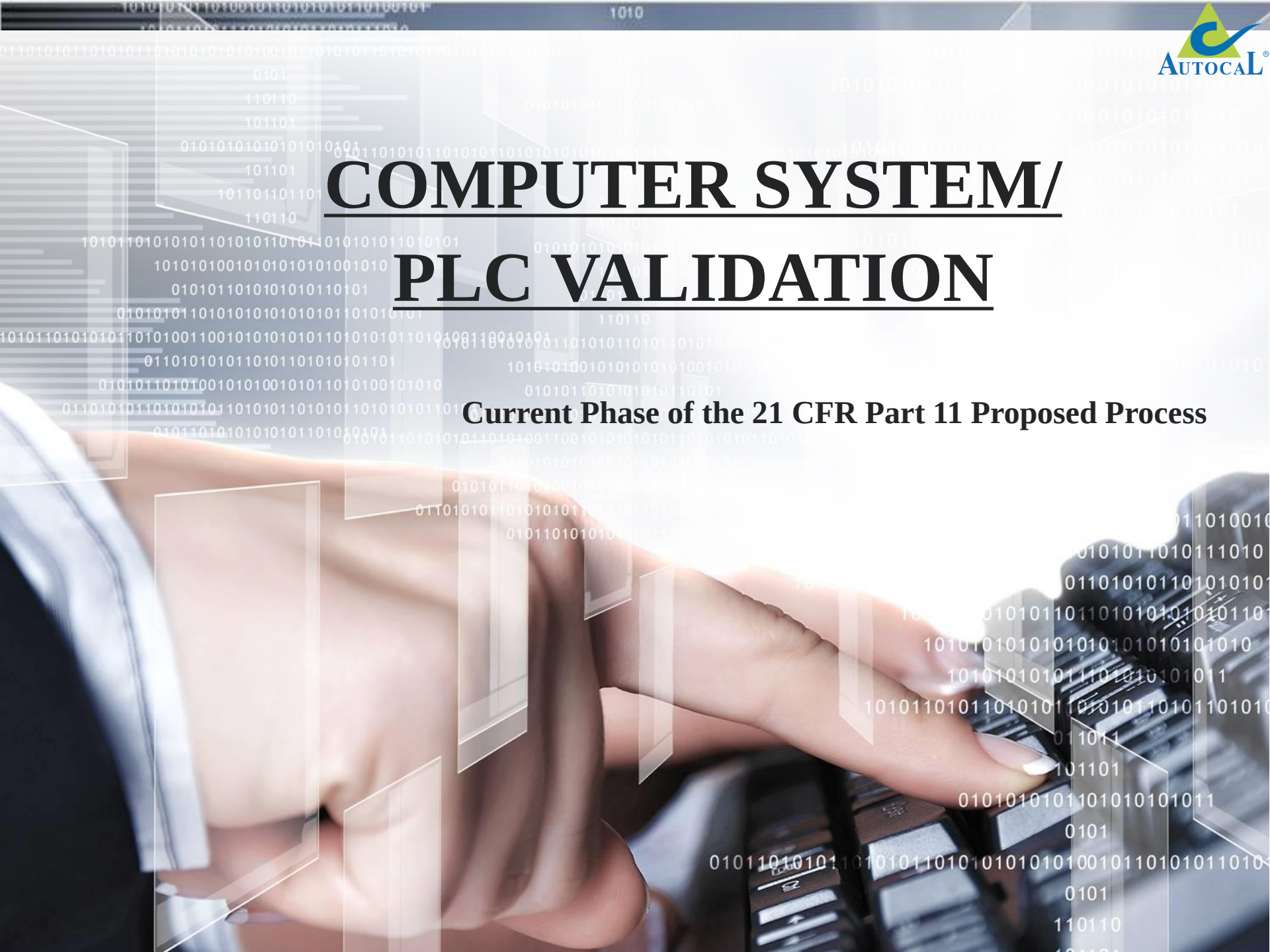
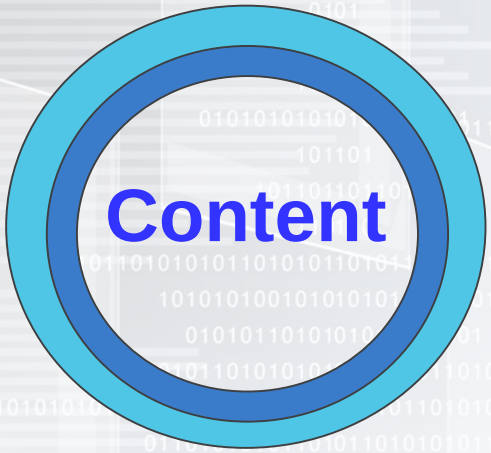
COMPUTER SYSTEM/ PLC VALIDATION

