

# The Use of Statistical Process Control (SPC) Using Control Charts to Maintain Compliance in the Laboratory

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Compliance under GLP can be difficult. The setting up of a system to monitor the performance of methods and instruments can lessen this. Statistical Process Control (SPC) uses control charts and statistical guidelines to monitor a wide variety of things in the compliant laboratory. These generate a proactive system to assess problems early on and quickly to be handled by adjustments rather than the strict situation of a non-compliance event.

Control charts are based on the distribution of data expected in a laboratory, the Gaussian distribution of occurrences. There are well-defined probabilities for the data. Guidelines for good or unacceptable behavior are well known. The most common of these are Nelson Rules, in use for over a century. With a wide selection of the variables to monitor, assessing performance can be simple.

## LEARNING OBJECTIVES

How to understand control charts and their underlying statistics, how to choose variables to monitor, how to maintain the records, and to plan adjustments. There will be examples and walkthroughs of control chart implementation and use. A review of the relevant statistics will also be done.

## INSTRUCTOR PROFILE

### JOHN C. FETZER

John C. Fetzer has had over 30 years of experience in laboratory compliance, including developing methods, writing SOPs, training, and auditing. He has served on the editorial advisory boards of the Journal of Chromatography, Analytical Chemistry, and Analytical and Bioanalytical Chemistry.



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