



Control Chart Package



STATISTICAL PROCESS CONTROL

The Control Chart Package allows sophisticated statistical process control by plotting Shewhart I-Charts as recommended in the USP <1010>. Out-of-control data can be detected by defining upper / lower control limits and control rules (Western Electric, Nelson, and user-defined). A status display provides feedback about the impact of a rule violation. Optional features include events to mark changes in the process, sidecharts to contain basic statistics in a box plot, the creation of subcharts for a specific range, and confidence intervals. Moreover, a secondary column can be used to factorize the data series e.g. by an operator. Measurements can be aggregated directly from independent assay runs or from manual input.

FEATURES

The following list highlights the USP <1010> methods supported by the Control Chart Package

EXTENSIVE AND INDEPENDENT CONFIGURATION OPTIONS ON I-CHARTS

I-Charts (Individual chart) monitor data such as measurements and regression parameters at regular intervals, with each data point within the chart representing a sample or an observation respectively.

All charts generated by the Control Chart package are I-Charts. You can manually add the chart data, or aggregate it from other PLA 3.0 documents such as Quantitative response assays or Dose-response assays.

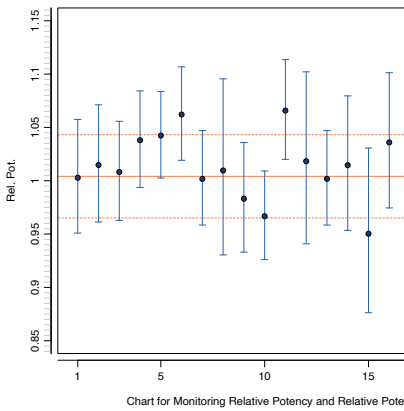
PARAMETER STATISTICS TO VIEW DESCRIPTIVE DETAILS FOR EVERY CHART

The Control Chart package automatically calculates the following parameter statistics for each data series: mean and median, standard deviation (SD), coefficient of variation (CV), 1st and 3rd quartile, min. and max. values, number of values, and missing values. The statistics are displayed on the Dashboard and in the reports.

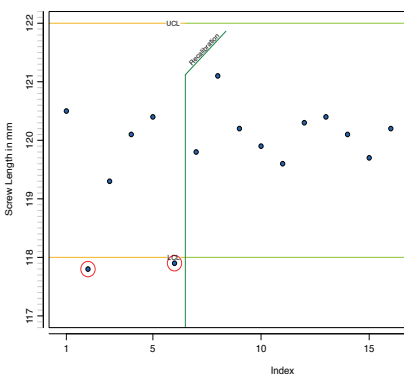
In addition, you can configure confidence intervals and sidecharts to deeply analyze your data.

STATISTICAL PROCESS CONTROL BY DEFINING CONTROL RULES AND CONTROL LIMITS

Control limits define a range of acceptable values, determined by an upper and a lower limit. Any value outside of this range is considered to be a rule violation and needs to be marked as such.



Plotting relative potency with confidence intervals as bars



Event marking the recalibration of a machine



Use the Control Chart Package to set up rule sets with independently defined upper and lower control limits. These rules will be drawn as horizontal lines on your control chart.

NELSON & WESTERN ELECTRIC COMPANY (WECO) RULES

These decision rules allow detecting out-of-control or non-random conditions on control charts, based on deviations from the mean. They are also capable of detecting patterns or trends. For example, you can apply Nelson rule 3 to detect when six (or more) points in a row are continually increasing (or decreasing).

The Control Chart Package provides a set of predefined control rules (Nelson rules 1 to 8 and WECO rules 1 to 4) and also allows you to set up user-defined rules. You can also base control rules on parameter statistics of historical data. In contrast to control limits, where the limits can be defined independently, a control rule automatically applies to both the upper and the lower limits.

CALCULATION OF THE STANDARD DEVIATION

USP <1010> recommends calculating the standard deviation using differences between consecutive data points instead of comparison to the overall mean.

The Control Chart Package supports both methods for estimating the standard deviation.