Current Phase of the 21 CFR Part 11 Proposed Process





WHAT IS CS/ PLC VALIDATION

The purpose of the validation process is to provide a high degree of assurance that a specific process (or in this case computer system) will consistently produce a product (control information or data) which meets predetermined specifications and quality attributes

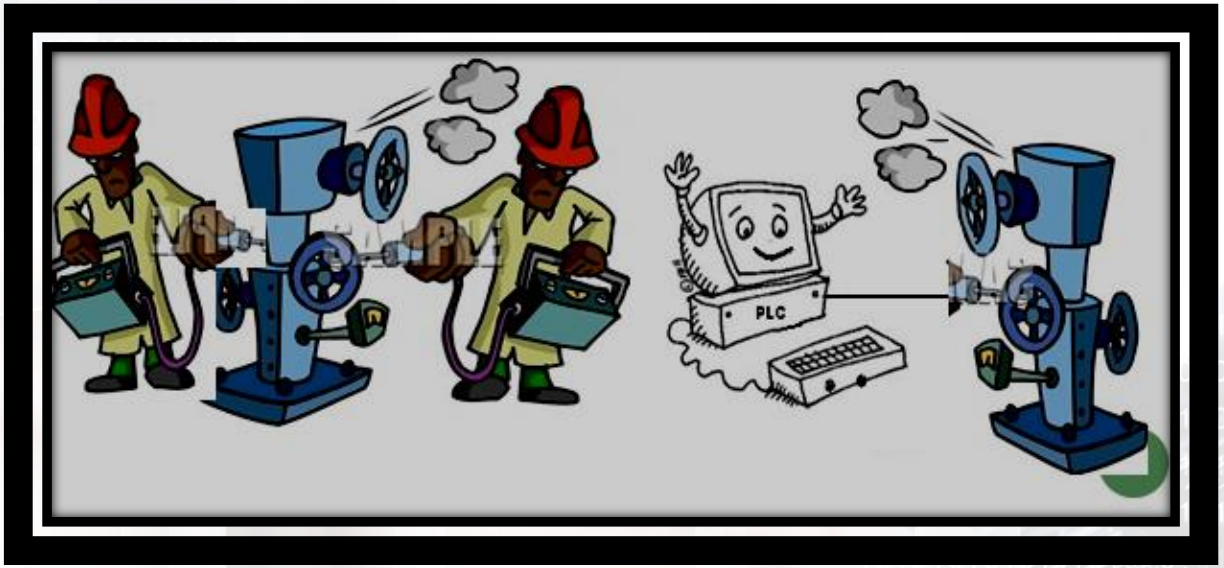
PLC

WHY VALIDATION IS NEEDED

- FDA regulations mandate the need to perform Computer System Validation and these regulations have the impact of law.
- Failing an FDA audit can result in FDA inspectional observations (“483s”) and warning letters.
- Failure to take corrective action in a timely manner can result in shutting down manufacturing facilities, consent decrees, and stiff financial penalties.
- The ultimate result could be loss of jobs, indictment of responsible parties (usually the officers of a company), and companies suffering economic instabilities resulting in downsizing and possibly eventual bankruptcy.

Key Objectives

- Patient safety
- Product quality
- Data integrity



WHY VALIDATION IS NEEDED

- Reduces risk and legal liability
- Having the evidence that computer systems are correct for their purpose and operating properly represents a good business practice
- Software is constantly evolving to keep up with the increasingly complex needs of the people that use it; therefore validation is an ongoing necessity
- Validation is applied to many aspects of the healthcare and other regulated industries and businesses.
- Examples include:
  - Services
  - Equipment
  - Computer Systems
  - Processes
- In each case, the objective of validation is to produce documented evidence, which provides a high degree of assurance that all parts of the facility will consistently work correctly when brought into use.
- Computer systems validation includes validation of both new and existing computer systems.

