Best practices for Process Validation

Mark Durivage, ASQ Fellow, CBA, RAC, CTBS
Managing Principal Consultant
Quality Systems Compliance LLC
✓ Define Validation
✓ Discuss Validation Requirements
✓ Define Risk
✓ Discuss Validation Pre-Requisites
✓ Discuss the Validation Life Cycle
✓ Discuss Common Validation Issues
“Validations are akin to scientific investigations in which the hypotheses are formulated, experiments are designed and conducted, data are collected and analyzed, and conclusions are reached.

And like scientific discoveries, validations must be questioned and retested for the life of the process they cover.”

D.M Carlberg

Validation Requirements

The importance of validating readily apparent in FDA regulations, ISO standards, and GHTF guidance documents
KEEP CALM AND VALIDATE ON

KEEP CALM AND CARRY ON

KEEP CALM AND VERIFY ON

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Definitions

• "Establish" means define, document (in writing or electronically), and implement
• “can” indicates a possibility or a capability
• “should” indicates a recommendation
• “shall” indicates a requirement
• “may” indicates a permission
Validation Activities

- Commissioning
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Process Performance Qualification (PPQ)
QSR Requirements

820.75 Process Validation

"Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures"
QSR Requirements

820.250 Statistical Techniques
"Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

Sampling plans, when used, shall be written and based on a valid statistical rationale"
820.70 Production and Process Controls

"Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications"
Guidance Documents

GHTF - Quality Management Systems - Process Validation Guidance
FDA - Process Validation: General Principles and Practices
FDA - General Principles of Software Validation

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm
GHTF Process Validation Decision Tree

Adapted from GHTF Study Group 3
Quality Management Systems Process Validation Guidance
January 2004
Process and System Validation

Inputs → Value Add → Outputs

Inputs → Value Add → Outputs

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ASQ Biomedical Division
Risk Management

Identify
Assess
Analyze
Reduce
Control
Transfer
Validation
Prerequisites
The Process Validation Life Cycle

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Retrospective and Re-Validation Activities
Retrospective Validation
Re-Validation Activities

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FDA Warning Letters Summary (Validation)

❖ Missing rationale for the comparison of data from old and new PQ runs
❖ Failure "maintaining the process in state of control"
❖ Missing "root cause analysis" as required in the validation plan for evaluating inadequate results
❖ Missing rationale for the number of PQ runs
❖ Arbitrary sampling plan

Source: http://www.gmp-compliance.org/eca_news_2025_6374,6246,6247,6418.html
Common Validation Issues
Summary
we are almost there
➢ Use a Risk-Based Statistical Rationale
➢ Keep Apprised of Current Industry Trends
➢ Under Promise – Over Deliver on Validation Commitments
➢ Perform Continuous Process Monitoring
➢ Document Your Plan, Actions, and Results
Questions
THANK YOU!
Contact Info

mark.durivage@qscompliance.com
www.qscompliance.com
https://www.linkedin.com/in/markdurivage