



A Tale of Two Projects

By Eric Felz, Genzyme, Validation Manager

Assisted by: Lou Traglia, CAI

Overview of presentation

- Provide scenario
- How we did Risk Based Verification
- What was done for traditional approach
- Compare approaches
- Discuss good, bad and ugly



Scenario - Two production Outages

Similarities

- Scope
 - Qualified (ISO 7/8) AHU replacement
 - Commissioning and Qualification Company
 - Time constraints
 - Area configuration
 - BMS upgrade coincidental

Differences

- Quality & Validation managers
- Buildings



Situation

Building 1

- Decided to use Risk Based Approach
- AHUs & associated rooms
- New RO generation/distribution
- Same group performed commissioning and validation

Building 2

- Used traditional methods
- AHUs & associated rooms
- Different teams performed commissioning and validation teams



Implementation

- Training and Briefs
- Write Risk Plan – Rules
- Risk Assessments
 - Done with SME teams
 - QA, Validation, Engineering, Manufacturing, Moderator, Facilities
 - Done for each System



One Way to implement

Top Down FEMA

- What are CQA/CPs?
- What are risks to Patient?
 - Severity/ Probability/Detection?
 - How do we control?
- Regulatory requirements?



Risk Assessment

- Discussed differences for
 - 100K rooms
 - 10k rooms
 - Cold rooms
- Any Regulatory Requirements
- Role of Commissioning
- From Risk Assessment- Specific items to verify



Risk Assessment Example

- Identify Risk to patient
- How does it manifest?
- Severity?
- How Controlled & Probability?
- Detection?
- Determine
 - Limits
 - How do we test controls



Risk Analysis Report

- Summary of exercise
- What we are going to test
- How to test
- Approved by all groups associated with assessment



Results

- HEPA filters - Integrity
- Static Press control & alarm
- Air flow
- Room Differential Pressures
- Air lock operation/interlocks
- Gowning SOP
- Cleanability
- HEPA PMs



Surprises

- Nothing on AHU
- No PMs
- Temperature wide specification

- RO System- caught low detectability of critical parameter



Traditional Method

IOQ Everything in Engineering specification

- Filters / Prefilters
- Motors
- Alarms
- Temp control
- Pressure control/ alarm of D/Ps



Comparison of items

Traditional

- MOC of AHU
- #, type of Prefilters
- Motor size/ direction
- #, type size of Filters
- Coil sizing
- P&ID of ducting
- Air Changes
- HEPA certs
- ALL instruments calibrated
- Pressure control (d/p)
- Temp control
- Flow certs (air changes)

Risk Based

- HEPA Certifications
- Temperature
- Room differential pressure calibration
- flow certification (air changes)
- Pressure control (duct static pressure)



Advantages of Risk Based Approach

- No IQ of AHU's
- All items commissioned
- Reduced load on Validation / QA
- Faster Approvals of protocols
- Cold rooms - no IQ of components



The D/P Advantage or the D/P debacle

What is differential pressure specification?

RA team discussed in assessment

- QA, VAL, Commissioning aligned

Traditional team

- Specification was “drawing”
- Disconnect between design specification and target values between Commissioning and Validation Teams
- Caused large setback in schedule



Advantages –cont'd

Avoided the “spec?” issue

- Temperature control
 - Not related to patient safety
 - No link to Tech Transfer
 - Is design specification- personnel comfort
- Patient doesn't care about all specifications
 - Business risk control
 - EHS risk control



Risk Based Advantage cont'd

- Early agreement on priorities
- Team mentality
- Minimizes deviations
- Aligns expectations



Things to consider

- High Startup costs
 - Training on approach
 - Doing the Analysis
- More involvement from QA
- More engineering decisions
- Mandates Commissioning



Overall

Significantly reduced IOQ work

Focused Efforts

Aligned and harmonized teams

Questions?

