ECA Academy
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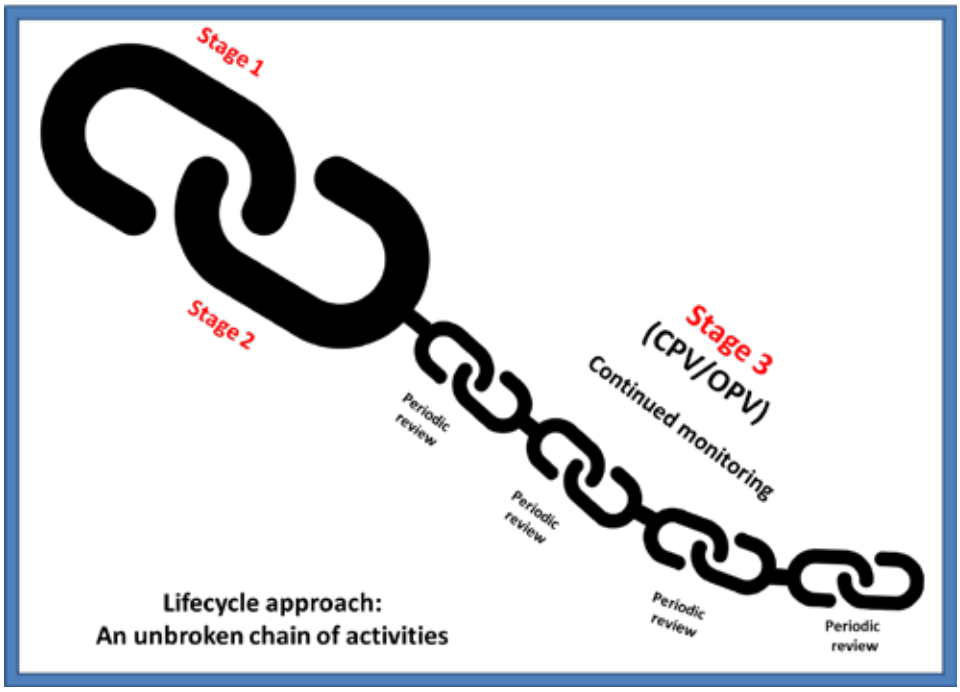
GMP Webinar
Ongoing/Continued Process Verification (Part 2)

Monitoring and Trending of Process Data – SPC rules in the real world for a CPV/OPV plan

Date:
Wednesday, 13 January 2021, 14.00 -15.30 (CET)

Speaker:
Dr Raphael Bar, BR Consulting, Israel



ECA has entrusted CONCEPT HEIDELBERG with the organisation of this webinar.

CONCEPT HEIDELBERG GmbH
Rischerstrasse 8
69123 Heidelberg, Germany
Phone +49 (0) 6221 - 84 44 0
Fax +49 (0) 6221 - 84 44 64
info@concept-heidelberg.de

Background
The EU GMP and FDA regulatory documents require manufacturers to monitor product quality to ensure that a ***state of control*** is maintained throughout the 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 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 Signals and defining types of responses to these signals. However, applying traditional SPC (Statistical Process Control) rules my lead to false signal alarms. Thus, collecting, charting and evaluating product and process data under relaxed and adjusted SPC rules allow a practical and streamlined implementation of the CPV/OPV program.

Educational Objectives
In part 2 of the webinar series, you will learn:

- Tools for detecting a trend and shift in process average and/or process variability
- The problem of too many statistical false signals
- Are all statistical assumptions valid in real-world process data?
- Which statistical rules can be relaxed?
- Control charts with practical limits
- Examples of process behaviour charts
- Building a CPV/OPV Plan
- Identification of CPV Signals
- Types of responses to signals

Remark: Part 1 of this webinar on the day before deals with Monitoring and Trending of Process Data with control charts – basic control charts

Target Audience
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.

Speaker

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

Fees (plus VAT)
Single participation: € 249.- for ECA Members
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https://www.gmp-compliance.org/about-the-academy).

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You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):
3-10 Persons € 254,15
11-20 Persons € 224,25
more than 20 Persons € 194,35

Registration
By mail, fax, e-mail or online on the Internet at
https://www.gmp-compliance.org/. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

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Presentation/Certificate
The presentation will be made available to you prior to the Webinar as a PDF file. After the Webinar, we will automatically send you a certificate of participation.

Organisation/Contact
CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,
Phone +49(0)6221 / 84 44-0, Telefax +49(0)6221 / 84 44 34
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?
For questions regarding content please contact:
Mr Sven Pommeranz, phone +49(0)62 21 - 84 44 47,
Email: pommeranz@concept-heidelberg.de.

For questions regarding organisational aspects please contact:
Ms Julia Grimmer, phone +49(0)62 21 - 84 44 44,
email: grimmer@concept-heidelberg.de

Registration for the Webinar: "Ongoing/Continued Process Verification (Part 2)" on Wednesday, 13 January 2021, 14.00 -15.30 (CET)
Speaker: Dr Raphael Bar
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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Important: Deadline is 12 noon on 12 January 2021

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