WHO CARES ABOUT CSV?

- Systems throughout the organization involved in the development, production, storage and distribution of pharmaceutical products or medical devices have to be considered

- Resources involved in any way with IT, computer or automated systems is affected:
  - Developers
  - Maintainers
  - Users
  - Regulatory Authorities
  - QA

WHO GOVERNANCE

- Policies and procedures
- Roles and responsibilities
- Training
- Supplier relationships
- System inventory
- Planning for compliance & validation
- Continuous improvement

RESPONSIBILITES & SOPs

- Each corporate [business] unit is responsible for establishing a policy on computer systems validation requirements.

- Site or departments are responsible for:
  - Computer system validation Standard Operating Procedures (SOPs)
  - System inventory and assessment
  - System specific validation protocols
  - System specific validation documentation

SOPs must:

- Comply with the Computer Systems Validation Policy and any Business Unit policies that may apply
- Be approved by the appropriate management for that site or department

HOW DO I COMPLY

SYSTEM AND INVENTORY ASSESSMENT

- Site or departmental management is responsible for compiling and maintaining details about their computer systems.
  - This information includes identifying the systems that are being used and for what purposes those systems are being used.

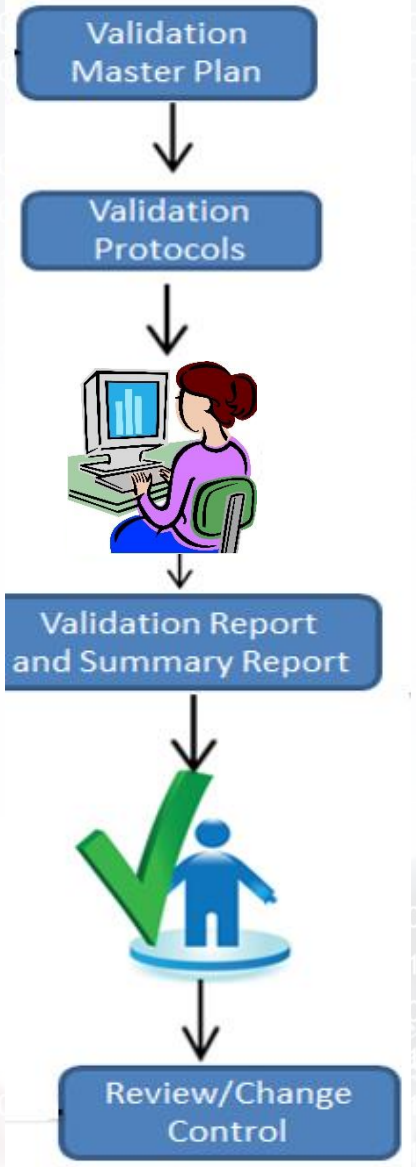
- The system inventory and assessment information is used to determine which systems need to be validated.

SYSTEM SPECIFIC VALIDATION PROTOCOLS

- Validation protocols are documents associated with each system identified as requiring validation.
- The protocol describes the scope, procedure to be followed, responsibilities and acceptance criteria for the validation.
- Validation protocols should comply with the SOPs.

