Quality Assurance
QA

ScientiCal Quality Training

Designing and Developing Quality Unit

1. Quality Organization Chart (Role, Responsibility & Accountability)
2. Developing Quality Pillars namely:

2.1 Quality Manual (Received from Corporate Level)
2.2 Change Control SOP
2.3 Non-Conformity SOP
2.3 Audit SOP
2.4 CAPA SOP
2.5 Validation (Master) SOP
2.5 Batch Release SOP (Product Release)
2.6 Recall SOP

Quality Control

ScientiCal Quality Training

Defining QC Organization

1. QC Organization Chart (Process-based from Starting Material, Sampling to Product Analysis)
2. QC Role, Responsibility, Accountability and relation to QA
3. QC Documentation

3.1 Change Control, CAPA, Non-conformity (Deviation Handling), Batch Documentation and Product Specifications (-SOP)

3.2 Process SOP (e.g. Sampling, Lab Analysis, Documentation incl. Training and Archiving)

3.3 Lab Equipment (Validation, Qualification, Calibration)

Validation

ScientiCal Validation Training

Fundamentals in Validation

- Definitions, Terms & Concepts
- Compliance US 21 CFR & EMEA Annex, Quality Systems, GMP,
- Documentation Lifecycle (VMP, DQ, IQ, OQ, PQ & VSR)

Advanced Validation

- Process Validation
- Cleaning Validation
- HVAC System l Validation & Cleanroom Validation
- Equipment Validation (Production and Lab Equipment)
- Computerized System Validation (CSV) incl. Networks

Validation Projects

- Validation Project Management , Preparing Validation Master Plan (VMP)
- Executing Validation Plan, producing the evidences i.e. IQ, OQ, PQ, identify responsibilities and accountabilities
- Finalizing Validation (Summary) Report, Freezing the system, Archiving the documents and Training

ScientiCal Validation Training

ScientiCal AG is able to offer wide range of validation:

We suggest to start with a mandatory Basic Validation Training known as "Principals in Validation" or "Fundamental in Validation" for all

Then Advanced Validation Training for each special field and based on the function: like Process Validation for Production, Lab Equipment Validation for Lab & QC etc

ScientiCal Validation Training

Advanced Validation

Based on the role and function i.e. Production, QA/QC and Validation Departments

1. Production and Lab Equipment (fully and semi automated systems) Validation
2. Non-Sterile Process Validation throughout the product lifecycle (CFR 210, 211)
3. Computerized System Validation (21 CFR Part 11 & Risk Based Approach GAMP®5, Annex 11, ICH Q8-Q9)
4. Medical Device (21 CFR 820 & ISO 13485)*

* **If it is needed**

ScientiCal Validation Training

Projects and Workshops

The training should be followed with well-defined Projects to produce all evidences i.e. GxP documentation

1. Process Validation: a production line validation (product lifecycle)
2. Equipment Validation: Packaging machine, or Tablet machine etc.
3. Lab Equipment Validation: Dissolution, Disintegration machines with refer to (US/EU/IR) Pharmacopoeia and HPLC
4. CSV (electronic records & electronic signature): Network, servers and databases which the data stored and automated and semi-automated machines or lab equipment

Validation Projects

ScientiCal Validation Projects

To follow the training with well-defined Validation Projects in 3 main fields

Lab Equipment Qualification / Validation

- Exercise with risk based approach , V-Validation Model based on 21 CFR Part 11 (GAMP) , Annex 11, (US/EU/IR) Pharmacopeia for Dissolution Tester and HPLC

Production Equipment Validation

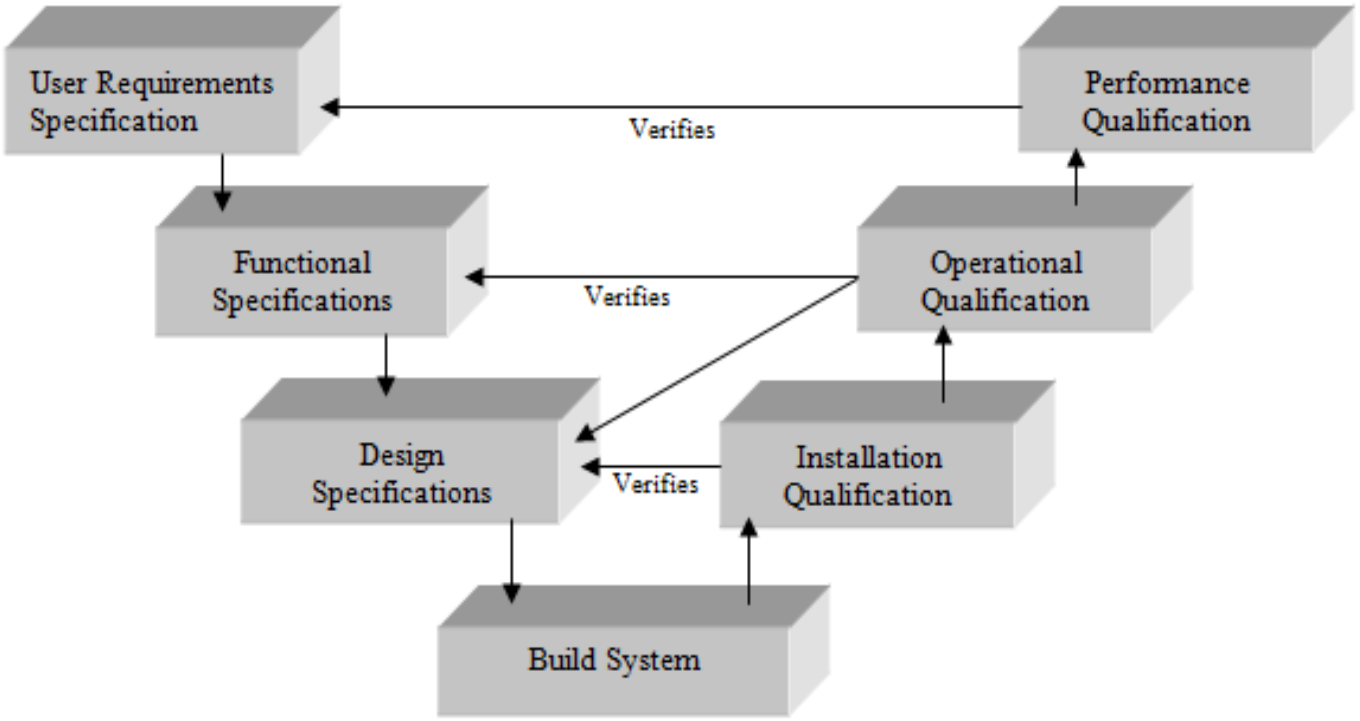
- For Production Equipment like Tablet and Packaging Machines, V-Validation Model based on 21 CFR Part 11 & Annex 11 (GAMP5)

Process Validation

- For new or existing Products based on Annex 4, 21 CFR 210 & 211 and ICH Q8-9 (Risk Based Approach)

Validation Model

- **Traceability & Link (V-Validation)**



Timelines

ScientiCal Validation Projects

Defining Validation Timeline needs to assess:

Validation Steps, Actions and Milestones

A detailed analysis of resource allocation, activities and timing would usually be given in some subsequent document such as a Quality and Project Plan

This means that it needs a well describe validation Project Plan, assess the existing document, and resources

Thank you.