IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
Unlimited Validation Knowledge Awaits...
UBM A division of UBM Americas
Published on *IVT Network* (http://www.ivtnetwork.com)

A Quality Risk Management Approach for Qualification and Commissioning

Jan 10, 2014 7:21 am PST

*Adapted from a Jorge Cordero presentation given at IVT's**Validation Week** Canada*

For commissioning and qualification of facilities, utilities, and equipment (F/U/E), a quality risk management approach can be used to identify and evaluate risk. The strategy will identify areas that will require more evaluation, adjustments, or re-design prior to implementation. Furthermore, it will provide controls to reduce risk to an acceptable level, avoid wasteful effort and duplication, and minimize down time of operators. The process concept of the quality risk management approach for F/U/E qualification and commissioning can be seen the Figure. A comparison of the approach for facilities, utilities, and equipment can be seen in Table I.

Figure: **Quality Risk Management Process Concept for Qualification and Commissioning.**

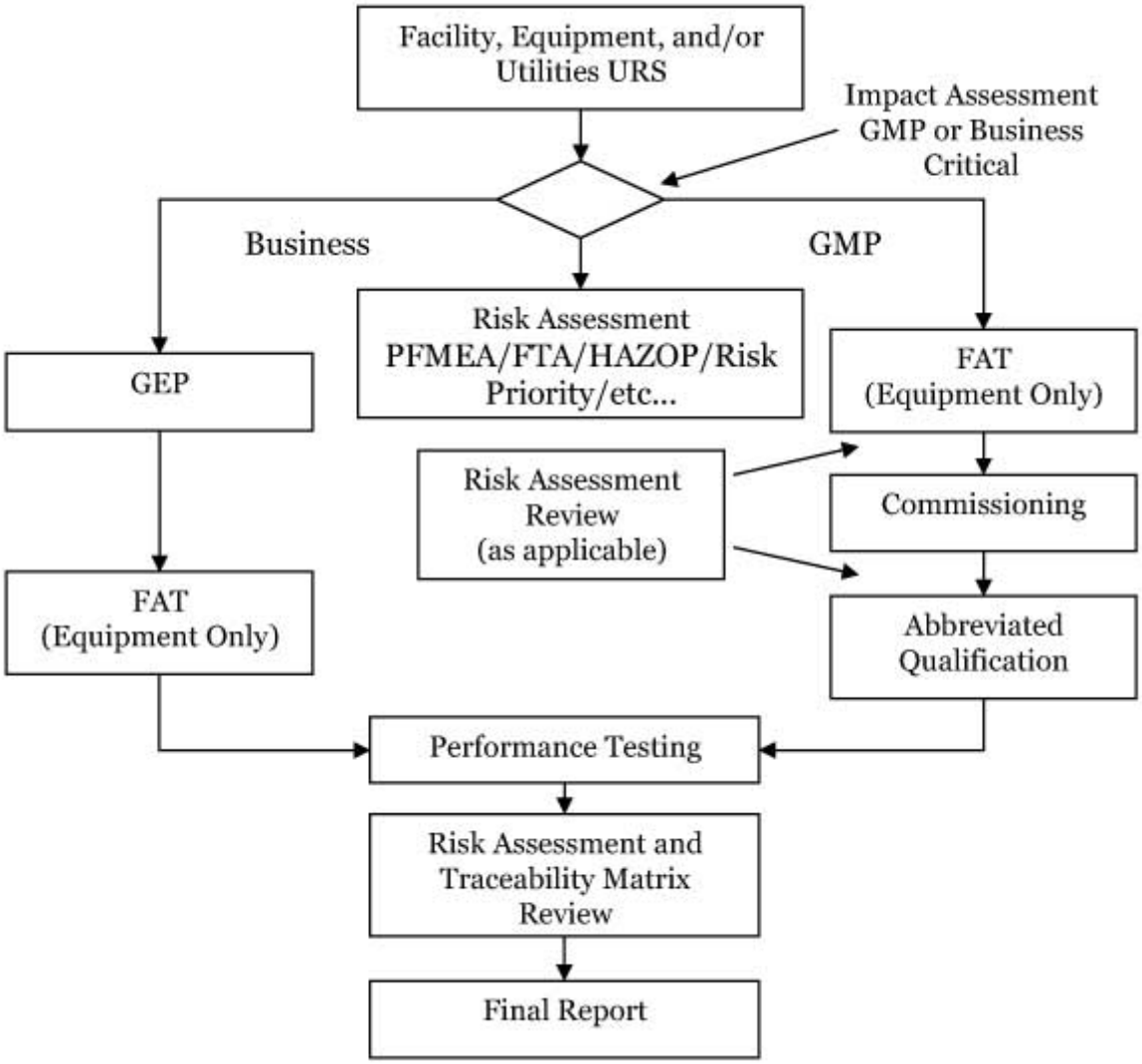

Table I: Comparison of Quality Risk Management Process for GMP Facilities, Utilities, and Equipment

GMP Facilities	GMP Utilities	GMP Equipments

• User Requirement and Design Review • Risk Analysis • Validation Strategy based on complexity • Commissioning • Risk Analysis Review (as applicable) • Facility Qualification (Abbreviated) • Risk Analysis Final Review • Traceability matrix • Final Report.	• User Requirements, Functional Requirements, and/or Design Review • Risk Analysis • Validation Strategy based on complexity • FAT (Functionalities) • Commissioning • Risk Analysis Review (as applicable) • Qualification (Abbreviated) ○ Critical Parameter verification under operation conditions • Risk Analysis Final Review • Traceability matrix • Final Report.	• User Requirements, Functional Requirements, and/or Design Review • Risk Analysis • Validation Strategy based on complexity • FAT (All configurations/capacities/functionalities) • Commissioning • Risk Analysis Review (as applicable) • Qualification (Abbreviated) • Risk Analysis Final Review • Traceability matrix • Final Report.

