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Validation, Verification, Qualification:
Which is right and does it really matter?

Definitions:

(According to Webster, relative to quality endeavors)

- Validation is an act, process, or instance to support or corroborate something on a sound authoritative basis
- Verification is the act or process of establishing the truth or reality of something
- Qualification is an act or process to assure something complies with some condition, standard, or specific requirements

Definitions:

(According to the FDA)

Per the Code of Federal Regulations Title 21 – Food and Drugs, Part 820 – Quality System Regulations:

- Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. [CFR 21 Part 820.3(z)]
- Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. [CFR 21 Part 820.3(aa)]
- Qualification – NOT DEFINED

Validation Examples:

- Design Validation, Sterilization Validation, Test Method Validation, Software Validation, and Process Validation

Verification Examples:

- Design Verification and Process Verification.

Qualification Examples:

- Installation Qualification, Operational Qualification, Process Performance Qualification, Product Performance Qualification, and Supplied Material Qualification

Some General Observations

(When the Terms are Used)

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- Verifications tend to be used when assessing something completed that is static and is not prone to inadvertent change.
- Validations tend to be used when assessing something dynamic that is more prone to inadvertent change. They also tend to be larger endeavors including one or more subordinate qualifications (and/or verifications).
- Qualifications tend to be smaller in scope than validations, tend to be less dynamic, and are frequently a subset of a greater validation initiative.

General Observations (BSC Examples)

- A Design Verification verifies that a frozen (static) design meets top level product specifications.
- A Process Validation validates that the on-going (dynamic) manufacturing process produces product that meets product/print specifications and consist of Installation Qualifications, Operational Qualifications, Process Performance Qualifications, a Product Performance Qualification and perhaps Process Verifications.
- An Installation Qualification qualifies that equipment was installed correctly and are a subset of a Process Validation (or possibly a Test Method Validation).

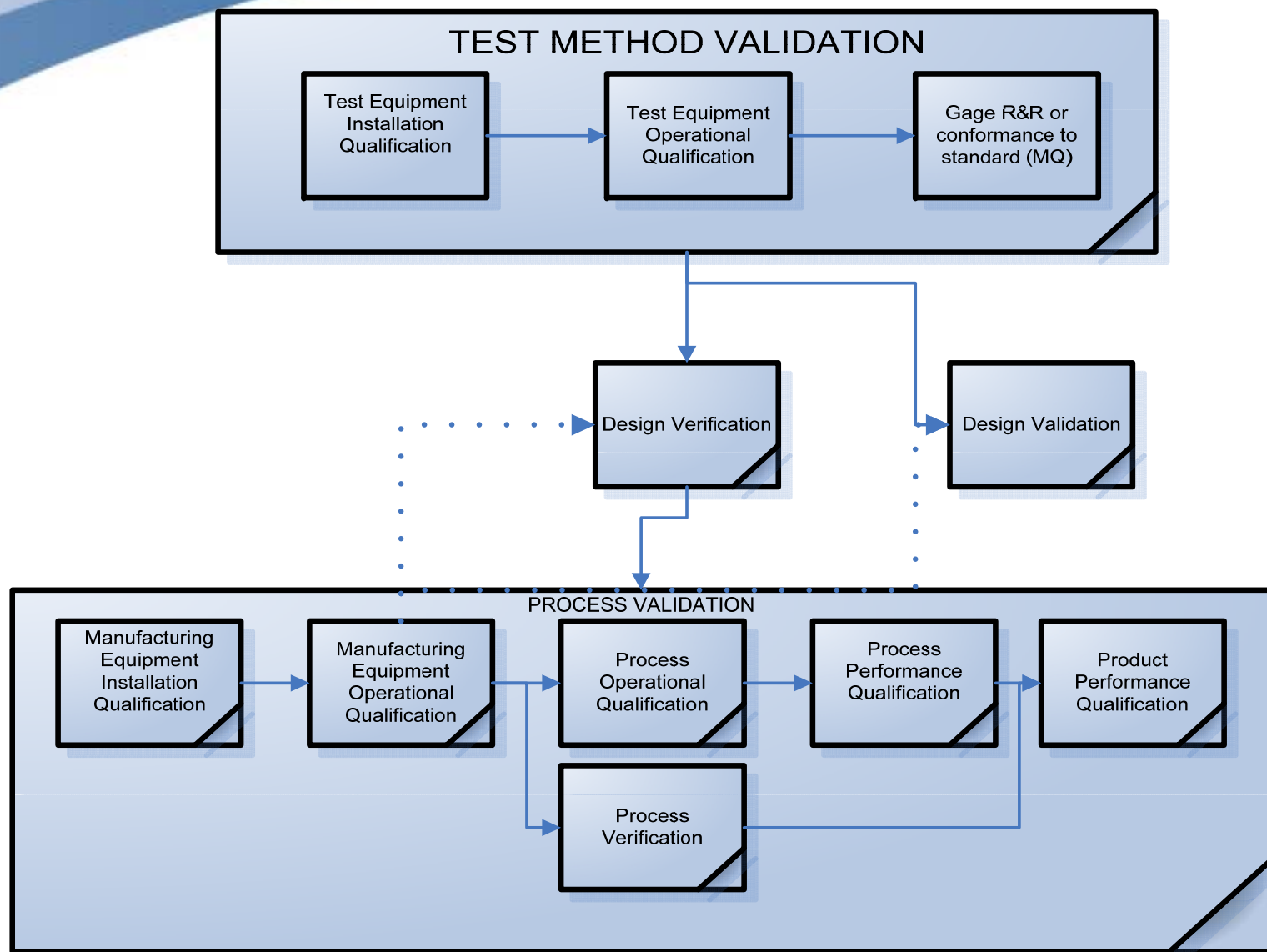
So how important is the name of these activities (Val, Ver, Qual)?
Not that important at all.
So what does matter in all of this?