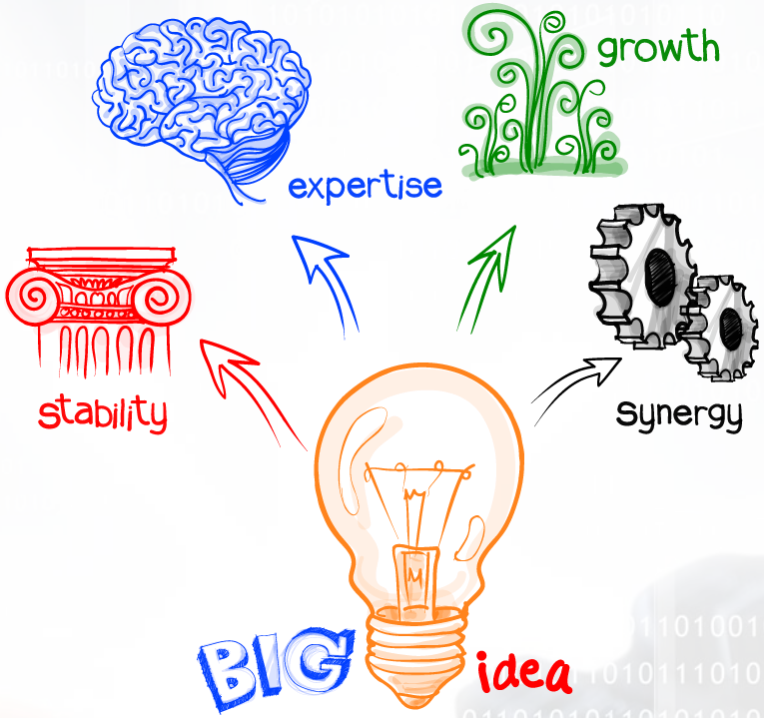
VALIDATION DOCUMENTATION

- Documentation that verifies each validation activity must be generated and stored with the validation protocol in the appropriate archive.
- Validation documentation may include:
  - Test data
  - Summary reports
  - Procedures
  - Certification forms produced during the validation process



PRE-VALIDATION PROCESS

- Before you can validate a system, you need to identify the systems that require validation.
- Determining if a system requires validation involves analysis of the following areas:
  - 21 CFR Part 11 – electronic records and signatures;
  - Manufacturing processes;
  - Product [drug material] release or stability information;
  - Regulatory information;
  - Support GxP activities.
- All users must be trained on current SOPs related to computer system development and validation.



VALIDATION MASTER PLAN

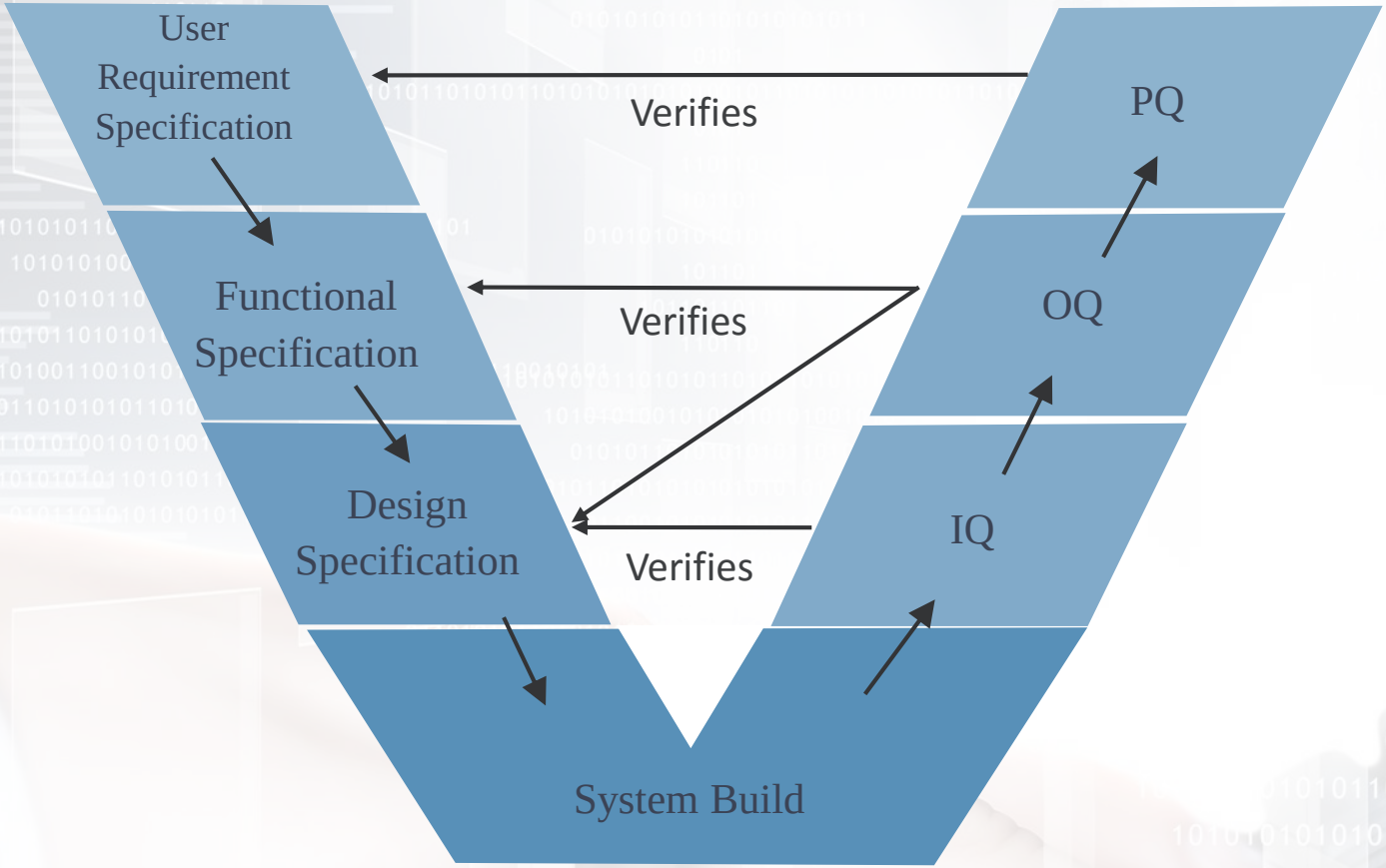
- The validation of all computer systems will be documented in a Validation Master Plan (VMP)

