Validation Procedures for Automated Control of Food Processing Systems

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Why Validate ?

- Electronic record keeping for food processing in retorts or aseptic systems (21 CFR Part 11)
- Good Manufacturing/Engineering Practice -

1) Food Safety
2) System Efficiency

Validation Procedures

- GAMP Guidelines – Good Automated Manufacturing Practice – Pharmaceutical Companies
- Bulletin 43-L Guidelines – GMA formerly NFPA guidelines – some Food Companies
- IEEE Guidelines – software development

Validation Procedures

- Validation Plan
- Responsibility Matrix
- User Requirement Specification
- Function/Design Specifications
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Traceablity Matrix
- Validation Report

Life-Cycle of System

- Systems have a Life-cycle
- Validation Plan – start of process
- Validation Report – completion of process
- CHANGE CONTROL throughout the life of a system

Validation Plan

- Simple or Complex depending on system
- Summarizes Activities (e.g. Installation Qualification)
- Summarizes Documents (e.g., Validation Report)

Validation Plan

- Get SENIOR MANAGEMENT to review plan
- Get SENIOR MANAGEMENT to sign off on plan

Responsibility Matrix

- Designates personnel responsible for various validation activities
- Need a team not just one individual
- Need to have senior management support

User Requirement Specification (URS)

- What the system is “supposed to do” - usually prepared by food company
- Requirements not solutions
- Critical parameters/instruments
- Modes of operation
- System alarms/system responses
- System data handling/recovery
- Security
- Software/hardware

Functional Specification (FS)

- What the system “will do” - written by the equipment supplier
- Control system description
- Hardware-PLC, interface,instruments
- Software-modes, interlocks, alarms
- Data handling/production records
- Emergency requirements
- May be a Functional/Design Spec.

Design Specification (DS)

- Complete definition to build system
- Some companies use Functional/Design specifications
- Software design standards/SOPs
- Hardware/software complete specs.
- Mechanical/Electrical specifications and drawings
- Network specifications

System Qualification

- Installation Qualification (IQ): confirms functional design/design specifications – SYSTEM BUILT PROPERLY
- Operational Qualification (OQ): confirms system operates properly under NORMAL and ABNORMAL CONDITIONS
- Performance Qualification (PQ): confirms system meets Processor's URS – processor should conduct

Qualification Protocols

- Company, equipment supplier or consulting group develops IQ, OQ and PQ protocols
- Recommend company develop PQ protocols and conduct PQ (taking ownership)
- Protocols can be variable in format – no problem as long as proper testing and review are conducted and proper documentation is made

Installation Qualification

- Critical instrument calibration review and documentation
- Critical instrument, control system, equipment, and piping installation review and documentation:

1) Critical P&ID review/check off
2) Hardware installation/IO checks and documentation

Installation Qualification

- Software Review:

1) Development procedures and SOP(s) review and documentation

2) Code review and documentation

- Deviation Handling:

1) Documentation of deviation

2) Follow-up corrections and documentation (OQ or PQ)

Operational Qualification

- Critical maintenance/equipment manual review and documentation
- Critical SOP review and documentation
- Alarm and interlock testing and documentation – test system to failure when possible or simulate deviant conditions through software manipulation

Operational Qualification

- System failure and data recovery tests and documentation
- CHANGE CONTROL procedure review and implementation before end of OQ
- Deviation Handling:

1) Documentation of deviation
2) Follow-up corrections and documentation (OQ or PQ)

CHANGE CONTROL

- Start near middle or end of OQ for critical software, hardware, instruments and equipment.
- Critical Equipment and Instrument List
- SOP and paper or software documentation methods should be in place
- Can combine with Preventative Maintenance programs/software

EXAMPLE Critical Equipment and Instrument List
(Not Accurate or Complete)

Equipment/Instrument	Tag Number	Properties/Operating Range	Manufacturer/Model #
Processing Vessel Pressure Sensor	PT22	4-20 mA 0-145 psig	ABC / #123
Water Recirculation Flow Meter	FE123	4-20 mA 0-1800 gpm	ABC / #456
Hot Well Level Probe	CON11	4-20 mA 0-100%	ACME / #321
Heat Exchange Exit Temperature Sensor	RTD44	4-20 mA 32-302°F	ABC / #1212
Chart Recorder	TRC12	4-20 mA	Great Records / #777
Vent Control Valve	VAL56	4-20 mA 0-100% 3-15 psig	Aseptodynamic / #345
Recirculation Water Pump	PUMP1	On/Off 24 VDC	Mega Flow / #456
Aseptic Tank Temperature Sensor	RTD55	4-20 mA 32-302°F	ABC / #999

Bulletin 43-L Appendix D – CHANGE CONTROL

System/Project Identification:	

PROGRAM CHANGE CONTROL

	Input Individual	Review Individual	Associated Program	Change to Program	Supplier Program Change Approval	Recipe Code	Product Number	Date of Change	Change Description
1									
2									
3									
4									
5									

Approval	Date
Development Team Leader	
Implementation Team Leader	
User Team Leader	
QA Manager	
Engineering Manager	
Validation Team Leader	

Performance Qualification

- Final Phase using production conditions
- Confirms URS so processor should conduct and complete
- Use properly trained personnel
- Document Employee TRAINING sessions
- If necessary, follow up on all DEVIATIONS found in IQ or OQ

Validation Report

- Validation activities summarized
- Signature(s) of person(s) conducting validation activities
- Covers initial validation/qualification work
- Re-validation work through proper CHANGE CONTROL

Traceability Matrix

- Follows user requirements through validation process
- Concentrates on system CRITICAL parameters/factors
- Can get LARGE and COMPLICATED
- Identifies specific validation documentation location for URS, FS/DS, IQ, OQ and PQ for critical factors

Preventative Maintenance

- Proper preventative maintenance needs to be conducted on systems
- Proper documentation of “like for like” replacement of critical instruments, equipment, etc.
- Can be combined with CHANGE CONTROL using some COTS software programs

System Security

- 21 CFR Part 11: Is system OPEN or CLOSED to data manipulation
- Only a few KEY individuals have access to complete system
- Combination of HARDWARE and PROCEDURAL CONTROLS – must get HR management involved in process (no password sharing)
- Reviewed and documented in IQ, OQ, PQ and Validation Report

Documentation Preparation

- In house experts
- Hire a consultant or consulting group
- Follow examples in guidelines such as GAMP or 43-L
- A number of ways to conduct validation and prepare documents

Thank You!