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
Sylvan Poeckh
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 (?)
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
Freezer XYZ
Example 1 – Taking a closer look
Example 1 – Taking a closer look
### Example 3 - Presentation

<table>
<thead>
<tr>
<th>MIN</th>
<th>MAX</th>
<th>AVG</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC01</td>
<td>36.6</td>
<td>36.6</td>
</tr>
<tr>
<td>TC02</td>
<td>37.0</td>
<td>37.0</td>
</tr>
<tr>
<td>TC03</td>
<td>37.2</td>
<td>37.2</td>
</tr>
<tr>
<td>TC04</td>
<td>36.8</td>
<td>36.9</td>
</tr>
<tr>
<td>TC05</td>
<td>37.1</td>
<td>37.2</td>
</tr>
<tr>
<td>TC06</td>
<td>36.9</td>
<td>36.9</td>
</tr>
<tr>
<td>TC07</td>
<td>37.2</td>
<td>37.2</td>
</tr>
<tr>
<td>TC08</td>
<td>37.4</td>
<td>37.4</td>
</tr>
<tr>
<td>TC09</td>
<td>36.8</td>
<td>36.9</td>
</tr>
<tr>
<td>TC10</td>
<td>37.2</td>
<td>37.3</td>
</tr>
<tr>
<td>TC11</td>
<td>37.0</td>
<td>37.0</td>
</tr>
<tr>
<td>TC12</td>
<td>37.3</td>
<td>37.3</td>
</tr>
<tr>
<td>TC13</td>
<td>37.3</td>
<td>37.3</td>
</tr>
<tr>
<td>TC14</td>
<td>37.0</td>
<td>37.1</td>
</tr>
<tr>
<td>TC15</td>
<td>37.4</td>
<td>37.4</td>
</tr>
<tr>
<td>TC16</td>
<td>37.3</td>
<td>37.4</td>
</tr>
<tr>
<td>TC17</td>
<td>37.3</td>
<td>37.3</td>
</tr>
<tr>
<td>TC18</td>
<td>36.7</td>
<td>36.7</td>
</tr>
</tbody>
</table>
Operation

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