BASIC CONCEPT

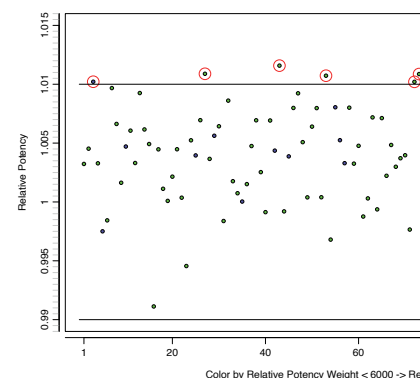
The Control Chart Package supports you in statistical process control independently whether the data is derived from biological assays or your individual work environment.

You can plot data series into customizable charts to fit your needs: There are options to add intervals, sidecharts, and event markers, to create subcharts, or to define the coloring of data points by secondary characteristics or by threshold values, for instance. Furthermore, rule sets allow you to detect out-of-control data by configuring control limits and rules. A status display about the criticality of a rule violation provides visual feedback at a glance for you to take action on the process.

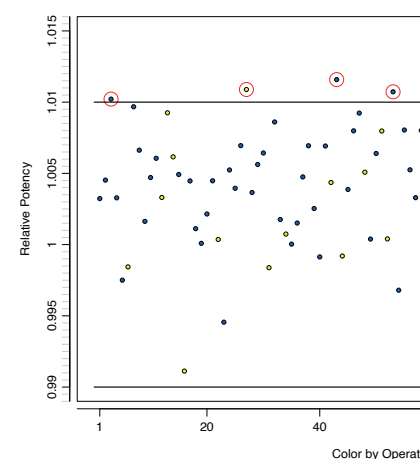
USE CASES

The Control Chart Package covers a broad range of use cases not limited to biological assays.

You can aggregate data from individual assay documents (for example, quantitative

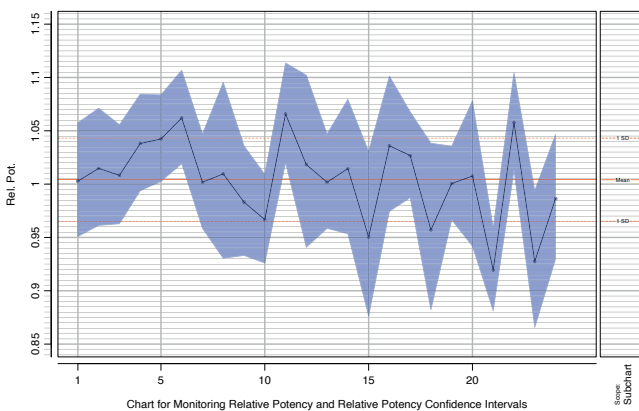


Visualization of colors based on threshold value

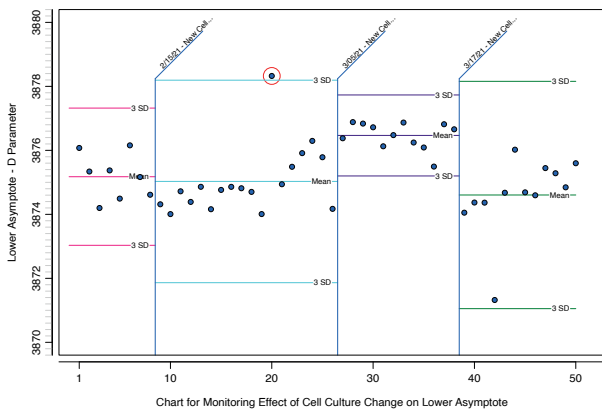


Visualization of colors based on text values

response assays, dose-response analysis assays, or microbial assays for antibiotics) or enter data of any type manually. For example, you can plot a data series to get a first glimpse of descriptive statistics. Based on the statistical characteristics, you can apply control limits and rules to monitor the process and reveal out-of-control data. Use events to mark changes in the process, for example, when you changed the cell culture or updated your SOPs. Moreover, you can create subcharts if you wish to monitor a specific range of data separately, such as the most recent days only. Finally, you are able to color data points by threshold values or a secondary characteristic like the operator to associate conspicuities accordingly.



Plotting relative potency with confidence intervals as areas



Visualization of events, including the detection of out-of-control data based on Nelson rule 1 (beyond 3*SD)

Questions about PLA 3.0?
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