Validation

Why, how, wherefore?

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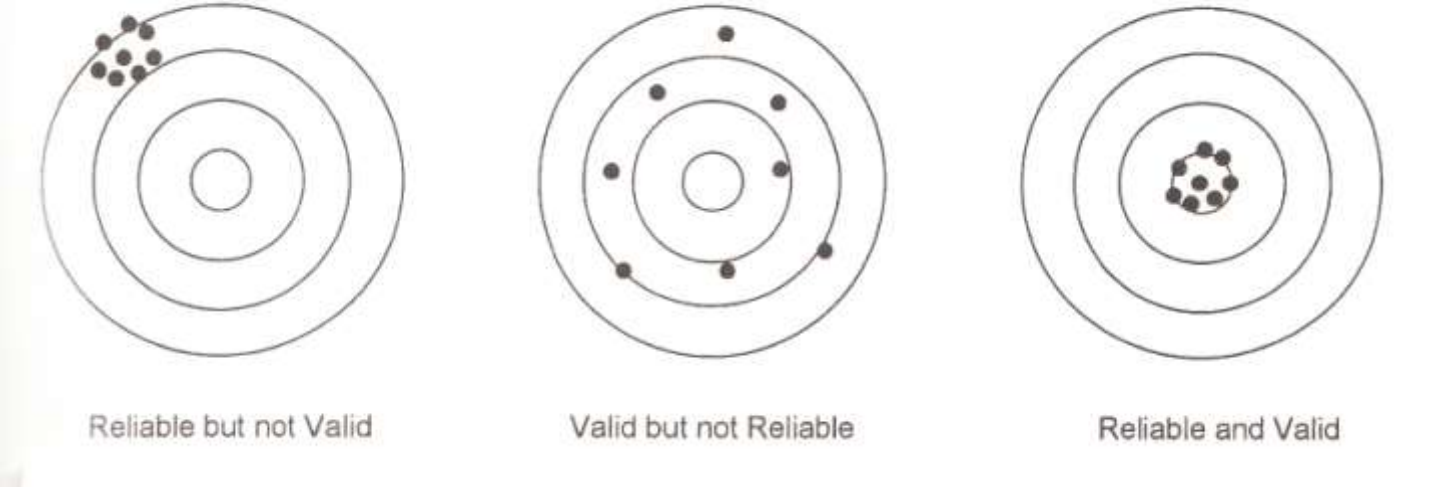
The “Why”

“ Establishing documented evidence that provides a high degree of assurance that a specific process will consistently product a product meeting its predetermined specifications and quality attributes”

FDA 1987

Validation

A prevention based activity



How are we going to get there?

Assumption

- The facility is an end user
- The facility does not “grow” in-house designed products
- The facility does not customize commercial off the shelf (COTS) software

Definitions

- Validation = confirmation by examination of objective evidence that specific requirements and/or specified intended use(s) is/are met
- Verification = act of reviewing inspecting, testing, checking, auditing or otherwise establishing and documenting whether items, processes, services or documents conform to specified requirements

Validation

Are you building the right thing?

Verification

Are you building the thing right?

Usually contains elements of design qualification

Definitions (con't)

- Calibration = process used to maintain the performance of a measurement system. For physical measurements we determine under a performance set of conditions that values indicated agree with results for a standard that is independently tested

Note: in the USA that is typically a standard traceable to NIST

Definitions (con’t)

Qualification = demonstrating the reproducibility of a calibrated element.

Definitions (con’t)

- Process Certification = equipment qualification performed by an endorsed 3rd party ISO standard accredited company

What do we do?

Calibrate

Thermometers
Balance
Centrifuges
Incubators (wet / dry)

Validate

Alarm systems
Apheresis equipment
Pneumatic tube systems
(Computer systems)

When do we do “it”

Upon

- Receipt
- Relocation
- Replacement of [essential] part
- Replacement (upgrade) of software

Types of Process Validation

- May be conducted at different points during the life cycle of a product
- May be
  - Prospective
  - Concurrent
  - Retrospective

Where does this take us to?

- Responsibility to our customers
- Responsibility to our staff
- Responsibility to our management
- Responsibility to ourselves


Pustefix

A Comparison - 1

Another Widget

- Install & Document
- Execute [existing] Plan including calibration(s)

A New Widget

- Develop IQ
- Install & Document
- Learn to Use
- Develop Validation Plan
- Review & approval - Plan
- Execute Plan including calibration(s)

A Comparison - 2

- Review & approve validation data
- Release to use

- Develop SOPs
- Review & approve validation data
- Validate SOPs
- Review & approve SOPs
- Train Staff
- Release to use

Validation – What are you testing for?

Specificity

Accuracy

Precision

Reproducibility

Making it Easy (ier)

- An SOP that says how, where, when are you going to develop a plan
- A format included in your SOP for consistency that allows for “tweaking” as needed
- A validation library that allows for re-use of plans without reinventing the wheel

The Validation Protocol

A document that specifies how the validation will be conducted, what our testing parameters, product (result) characteristics and decision points to determine acceptable test results

Basic Principles

- Equipment operates within required ranges
- Controlling, and monitoring elements demonstrate that they are capable of operating within the same ranges as equipment requires
- Replicates representing the operating ranges demonstrate that output consistently meets specifications
- Defined parameters are monitored during routine operations and re-qualified, re-certified or re-validated as necessary

The SOP Driving the Process

- Purpose
- System Description
- Responsibilities
- Protocols
- SOPs / People / Equipment / Materials
- Test samples
- Testing conditions
- Data collection
- Acceptance criteria
- Results
- Approvals

Organization

- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)

Note: for most of the basic equipment you use an IQ and calibration with possibly a PQ

Helpful Hints

- Develop a library of the basic and complicated plans
- Don’t reinvent the wheel
- Review plans before you reuse them
- Compare against equipment
- Revise as necessary

Serofuge™ - IQ

- Clean, level surface
- Boundary no less than 11.8” around the centrifuge
- Located so that ambient air can circulate
- Install & lock desired rotor into place

Serologic Cell Washer: IQ & OQ

- IQ
  - Bottom of cell washer must be high enough so the drain hose is pitched downward with no constriction
  - 5 “ clearance all sides for air cooling
  - Install proper fuse for AC power at site
  - Properly grounded receptacle to use
  - Connection of saline source

Serologic Cell Washer: IQ & OQ -2

- OQ
  - Tachometer and timer check
  - Serologic calibration to determine spin times/speeds for all test media used

The Big Machine: IQ, OQ, PQ

- IQ – prepare the site prior to receipt, install in accordance with mfg instructions, or by mfg
- OQ – test the elements of the software you're going to be running, .i.e.,
  - Security - Assay
  - Results configurations - Data transfers
- PQ – "parallel testing" with data uploading in large volumes

A Useful Example – pneumatic tube system

- Probably already installed
  - Installation information & specifications with facilities management
  - Configurations of tubes it uses
  - How long are the distances you will need to “ship products” - time
- Operations
  - How much force does it generate to move materials through system
  - How much force is the material you want to send capable of surviving

Tube System (con't)

- OQ
  - Switching stations: all straight runs, or are there manual/automated transfer points
  - Operating temperature of the tube system, if known
- PQ
  - The trials: time & temperature of numerous products to and from the Blood Bank (use expired product)

The outcome!

If you're Lucky Enough

To get a new pneumatic tube system ??