- The Validation Master Plan will include:
  - Identifying components requiring validation
  - Prioritizing and justifying the validations to be performed
  - All activities and assigned responsibilities
  - Establishing site specific procedures to support validation

GAMP CATEGORIES

Category	GAMP 4	GAMP 5
1	Operating System	Infrastructure Software
2	Firmware	NO LONGER USED
3	Standard Software packages	Non-configured products
4	Configurable software packages	Configured products
5	Custom (bespoke) software	Custom products

SPECIFICATION AND QUALIFICATION RELATIONSHIPS

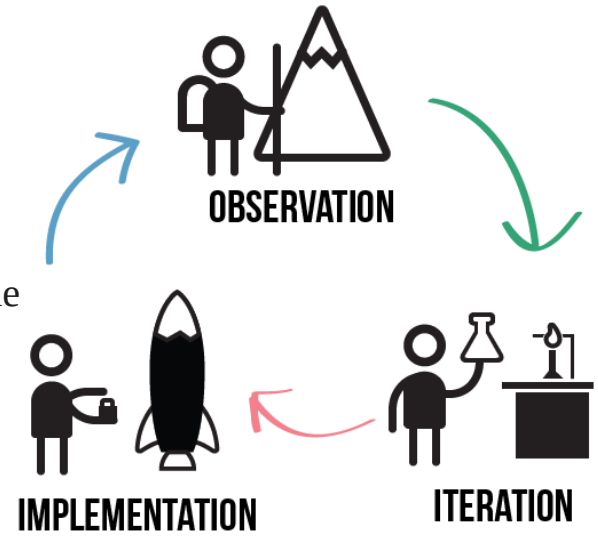


THE VALIDATION PROCESS

- Consists of five specific processes
  - Validation Master Plan (VMP)
  - Project Plan
  - Installation Qualification (IQ)
  - Operational Qualification (OQ)
  - Performance or Process Qualification (PQ)

VALIDATION PROCESS STEPS

- Establish Team's
  - These are the teams that will be responsible for the validation process
- Determine Validation Activities
  - Validation activities are the exact details or activities that will be required for each of the steps in the validation process
  - The output from this activity will be the Validation Plan
- Write the Validation Protocol
  - Describes the procedure and the steps within the procedure that will be followed in order to validate the system
  - The Validation Protocol must also provide a high level description of the overall philosophy, intention and approach
- Perform Qualification Activities
  - Design, IQ, OQ, PQ
- Review Controls and Procedures
  - SOPs (Standard Operating Procedures)
  - Training procedures and Training records
- Certify the System
  - This step is where you certify that the validation deliverables have met the
  - acceptance criteria that were described in the Validation Protocol
  - When you certify the system you should prepare a Validation Report
  - The validation report should outline the details of the validation process



