Wyeth

ENGINEERING PHARMACEUTICAL INNOVATION

If looks could kill…

No work would get done

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Disclaimer

This material does not represent Wyeth Policies, Practices or Procedures and is intended only to stimulate discussion among congenial industry colleagues who won't throw things at the speakers

or each other

Have you ever heard:

- Those QA guys don't get it…
- Those engineers don't get it…
- Quality requirements are half folklore…
- Engineers are always late and blame QA…
- Quality only works half days…
- Engineers can't explain anything in English…
- We have to do everything twice…

Were there ever "good old days"?

- **Verification** – from Latin veritas, or truth
  - To establish the truth of correspondence between a "product" and related specifications
  - Simplified: Are we building the product right (met specs)?
- **Validation** – from Latin valere, or worth
  - To establish the fitness or worth of a "product" for its intended purpose
  - Simplified: Are we building the right product (are the specs right and meet process requirements)?

Paraphrased from "Software Engineering Economics, Barry W. Boehm, ©Prentice-Hall, Inc., 1981"

Thanks to ASTM and GAMP 5, these no longer apply

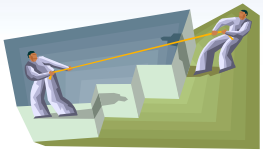
Why Do So Many Technical People Dislike IQ/OQ/PQ and the "V" Word (Validation)?

- Templates? The goals may have gotten lost by trying to over-standardize
- Arguments about "Quality" verses "Engineering" documentation
  - We often separate "validation" from engineering and construction activities because of documentation standards!
  - There is no requirement for separation
- Quality moving further into detailed document approvals and requiring tech personnel to meet evolving formatting standards

Why Do So Many…

- Several stages of testing exist, often nearly unrelated to FAT, SAT and commissioning which are GEP
- IQ, OQ, PQ developed to create a common approach for tech, quality and regulatory personnel
  - Often duplicate documentation
- Seemingly spend more time trying to fit tests into definitions than actually designing tests
- Projects driven by business schedules that cannot accommodate any delays (18/7?)
- The issues encountered in life sciences are not with the goals of V&V, but with the methods

So…



OR

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Backup slides

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A better way?

- Emphasize test design that results in meaningful challenges to systems instead of meeting some prescribed format – use industry standards for creating tests
- Eliminate duplicate testing due to document systems & artificial lines
  - all test documentation for life sciences must be accurate, and practical to execute

Why we have tested this way

- FDA added regulations after systems failures resulting in patient injury/death
- Regulatory agencies require that an independent quality organization oversees drug and device manufacture (this will not change regardless of testing methods!)

Compliance Programs Came From GEP

Engineering	Compliance
Test Plan	Validation Plan
Cross References	Trace Matrix
URS, Specs, Design	URS, FS, DS,
Truth Tables, Targets	Accpt Criteria
Tests	Protocols
Test Reports	Qual/Val Reports

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DQ (Design Qualification)

- Gaining steam in pharma
- One of the few activities that is truly "validation"
  - DQ examines designs to ensure the "product" is or will be appropriate for the purpose (intended use)
- Different from current "typical" design review
  - Often focused on the documentation process and the accuracy of revisions

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Installation Qualification (IQ) Concepts

- A verification activity
- Verify that what you have installed meets specifications
  - Too late to prevent building/purchasing the wrong equipment or system
- One common output is the “baseline configuration” for equipment and systems (a reactive result)

Operation Qualification (OQ) Concepts

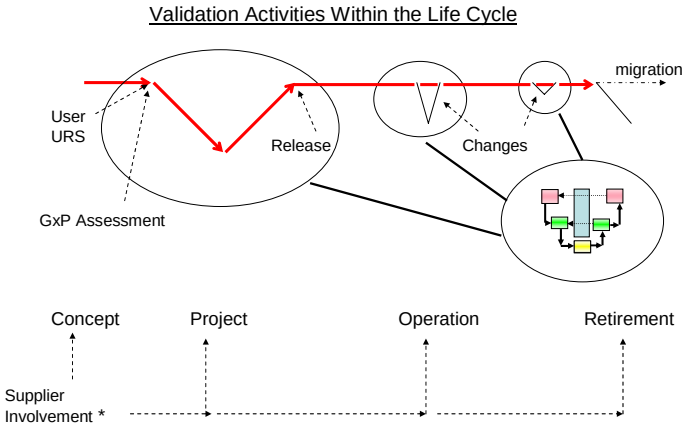
- Test the operation of modules and complete systems for correct operation
- Test to limits, e.g. demonstrate prescribed ranges of control are accomplished
- Verification and validation testing are often intermingled in this testing method
  - We place a large burden on writers and reviewers to make these documents understandable
  - Can be difficult to manage for complex, phased delivery/turnover and integrated systems and equipment

Performance Qualification (PQ) Concepts

- PQ = Performance Qualification or Process Qualification ?
- Verification or Validation ?
- Verify systems, equipment, infrastructure perform to specifications and are reliable over some period of time
- Verify products produced conform to specifications
- On the plant floor, rarely we test to limits, but just show it works (normally)
- Verify data from production represents the process outcomes

Could it be that PQ is a verification activity ? Or …is it validation if we concurrently make product to demonstrate operations ?

GAMP 5- Design



* - This could be a complex supply chain
- Supplier may provide knowledge, experience, documentation & services throughout lifecycle

Simplified V-Model

- **Plan**
- **Specify**
- **Build**
- **Verify**
- **Report**
- **Risk mgmt throughout process**

- Repetition of V-activities for changes
- Incorporates end-of-life activities

Thank You!