ECA Academy
Your GMP/GDP Information Source

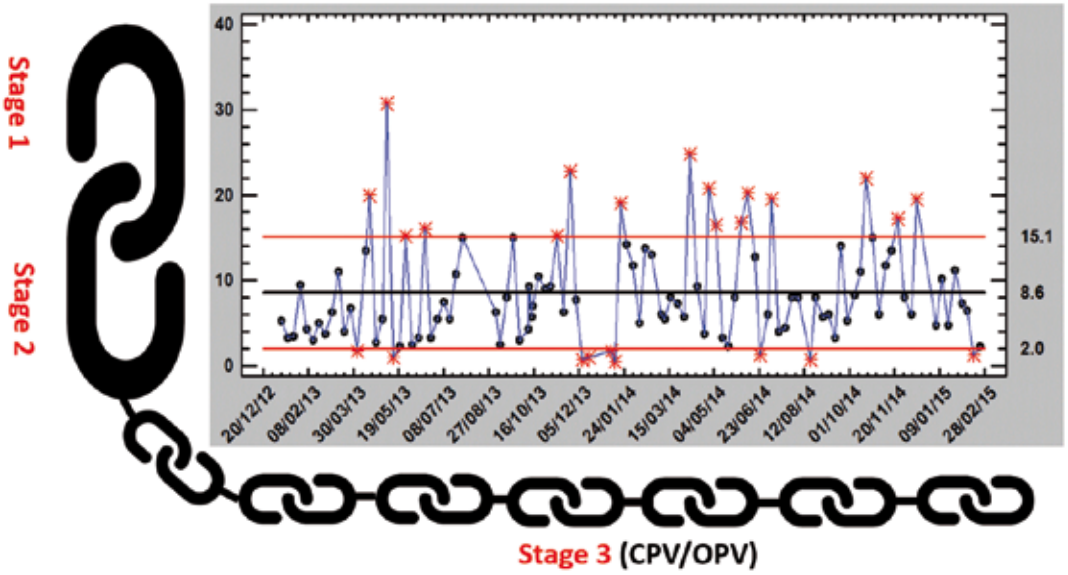
GMP Certification Programme
Certified Validation Manager

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 assumtioms 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

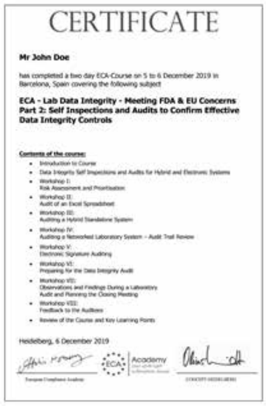
Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and subsequently the analytical QC Laboratory at Pharmos. For the last thirteen years, Raphael Bar has been a pharmaceutical consultant for the Pharma and Bio-Pharma industries.

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



Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

Would you like to present your company in an exhibition or as a sponsoring partner?

We offer you the opportunity to present your company, your products and services to your target group. Thus, participants can inform themselves during the breaks and gain additional benefit from the event. Alternatively, you can also become a sponsoring partner, for example by sponsoring lunch/dinner, coffee breaks or a social event. Interested? Then find out more about the possibilities at https://www.gmp-compliance.org/training/exhibitions-and-sponsoring

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Advanced Level Live Online Training
Trending of Process Data for OPV/CPV on 08/09 October 2024

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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

Technical Requirements
We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 990,-
APIC Members EUR 1090,-
Non-ECA Members EUR 1190,-
EU GMP Inspectorates EUR 595,-
The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21353.

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.

You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

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

CONCEPT HEIDELBERG
P.O.Box 10 17 64 | 69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Sven Pommeranz (Operations Director) at
+49(0)6221/84 44 47, or at
pommeranz@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Sonja Nemec (Organisation Manager) at
+49(0)6221/ 84 44 24, or at
nemec@concept-heidelberg.de.