STEP 1 – INITIAL RISK ASSESSMENT

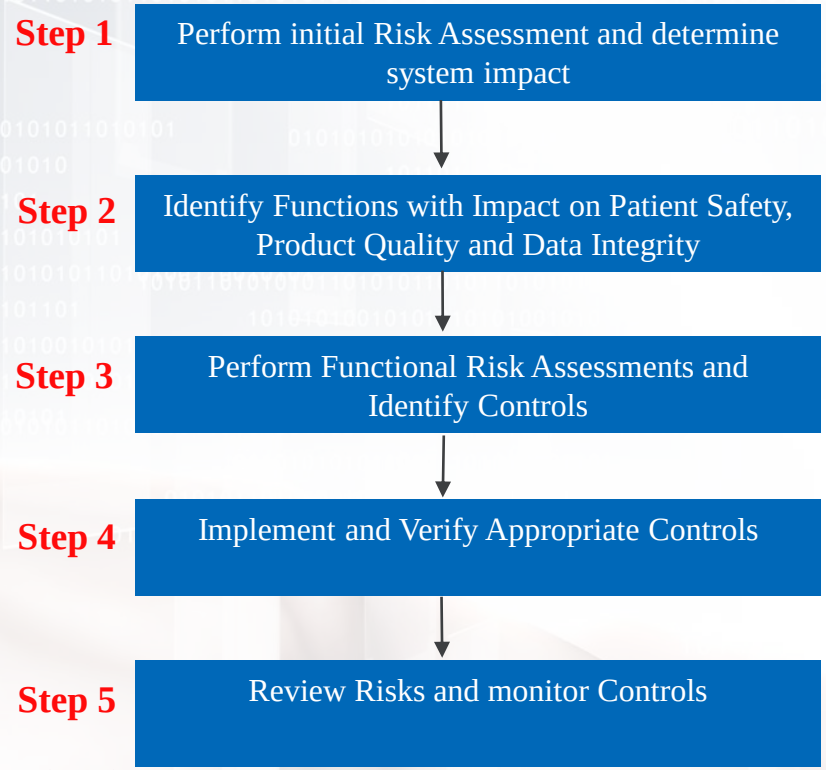
- Based on business processes, user requirements, regulatory requirements and known functional areas

Inputs

User Requirements

GxP Regulations

Previous Assessment



Outputs

GxP or non-GxP

Major Risks Considered

Overall Risk

Don't repeat Unnecessarily !

STEP 2 – IDENTIFY FUNCTIONS WITH GxP IMPACT

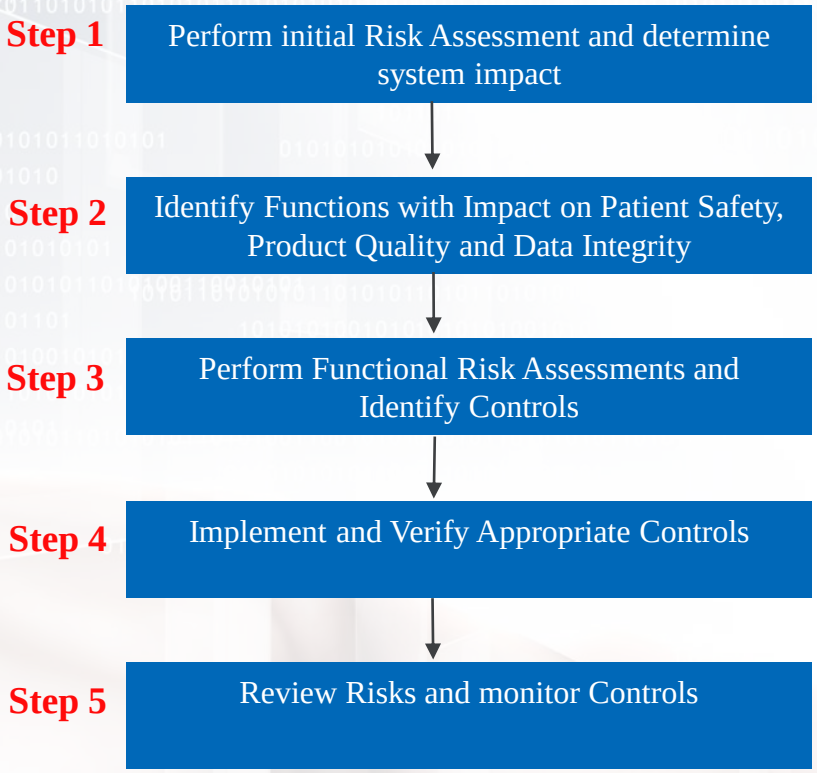
- Functions with impact on patient safety, product quality and data integrity

