The Role and Purpose of Data - before, during and after Qualification

PDA New England Chapter / ISPE Boston Area Chapter Joint Meeting
May 17, 2017
Woburn, MA
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What is Data?

- Facts that can be used in calculating, reasoning or planning (*Merriam-Webster*)
- Information expressed as numbers for use especially in a computer (*Merriam-Webster*)
- Information in a raw or unorganized form (www.businessdictionary.com)
- A set of qualitative or quantitative variables (*Wikipedia*)
- A subset of items that can be assembled or processed to produce meaningful information (?)

Characteristics

Accuracy  Validity  Reliability  
Relevance  Timeliness  Completeness
Role vs. Purpose

**ROLE** - an assumed function; the ‘what’
- Measurement values that represent a process or condition
- Also includes derived and statistical values

**PURPOSE** - the objective or reason; the ‘why’
- Provides the acceptance criteria values and the test result...
- Which tells us if the process or condition met our expectations (*compliance!*)

INFORMATION!

Equipment Design and Manufacturing

- Target industry
- Customer requirements
- Data collection and retention capability
- Performance specifications
- Pre-qualification
- Feedback / Analytics
Purchasing

• Analysis / Analytics
• Assessing business needs
• Assessing IQ, OQ and PQ requirements
• Communicate with vendor(s)
• Avoid unnecessary features

Qualification

• Defined Requirements
• Defined Acceptance Criteria
• Results & Supporting Data
• Quantity
• Quality
Qualification Data

- Pragmatic – Is this practical and does it add value?
- Quantity – What is the right amount?
- Quality – measurement instruments, data logging system, sampling locations...
- Statistical tools – use them (with care)
- Data visualization tools – use them (with care)
- Anything odd – don’t ignore a potential problem
- Black box testing – ask the vendor for calculation methods
Example 1 – Taking a closer look
Example 3 - Presentation

Operation

• What was learned from qualification?
• Maintaining compliance
  – Monitoring
  – Data collection and retention
  – Maintenance
• Data management system / process
• Redundancy
• Vigilance(!)
Summary and Q&A