
- GAMP categorization for Track and Trace system
- Essential Documentation and Deliverables for Validation
- Electronic Records and Electronic signature

Dear Customers / Friends,

Kevin has an impressive legacy of partnership with its customers in successfully applying technology-based solutions and supporting their competitiveness. We are proud of our reputation as a reliable & trustworthy solutions provider for factory automation as well as Regulatory Compliance Services.

Our corporate culture is one of dedication, respect, and continuous improvement. We measure our success by our customers' successes. In a time marked by rapidly changing customer expectations, I am enthusiastic about the opportunities available for us to address the emerging requirements of our customers.

It is always a challenge to maintain manufacturing and inspection systems in validated state in continuously demanding standard to achieve high levels and regulatory requirements. Apart from guideline requirements this industry also demand for maintain high quality and elevated level integrity to ensure compliance. Need a close monitoring with predefine intervals to schedule validation requirements. Especially for inspection systems in packing area which use computerized system also required documented evidences for validation to meet compliances such as GAMP.

Yours Sincerely,

Ketan Khambhatta,
Managing Director

Driving Performance with Technology

Providing world-class technologies and solutions

Founded in 2000, Kevin Technologies is a leader in Automation for Life Sciences, Starch & Edible Oil, Consumer Packaged Goods & MES (Manufacturing Execution Systems) solutions. We are also one of the largest companies, in the area of Regulatory Compliance & Validation for FDA approved facilities across pan India.

We specialize in conceptualization & development as well as engineering of automation and supervisory control systems. Kevin helps clients meet their business objectives by providing effective project management capabilities and expertise in state-of-the-art technologies including Regulatory Compliance & Validation Services.

Our Mission

To provide technical excellence through innovation teamwork and commitment.

Our Ultimate Vision

To be the number one company in the area of expertise that we operate in, especially Factory Automation & Regulatory Compliance Services.

Validation

How to keep up with Continuous Regulatory changes and maintain High Quality, Integrity while achieving Compliance ?

As per the recent guidelines requirement in the primary secondary and tertiary packing required complete documented evidences to ensure traceability of material shipped from the pharmaceutical factory.

The Various guidelines at different stages insure the quality and authenticity of the product. These guidelines are widely spread across the production floor. Some of them are as mention below.

Validation Introduction

- Regulatory Driven Industry

Guidelines for:

- Hardware+ Software of Machines
  - GAMP 5
  - 21 CFR part 11
  - EU Annex 11
- Packing/ Labeling Guidelines
  - DGFT
  - DSCSA Compliant

Inspection system like track and trace system has different guideline at various level i.e. guidelines for computerized validation like GAMP 5, 21 CFR part 11 and EU Annex 11, also at different level there are guidelines for labeling like DGFT, DSCSA compliant.

Type of Validation Approach

Prospective Validation Approach

Establishing documented evidence prior to system implementation that a system does what it proposed to do based on pre-planned protocols. This approach to validation is normally undertaken whenever the new facility, must be validated before routine pharmaceutical production commences.

Concurrent Validation Approach

Concurrent validation is used for establishing documented evidence that a facility and processes do what they purport to do, based on information generated during actual imputation of the process. This approach involves monitoring of critical processing steps and end product testing of current production, to show that the manufacturing process is in a state of control.

Retrospective Validation

Retrospective validation is used for systems already in operation use that have not undergone a formally documented validation process. Validation of these system is possible using historical data to provide the necessary documentary evidence that the process is doing what it is believed to do. Therefore, this type of validation is only acceptable for well-established processes and will be inappropriate where there have been recent changes in the composition of product, operating processes, or equipment. This approach is rarely been used today because it's very unlikely that any existing product hasn't been subjected to the Prospective validation process. It is used only for the audit of a validated process.

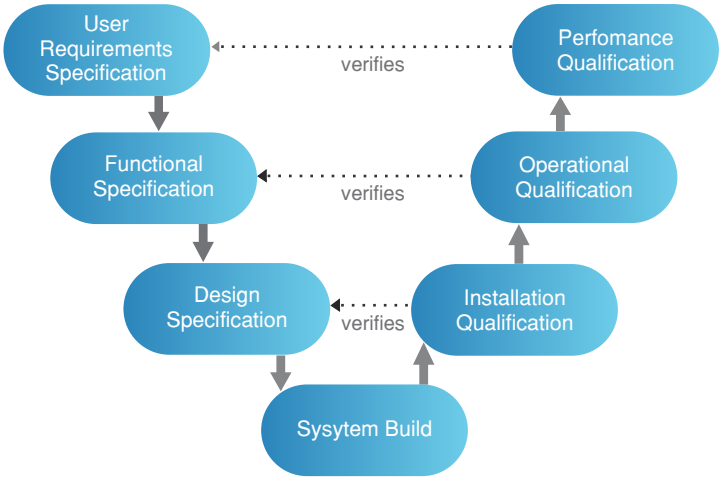
Re-Validation

Revalidation means repeating the original validation effort or any part of it, and includes investigative review of existing performance data. This approach is essential to maintain the validated status of the equipment and computer systems. Possible reasons for starting the re-validation process include:

- The transfer of a system from one plant to another.
- Changes to the system, the plant, the manufacturing process, the cleaning process, or other changes that could affect product quality.
- The necessity of periodic checking of the validation results.
- The scope of revalidation procedures depends on the extent of the changes and the effect upon the product.

