

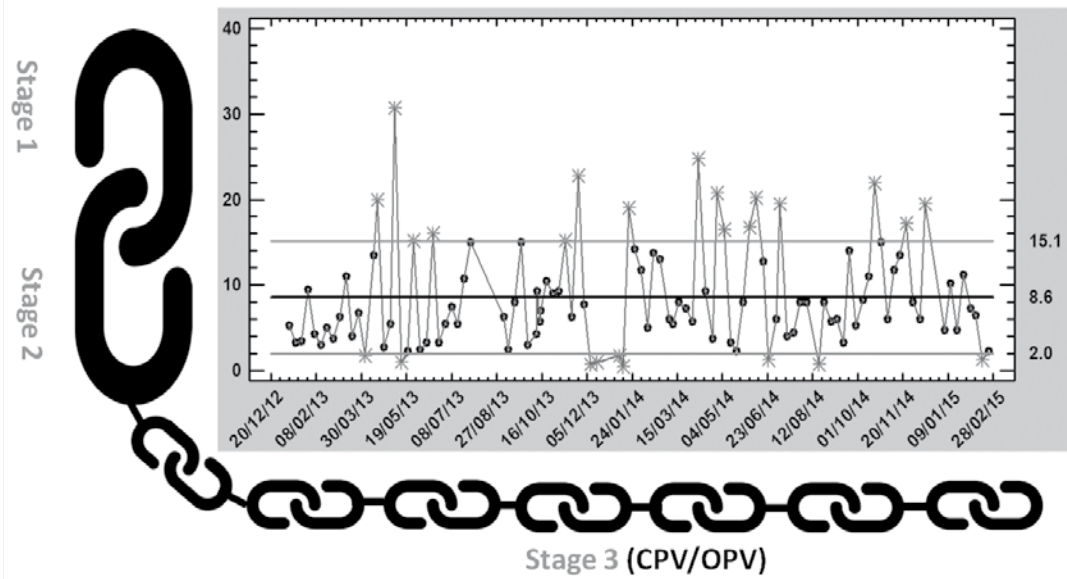
Speaker



Dr Raphael Bar
BR Consulting

Trending of Process Data for OPV/CPV

Advanced Level Live Online Training on 08/09 October 2024



A Practical Approach

Highlights

- Overview of control charts for grouped and individual data
- Overview of control charts of attributes
- Why fundamental requirements for control charts are not met in real-life process data?
- Why are there too many false alarm signals?
- Regulatory Language versus Statistical Language
- “State of Control” versus “State of Statistical Control”
- Process stability and capability
- Adjusting SPC rules to the real world for pharmaceutical/biopharmaceutical process data
- Components of a CPV/OPV plan
- Examples of pharma process behavior charts with StatGraphics software

SPC rules in the real world for an Ongoing/
Continued Process Verification Plan

Objective

This is an advanced level course divided into two half-day parts on 08 and 09 October 2024.

You will learn:

- What is Ongoing/Continued Process Verification
- Overview of Control Charts of grouped and individual data
- Overview of Three-Way charts
- Overview of Attributes charts
- Stability and capability of a process
- Tools for detecting a trend and shift in process average and/or process variability
- Reasons for too many statistical false signals in real-life process data
- Ways to minimize false signals in real-life pharmaceutical and biopharmaceutical processes
- Components of a CPV/OPV plan
- Integration a practical SPC approach into the CPV/OPV plan
- Examples of control charts of real-life data of pharmaceutical processes, generated with StatGraphics, will be shown throughout the course

Background

FDA's Process Validation Guidance and Annex 15 to the EU GMP Guide require manufacturers to monitor product quality to ensure that a **State of Control** is maintained throughout the validation lifecycle of new products and legacy products during the third process validation stage called **Continued Process Verification (CPV)** or **Ongoing Process Verification (OPV)**. Indeed, regulatory agencies expect manufacturers to implement also a CPV plan as reflected in FDA warning letters.

The implementation of **Stage 3** is translated into establishing an ongoing CPV/OPV program which allows Identification of CPV/OPV signals and defining types of responses to these signals. However, real-life data of pharmaceutical and biopharmaceutical processes rarely meet the fundamental assumptions of the conventional SPC (Statistical Process Control). This in turn leads often to false signal alarms, which entail futile investigations of innocuous events. Thus, a practical approach is called for and it consists of collecting, charting and evaluating product and process data under relaxed and adjusted SPC rules, allowing a streamlined implementation of the CPV/OPV program.

Target Audience

This is an advanced level course, therefore a knowledge on control charts is an advantage. Employees from companies, who are involved in pharmaceutical process validation activities (developers, QM, manufacturing, heads of validation departments, etc.) especially regarding stage 3 Ongoing/Continued Process Verification, are addressed. Of course consultants in this field, who want to get information from the view of the medicinal product manufacturers, are addressed too.

Programme

Introduction

- What is Ongoing/Continued Process Verification?
- Regulations
- What data to trend
- Process inputs and outputs: CPP and CQA
- NOR, PAR and Design Space
- Run Chart versus Control Chart
- Common cause variation versus special variation
- "State of Control"

Overview of Control Charts of Variables

- Overview of Control Charts of grouped data
- Overview of Control Charts of individual data
- Overview of Three-Way charts
- Capability indices (Cp, Cpk, Pp and Pk)
- Stability and capability of a process
- **Examples:** control charts of Assay, impurity, of UOC, dissolution

Overview of Control Charts of Attributes

- Their use in the pharmaceutical industry
- Np and p control charts
- c and u control charts
- Examples: control Np charts of inspected packages (defective), c charts of non-conformities (defects) in labels of a drug product; c chart of environmental microbial counts

Evaluation of a Control Chart

- Nelson rules for detecting trends and shifts
- "State of Control" versus "State of Statistical Control"
- Phase I and Phase II in control charting
- "Statistical Limits" versus "Regulatory Limits"
- Are all statistical assumptions valid in real-world pharmaceutical process data?

Adjusting SPC Rules to Pharmaceutical Process Data

- Which statistical rules can be relaxed
- Setting practical limits
- Examples of process behaviour charts
- Components of a CPV/OPV Plan
- Identification of CPV Signals
- Types of responses to signals

Structure of OPV/CPV Plan

- Basic components of an OPV/CPV Plan
- Set of SOPs
- Identification of OPV/CPV signals
- What level of monitoring?
- Types of responses to OPV/CPV signals
- Roadmap of OPV/CPV Plan

Speaker



Dr Raphael Bar
BR Consulting

Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and subsequently the analytical QC Laboratory at Pharmos. For the last thirteen years, Raphael Bar has been a pharmaceutical consultant for the Pharma and Bio-Pharma industries.



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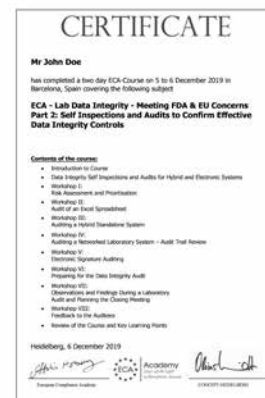
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Date of the Live Online Training

Tuesday, 08 October 2024, 09.00 - 13.15 h
Wednesday, 09 October 2024, 08.30 - 13.30 h
All times mentioned are CEST

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The conference fee is payable in advance after receipt of invoice.

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Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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