The Steps

Combining the different requirements for facilities, equipment, and utilities, the steps for the quality risk management approach can be combined summarized as the following:

1. Impact Assessment by answer the critical determination questions
2. Write a user requirement specification document that describe all the process owner requirements.
3. Perform a risk assessment that covers user requirement specifications
4. Most Common Models:
    - Failure Modes & Effects Analysis (FMEA), Fault Tree Analysis (FTA)
    - Hazard Operability Analysis (HAZOP), Risk Priority, Etc…
5. Validation Strategy (for GMP Critical [F/U/E only])—Establish the risk based approach strategy. How, when, and who will be testing and verifying the risk assessment outcomes
6. Develop FRS (for Equipment and Utilities that have control systems/software)
7. Perform a risk assessment that covers functional requirement specifications.
8. Perform Factory Acceptance test (Equipment and Utilities only):
    - Drawings and Specs, Material of Construction
    - Alarm & Interlocks, Power Failures, Loss Communication
    - Environmental Health and Safety (EHS) Evaluation
    - Critical Instruments and major components
    - Performance (Cycles, set-ups, Range, etc…)
9. Revise the risk assessment and/or validation strategy based on FAT results. Rational for change in

strategy must be provided.

10. Perform commissioning to ensure that the installation was performed adequately, verify changes in software (Equipment and Utilities only), confirm that all documentation was provided, and verify that the equipment/utility components work as specified.
11. Revise the risk assessment and/or validation strategy based on commissioning results. Rational for change in strategy must be provided.
12. Perform Qualification to demonstrate that the F/E/U is suitable for intended used:
    - Worst case scenarios or bracket approaches (Equipment and Utilities only)
    - Critical Parameter verification under operation conditions:
        - Environmental Monitoring
        - Area Classification, Air Flow pattern, Air Changes, and T & RH
13. Final Review to Risk Assessment to answer how the identified risk were mitigated, controlled or monitored.
14. Traceability Matrix to track all critical requirements (Recommended)
15. Final Report to close the qualification.

Recommendations

It is recommended that the quality group be involved from the beginning of the project. The process owner and process engineer should provide detailed requirements. All deliverables and risk assessments shall be revised and/or approved by quality. For a complete list of deliverables, see Table II.

Table II: Deliverables for the Quality Risk Management Process.

Legend: **D = Develop** **E=Execute** **R=Review** **A=Approval**	**Process Owner**	**Project Engineer**	**Commissioning / Executer Leader**	**QA-Validation**	**Vendors/ Contractor**
Project Proposal / Request	D	D		R	
User Requirement Specification	D	R/A		R/A	
Impact Assessment	R/A	R/A		D	
Risk Assessment (URS and Process)	D	R/A		R/A	
Validation Strategy	R/A	R/A		D	
Functional Requirements specification	R/A	R/A		R/A	D
Design Specification	R/A	D		R/A	R/A
Risk Assessment (Functional and Design Requirements)	D	R/A		R/A	D
Traceability matrix development	R/A	R/A	D	R/A	D
Design Review (Enhance Design Review)	R/A	D		R/A	R
Factory Acceptance Test Development	R/A	R/A	D	R/A	D

Factory Acceptance Test Execution	R/A	R/A	E	R/A	E
Commissioning Development	R/A	R/A	D	R/A	D
Commissioning Execution/Verification	R/A	R/A	E	R/A	E
Risk assessment review/update	R/A	R/A	E	R/A	E
Installation Qualification	R/A	R/A	R	R/A	D/E
Operational Qualification	R/A	R/A	R	R/A	D/E
Performance Qualification	R/A	R/A	R	R/A	D/E
Individual summary reports	R/A	R/A	R	R/A	D
Final Risk Assessment Update	R/A	R/A	E	R/A	E
Traceability matrix update	R/A	R/A	E	R/A	
Final Report	R/A	R/A		D	

Good engineering practice must be followed at all times. Periodic risk assessments should be performed as well. Any test or requirement leverage from FAT or commissioning should be justified and all requirements tested in at least one of the executable deliverables.

Have you or your company executed a commissioning or qualification using this approach with any success? Are there any other recommendations you could offer? If so, please respond in the comments!

Facebook Twitter Pinterest Email Add This

Tags:
GMP - Risk, Facilities Utlities and Equipment

Source URL: http://www.ivtnetwork.com/article/quality-risk-management-approach-qualification-and-commissioning