



# Validation

Performance  
Qualification

Participant Notes

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# PROGRAM OVERVIEW – ONE PAGE SUMMARY

**Audience & Group Size:** Maximum 12 people. Anyone in COMPANY who will be required to participate in technology transfer for new products and/or processes into production.

**Duration:** 3.0 days for the Validation workshop. Optional additional 2.5 days for Train-the-Trainer components

**Aim:** This workshop is designed so that participants become comfortable with the statistical approach to validating a manufacturing process which is either new or which involves a new product. It does so by giving participants practice using some of the basic tools in realistic validation scenarios. It also aims to equip participants to work effectively with Company’s Statistical Competency Group when more advanced approaches are necessary or when questions beyond their scope of knowledge are encountered. The focus is on the Performance Qualification stage of Validation.

The workshop includes a “Learning Unit” which can be used back on the job to reinforce the learning and transfer the learning gained by workshop participants to other people in the workplace.

## Objectives:

At the end of the Program, Participants should be able to:

- ◆ Explain the purpose and steps of Process Validation and Performance Qualification using the provided Validation Roadmap.
- ◆ Explain the need for and benefits of using a statistical approach when doing Performance Qualification
- ◆ Plot data for Key Product Characteristics (KPC’s) as initial step in “seeing” what the process is doing
- ◆ Identify factors that influence variability and test their significance
- ◆ Apply statistical tools to determine mathematical relationships between KPC’s and process parameters; use this information to reduce variability and optimize the process.
- ◆ Determine when a process is stable and in control and be able to calculate Control Limits and check process capability.
- ◆ Interpret Control Charts to identify potential improvements to the process. Understand how such improvements should impact Control Limits.
- ◆ Demonstrate the complete process of Performance Qualification upon being given data from a completed EMO, including completion of necessary paperwork.
- ◆ Know how to continue using the tools past the PQ.

<b>DAY 1 (Sections 1 &amp; 2)</b>	<b>DAY 2 (Sections 3 &amp; 4)</b>	<b>DAY 3 (Sections 5 &amp; 6)</b>
<p><b>Section 1- Introduction (2hr)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Icebreaker &amp; Learning Objectives (30 min)</li> <li><input type="checkbox"/> Overall Journey to Validating a Process (30 min)</li> <li><input type="checkbox"/> Performance Qualification- Our Approach(1 hr)</li> </ul> <p><b>Sect. 2- Initial Exploration with Plots &amp; Variability (4hr)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Use Information Effectively for PQ (1 hr)</li> <li><input type="checkbox"/> ‘See’ the Process- Interpret Data Plots (1.5 hr)</li> <li><input type="checkbox"/> Differentiate between Multiple Treatments with Confidence- ANOVA (1.5 hr)</li> </ul>	<p><b>Section 3- Variability Causes &amp; Relationships (3 hr)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Uncovering causes of variability (30 min)</li> <li><input type="checkbox"/> Methods to determine which factors have greatest affect on response (2 hr)</li> <li><input type="checkbox"/> Find relationships to improve process (30 min)</li> </ul> <p><b>Section 4- Calculating Control Limits (3 hr)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Control Chart Concepts (1 hr)</li> <li><input type="checkbox"/> Choosing Correct Control Chart (30 min)</li> <li><input type="checkbox"/> Setting &amp; Refining Control Limits (1.5 hr)</li> </ul>	<p><b>Section 5- Verifying Process Capability (2.25 hr)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Capability Concepts (1 hr)</li> <li><input type="checkbox"/> Calculate Process Capability (1 hr)</li> <li><input type="checkbox"/> Sign off a capable process (End of Example 1) (15 min)</li> </ul> <p><b>Section 6- Final Assessment (4.25 hr)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Putting all the tools together (Example 2) (3.75 hrs)</li> <li><input type="checkbox"/> Summary &amp; Participant Feedback (30 min)</li> </ul>