Good Automated Manufacturing Practice

New Generic V- Model



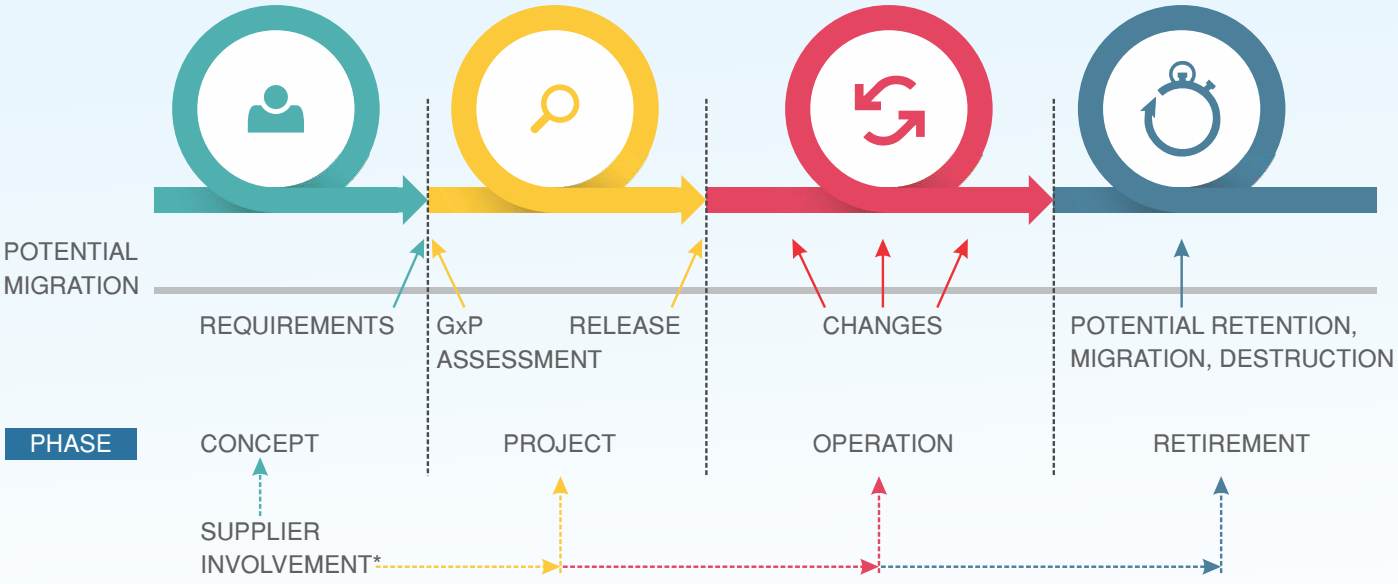
This new generic V-model provides approach for validation which verifies at different stage of project/execution phase. Each stage has co-relation with another stage i.e. User Requirement Specification (URS) co-relate with Performance Qualification. This V-model applies to all basic four phases of equipment life cycle -Concept, Project, Operation and Retirement. With this V-model, Risk assessment is also associated at different level of each phase of equipment life cycle.

As Per Generic V-Model

- Prepare Validation Plan
- Prepare Specification
- Configure the risk associated with the system
- Verify/Qualify the system
- Report Submission

Note: High Risk systems will include more verification tests Old (GAMP 4) V Model is optimal

Validation Approach



* This could be a complex supply chain
Supplier may provide knowledge, experience, documentation, and services throughout lifecycle.

Generic Life-Cycle

GAMP5

5th version of Good Automated Manufacturing Practice(GAMP) is guideline applies to computerized systems. This guideline is categorized in majorly 4 categories i.e

Category - 1 Infrastructure Software
Category - 3 Non-Configured Software
Category - 4 Configured Software and last
Category - 5 Custom Software

A equipment with Industrial computer falls in category 4 and 5 and in general , it falls in category 4 .

Category 4: Software / Computer System

Category	Description	Validation Approach	Typical Example
Category-4 Configured Software	• Software, often very complex, that can be configured by the user to meet the specific needs of the user's business process. Software code is not altered	• Life Cycle Approach • Risk-based approach to supplier assessment • Demonstrate supplier has adequate QMS • Some life cycle documentation retained only by supplier (e.g. Design Specification) • Record Version Number, Verify correct installation • Risk-based testing to demonstrate application works as designed in the test environment • Risk-based testing to demonstrate application works as designed within the business process • Procedures in place for maintaining compliance and fitness for intended use • Procedures in place for managing data	• LIMS • Data Acquisition System • SCADA • ERP • DCS • BMS • Spreadsheets • PLC+SCADA • PLC+HMI

GAMP Essential details required for Validation

- UPS Specification Details
- Network Diagram
- Redundancy System Details (if any)
- Standard Operational Procedures (SOP)
- Training Records
- Operational Manuals
- Security Details/ Policy
- IT Policy
- Server Software Details
- Server Hardware Details
- Client Software Details
- Client Hardware Details
- Application Software Details
- Antivirus Details
- Licenses Details

Deliverables for Track & Trace System Validation

- Functional Specification (FS)
- Design Specification (DS)
- Functional and Design Specification (FDS)
- Operational Manual
- GAP Assessment
- Functional Risk Assessment (FRA)
- ERES Assessment
- Installation and Operational Qualification Protocol (IOQ)
- Traceability Matrix (TM)
- Summary Report (SR)

Kevin Technologies Pvt. Ltd.: 201, Shapath 1 Complex, Opp. Rajpath Club, S.G. Highway, Ahmedabad 380 015. India.
Call: +91 79 2687 2555 ,+91 79 2687 0556 | info-ktpl@kevin.in I www.kevintech.com