Inputs

Specifications

System Architecture

Categorization of Components



Outputs

List of Functions to be further evaluated

STEP 3 – PERFORM FUNCTIONAL RISK ASSESSMENTS & IDENTIFY CONTROLS

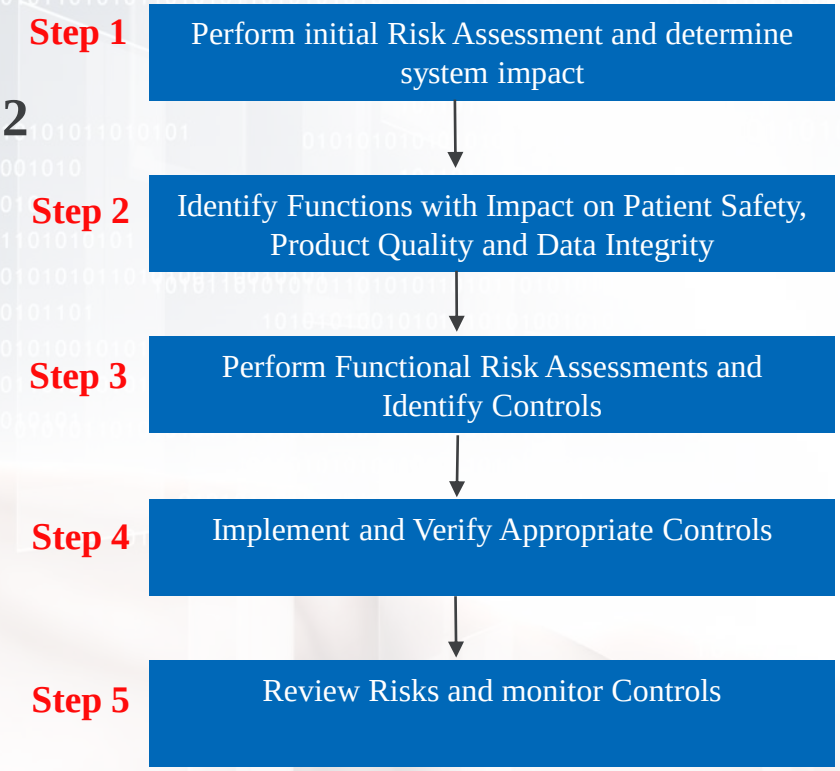
Inputs

Functions from step 2

SME Experience

Scenarios

Possible Hazards

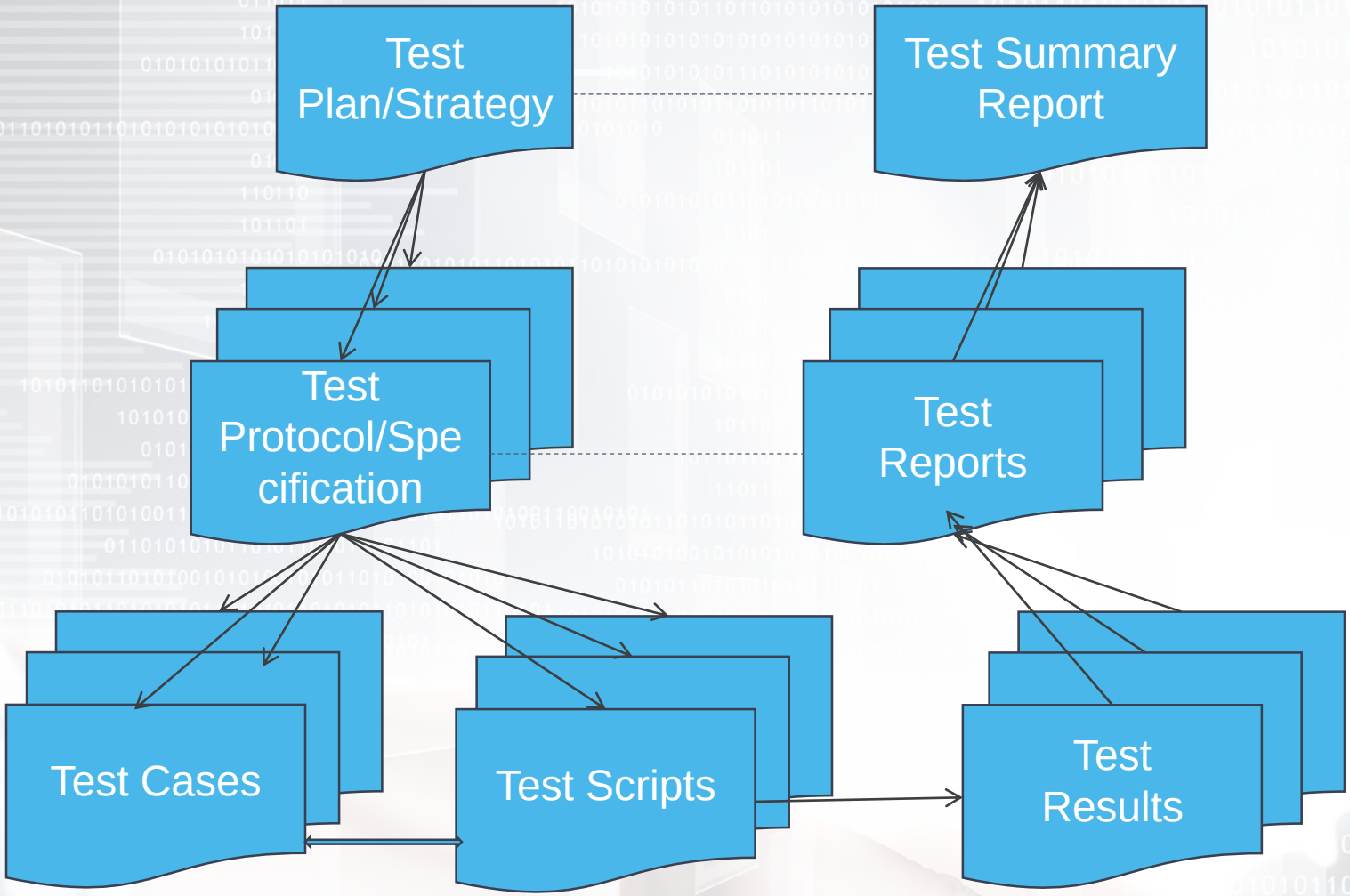


Outputs

Breakdown of Risks to Low, Medium and High.

Detailed Assessments and Mitigation for High

TESTING DOCUMENTATION



FUNCTIONAL RISK ASSESMENT

- Identify
- Hazards and risk scenarios
- Severity – impact on safety quality or other harm
- Probability
- Detectability

LEVERAGING SUPPLIER INVOLVEMENT

Activities

- Requirements Gathering
- Risk assessments
- Functional / other Specifications
- Configuration
- Testing
- Support and maintenance

Principles

- Assess:
  - Suitability
  - Accuracy
  - Completeness
- Flexibility:
  - Format
  - Structure

RESOURCES AND REFERENCES

- Computer System Validation (FDA)
- 21 CFR Part 11
- FDA Guidance for Industry – Computer Systems Used in GxP Environment
- Computer System Validation – It's More Than Just Testing
- GAMP 5 A Risk Based Approach to Compliant GxP Computerized System
- WHO-world Health Organisation
- PIC/S-PHARMACEUTICAL INSPECTION CONVENTION
- EU GMP Annex 11

THANK YOU

TOGETHER WE CAN CREATE
GOOD BUSINESS RELATION

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