SQT

TRAINING THAT DEVELOPS
*REAL* CAPABILITY









# Statistical Process Control - CPV

**CPI009**

# Statistical Process Control – CPV

Statistical process control (SPC) is essentially a combination of two different but directly linked statistical tools; (a) capability analysis, (b) control charts. Capability analysis provides information on the ability of the process to meet specification; while control charts must be used to ensure process stability and that the goal of optimum capability, is achieved at all times.

SPC is used in all manufacturing industries, and SPC control chart are also used to identify trending in laboratory data. In the pharmaceutical industry SPC is often referred to as **Continued Process Verification (CPV)**. The FDA has identified CPV as an essential third phase of process validation, providing "continual assurance that the process remains in a state of control (the validated state) during commercial manufacture" – FDA Guidance for Industry, January 2011. This objective is achieved through the use of SPC control charts. Pharmaceutical plants worldwide are urgently gearing up to implement control charts on the production line in order to meet the goals of CPV set by the FDA.

Cp/Cpk and Pp/Ppk are two sets of indices commonly used as measures of capability. There is a high degree of confusion across manufacturing industry as to the relationship between these two set of indices, and the specific circumstances in which each of the two sets should be used – they are frequently used incorrectly. Major emphasis will be placed during this course on providing delegates with a thorough understanding as to why there are differences between the two set of indices, and their appropriate usage.

Statistical process control is most usually associated with measured product characteristics; the resulting data is usually known as variables data. However, SPC also has a major role as a tool for the monitoring and control of manufacturing defects (commonly known as attributes). The control chart for attributes provides personnel with responsibility for quality of product with crucially important information, which will assist them in controlling and reducing the incidence of defects. There are four types of attribute control charts and use of these will be described during the training course.

## Duration & Price

Duration: 2 days
Delivery mode: This programme is available In-Company

## Dates & Locations

*In-Company training programmes are customised for your organisations specific needs. Most In-Company training is now delivered virtually.*

## In-Company Training

Please contact us for more information on our In-Company training options

## What's covered?

**Day 1**

- The objectives and benefits of SPC – assessing process performance, distinguishing special from common causes
- Introduction to Statistics Underlying SPC
- Variation in manufacturing processes and its causes; Calculation of basic statistics including standard deviation
- The normal and standard normal distribution and use of the normal tables to calculate tail values
- Sampling distribution of the mean
- **Process Capability Analysis**
- Conducting process capability studies – identifying characteristics, specifications, and/or tolerances
- Distinguishing between natural process limits and specification limits, and calculating process performance metrics including percent defective and PPM
- Calculating process capability indices Cp, Cpk, capability ratio, and assessing process capability
- Calculating process performance indices Pp and Ppk and assessing process performance
- Process capability analysis involving non-normal data:
- Using Box-Cox and Johnson transformations
- Fitting non-normal distributions such as Weibull, Smallest Extreme Value and Largest Extreme Value

**Day 2**

- **Variables Control Charts**
- Identifying and selecting characteristics for monitoring by control chart
- Rational subgrouping
- Construction and interpretation of the X-bar and R chart. Distinguishing between common and special causes using the rules for determining statistical control
- Individual and moving range charts
- The role of control charts in optimising capability – explanation of how the differences between Cp/Cpk and Pp/Ppk arise.
- **Attributes Control Charts**
- The four attributes control charts; p, np, c, and u charts and when it is appropriate to use them
- Laney p’ and Laney u’ charts to be used when the sample size is very large
- The advantages/disadvantages of attributes control charts versus variables control charts.
- Interpreting the charts using the rules for determining statistical control

## Who should participate?

- Product managers and team leaders
- Quality engineers, process engineers and technicians
- Staff concerned with controlling and monitoring manufacturing processes

## What will I learn?

Participants achieve the following learning outcomes from the programme;

- Undertake capability analysis, including analysis of non-normal data, and understand the meaning of the indices Cp/Cpk and Pp/Ppk
- Implement statistical process control methods in production
- Construct and interpret control charts for variables and attributes
- Demonstrate understanding of the important relationship between capability analysis and process stability, as observed on control charts
- Use Minitab software for data analysis and identifying trends

## What are the entry requirements?

Participants don't require a prior knowledge of statistics as the course will commence with a session on basic statistics. However, having knowledge of mathematics, for example Pass Leaving Certificate level, will be helpful in understanding the statistical concepts presented on the course.

## How do we train and support you?

**In-House Courses**

For In-House courses, the tutor will contact you in advance to discuss the course programme in more detail in order to tailor it specifically for your organisation.

**Course Manual**

Delegates will receive a very comprehensive course manual written by the course tutor, which explains the statistics underlying SPC and worked examples of the calculation of process capability analysis and the calculation of control chart limits. The manual will be prepared using data collected in advance from the company, and the participants will undertake exercises in the manual using their own workplace data.

## What software do we use?

Minitab will be demonstrated as part of the training so if delegates are in a position to bring along a laptop with Minitab 20, 21 or 22 pre-loaded (free 14 day trial of Minitab 22 available on www.minitab.com) they can utilise this during the training. If delegates don't have a laptop, they will still benefit greatly from the programme.

## Tutors



**Albert Plant**
View Profile



**Grainne Heneghan**
View Profile

## What Our Learners Say

We believe in excellence through transparency and continuous improvement. That's why we invite all our delegates to share their experiences on CourseCheck.com, an independent platform dedicated to genuine, unfiltered feedback. Learner insights help us not only to enhance our training programmes but also empower potential learners to make informed decisions. Click on the link below to read firsthand experiences and testimonials from past learners.




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