

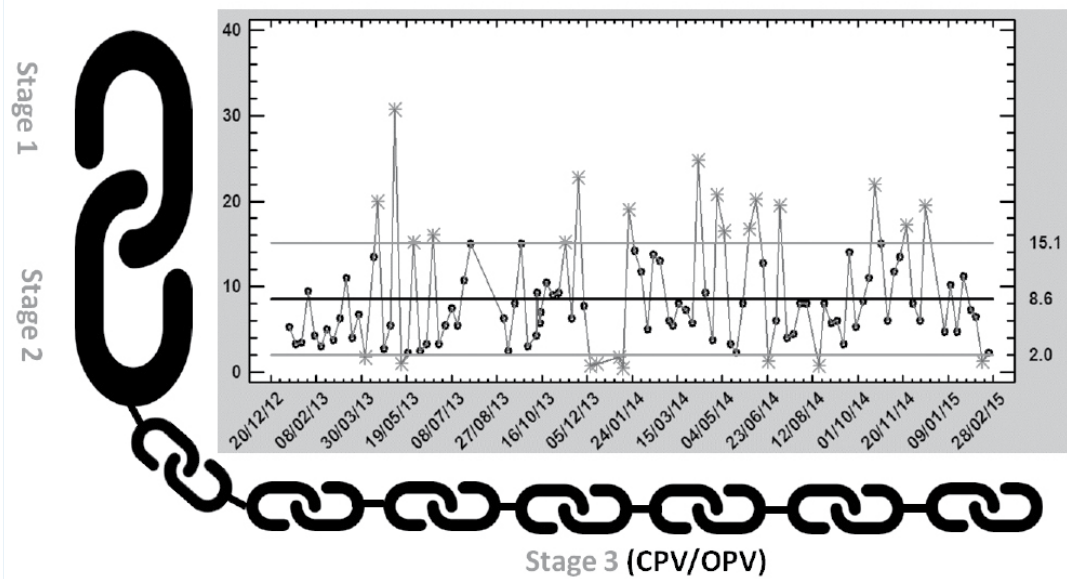
## Speakers



Dr Raphael Bar  
BR Consulting

# Trending of Process Data for OPV/CPV

Advanced Level Live Online Training on 12/13 October 2021



## 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 a Ongoing/  
Continued Process Verification Plan

## Objective

This is an advanced level course divided into two parts on 12 and 13 October 2021.

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

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- 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

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- 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

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- Their use in the pharmaceutical industry
- Np and p control charts
- c and u control charts
- **xamples:** 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

## Speaker



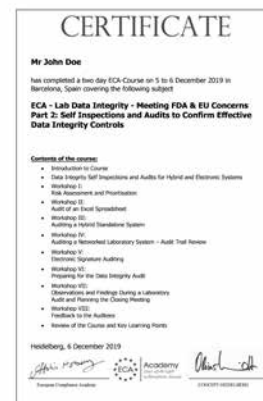
Dr Raphael Bar  
BR Consulting

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.

## Your Benefits

### Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“ This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.



### This Training Course is recognized for the GMP/GDP Certification Scheme

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Reservation Form (Please complete in full)



## Advanced Level Live Online Training Trending of Process Data for OPV/CPV on 12/13 October 2021, each from 13.00 - 16.30 h

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

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GERMANY

### General terms and conditions

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  2. If you have to cancel entirely we must charge the following processing fees:
    - Cancellation until 2 weeks prior to the conference 10 %
    - Cancellation until 1 week prior to the conference 50 %
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Important: This is a binding registration and above fees are due in case of can-

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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed). (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

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## Date of the Live Online Training

Tuesday, 12 October 2021, 13.00 - 16.30 h

Wednesday, 13 October 2021, 13.00 - 16.30 h

All times mentioned are CEST

## Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

## Fees (per delegate, plus VAT)

ECA Members EUR 790,-

APIC Members EUR 890,-

Non-ECA Members EUR 990,-

EU GMP Inspectorates EUR 495,-

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

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

## Conference language

The official conference language will be English.

## Organisation and Contact

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

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