COMPUTER SYSTEM VALIDATION WORK FLOW



System inventory and evaluation



Validation Report and System execution for operation

Operational Qualification protocol and results (PQPR)

Performance Qualification protocol and results (PQPR) - As per -

- **Current GAMP guideline**
- 21 CFR Part 11 USFDA guideline
- **EU Annex 11 guideline**

User requirement specification (URS)

Functional requirement specification (FRS)

Computer validation plan (CVP)

Validation requirement

Installation Qualification protocol and results (IQPR)

Network and Infrastructure Qualification (VIQ)

Validation traceability matrix (VTM)





