

Learner Name \_\_\_\_\_

# Validation- Performance Qualification



Attendees of Workshop for Validation-  
Performance Qualification

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## UNIT OVERVIEW

### Aim:

To demonstrate the ability to apply the tools and techniques of Company’s standard method for conducting a Performance Qualification as part of validating a new or modified process.

**Objectives** – at the completion of this Learning Unit, you will be able to:

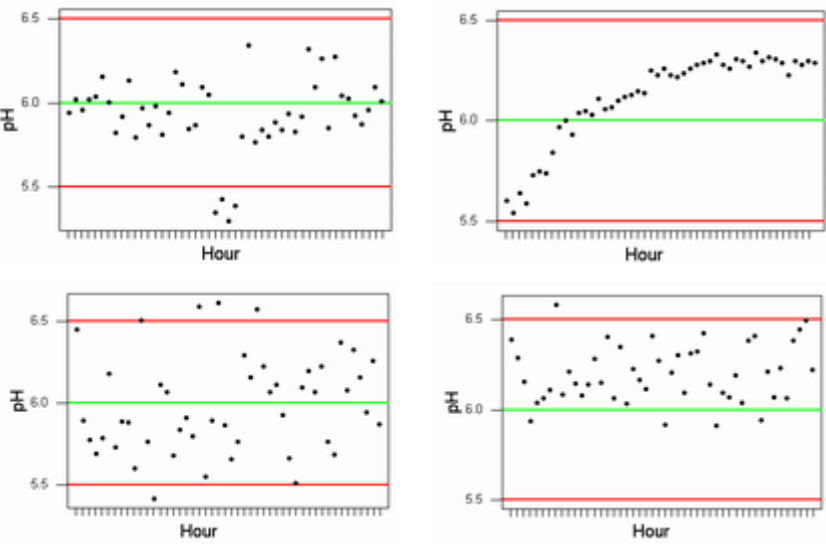
- ◆ Explain the purpose and steps of Process Validation and Performance Qualification using the provided Validation Roadmap.
- ◆ Explain the need for and benefits of using a statistical approach when doing Performance Qualification
- ◆ Plot data for Key Product Characteristics (KPC’s) as initial step 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.
- ◆ Discuss why it is useful to continue using the tools past the PQ .

### Structure:

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**Prerequisites:** Completion of SPC Workshop      **Associated Units:** SPC Learning Unit

Thanks to the following people for their help with the development of this Learning Unit: Rob Taylor

Ref	Learning Outcomes	C	Ver'd & Date	Notes
2.2	<b>'See' the Process- Interpret Data Plots</b>		♦	
2.201	Using these four plots as examples, discuss the value of using Time Plots early in the course of a PQ. Describe what each plot tells you about the process in terms of: <ul style="list-style-type: none"> <li>• data centering</li> <li>• spread</li> <li>• trends</li> <li>• problems</li> </ul> 			
2.202	Name at least three types of graphs that you may use to quickly determine if there appears to be a substantial difference between different test treatments. <ul style="list-style-type: none"> <li>•</li> <li>•</li> <li>•</li> </ul>			
2.3	<b>Differentiate between Different Treatments with Confidence- ANOVA</b>		♦	
2.301	Draw the following sketches: <ul style="list-style-type: none"> <li>• Group-to-Group Variation is large while Within Group Variation is small</li> <li>• Group-to-Group Variation is small while Within Group Variation is large</li> </ul> Point out which situation would likely mean that the data groups come from different populations having different Means.			
2.302	Explain how ANOVA does the same thing as the visual comparison of groups, but with greater precision. Be sure to discuss: <ul style="list-style-type: none"> <li>• meaning of F-ratio</li> <li>• a situation where it would be difficult to tell the difference by graphs alone</li> </ul>			

C = Critical ♦ = No verification required

