Pfizer’s Science and Risk Based Approach to C&Q

ISPE Boston Chapter
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Organizational Scope and Status of Verification Program

<table>
<thead>
<tr>
<th>Status</th>
<th>Pfizer Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>&gt;70</td>
</tr>
<tr>
<td>Newly implemented (&lt; 1 year experience)</td>
<td>9</td>
</tr>
<tr>
<td>In planning and implementation</td>
<td>16</td>
</tr>
<tr>
<td>Future Opportunities</td>
<td>&gt;45</td>
</tr>
</tbody>
</table>
Verification Flow chart

Comparison of Paperwork of Aseptic Filler
Comparison of Paperwork of Packaging Line

Compare C&Q cost data
Some Common Notions about Verification Seen at the Sites

The Verification Program = Spec/Design/Testing

Verification = Testing to Show Fitness for Use

GEPs take Engineering Management's Commitment

The SME is responsible for testing and evaluating the results

Engineering is responsible for Assuring Usefulness

Document Example

- Requirements Document
- Design Review Summary