What matters most is the nature and timing or the activity, not the name of the activity.

Nature: Who, what, (possibly where), why, and how is the activity being objectively demonstrated.

Timing: When can the activity be started and when must the activity be completed.

Validation, Verification, and Qualification



Validation, Verification, and Qualification

(Generic Verification/Validation/Qualification Considerations)

- Assessment conducted per pre-established plan and/or protocol(s) with clear vision of what constitutes “success.”
- Objective Acceptance Criteria (generally statistically based).
- Ideally, acceptance criteria determination should be risk based.
- Assessment should be thoroughly documented, yet concise.
- Final report should justify all deviations and have clear concise conclusion (i.e. Pass or Fail).

Validation, Verification, and Qualification (Test Method Validation Considerations)

PURPOSE:

- Demonstrate that the test method is appropriate for the specification being assessed.
- Provide objective evidence of consistent operation of test equipment and results.
- Demonstrate that the test method discriminates borderline acceptable from unacceptable product or part.

Note: Could entail meeting a standard or conducting analysis such as Gage R&R

Validation, Verification, and Qualification (Test Method Validation Considerations)

TIMING: Before Using in a formal study

RECORDS: TMV Protocol and Report

- Potentially: Equipment prints and specs, software validation documentation, data sheet validation documentation.

PERSONAL INSIGHT:

Make sure your acceptance criteria is realistic.

Validation, Verification, and Qualification (Design Verification Considerations)

PURPOSE:

- To establish documented evidence that the design output meets pre-established design input requirements as identified in the Product Specification.

TIMING:

- During development phase on a frozen design, generally prior to Process Validation

Validation, Verification, and Qualification (Design Verification Considerations)

RECORDS: DV Master Plan (DVMP), DV Protocols, DV Report(s) [Perhaps a DVMR]

PERSONAL INSIGHT:

- Remember it's a verification, not a discovery experiment. Success should be at least probable.
- Limit/Challenge testing (if not done earlier) is critical to defend spec tolerances.
- Should use risk based, statistical acceptance criteria
- Use contingency planning in DVMP and DV Protocols (e.g. double sample attribute plans vs. single sample attribute plans) anticipate issues (vs. writing deviations in the report)

Validation, Verification, and Qualification (Design Validation Considerations)

PURPOSE:

- To ensure that device designs conform to defined user needs and intended uses as identified in the Market Specification.

TIMING:

- Planning should start as soon there is a Market Specification. The Design Validation must be completed before full product launch.

Validation, Verification, and Qualification (Design Validation Considerations)

RECORDS: DVal Plan, DVal Protocols, DVal Report(s)

PERSONAL INSIGHT:

- The earlier, the better.
- Leverage DV results where appropriate (should be defensible).
- Be realistic in acceptance criteria (some requirements are very hard and/or very expensive to validate).
- Consider used risk based criteria.
- Avoid redundant assessments of the same requirement.
- Avoid over reliance on pre-release market evaluation product surveys.

Validation, Verification, and Qualification (Process Validation Considerations)

PURPOSE:

- To establish documented evidence that a process consistently produces an output that meets its predetermined requirements and that the overall manufacturing line produces a product that meets finished device requirements.

TIMING:

- Planning can start as design and process are solidified. The Process Validation must be completed before full product launch.

Validation, Verification, and Qualification (Process Validation Considerations)

RECORDS: Master Validation Plan (MVP), PV Protocols, Master Validation Report (MVR)

PERSONAL INSIGHT:

- Limit/Challenge OQ testing at parameter limits is critical to defending full process.
- Decide early what constitutes validated window for future process changes.
- Should use risk based, statistical acceptance criteria.
- As with DV, use contingency planning in MVP and PV Protocols (e.g. double sample attribute plans vs. single sample attribute plans) anticipate issues (vs. writing deviations in the report).
- Plan for line extensions and other likely future changes when planning and identify the requirements for implementing those future changes.

Questions, Discussion

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Wednesday, September 13, 4:00-8:00 P.M.

Weaver Lake III Building

I-94. Weaver Lake Exit, Maple Grove

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- **Chemists/Scientists**
- **Regulatory Affairs Professionals**
- **Production Supervisors - 2nd and 3rd shift**

**Positions above require a 4-yr. degree*

- **Technicians - Quality, Manufacturing, R&D, Process Development, Chemical and Laser**

**Position above requires a 2-yr. degree*

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