

# Validation

Why, how, wherefore?

Ellen Zeigler, MT(ASCP)SBB,  
CMQ/OE(ASQ)



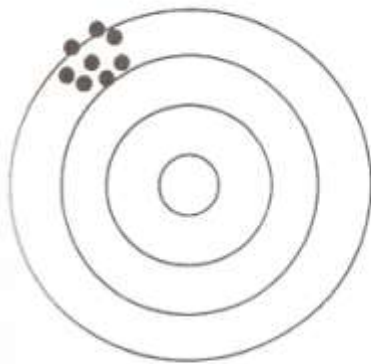
# The “Why”

“ 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”

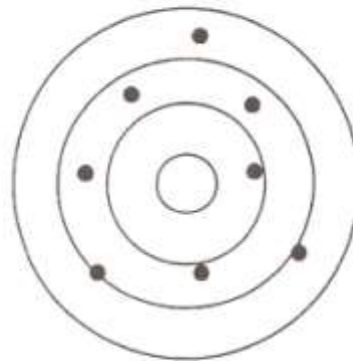
FDA 1987

# Validation

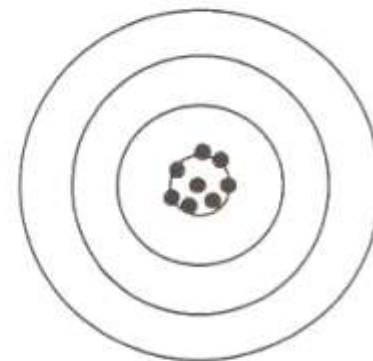
A prevention based activity



Reliable but not Valid



Valid but not Reliable



Reliable and Valid

# 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 3<sup>rd</sup> 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





# 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
  - Results configurations
  - Assay
  - 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 ??