ECA Academy
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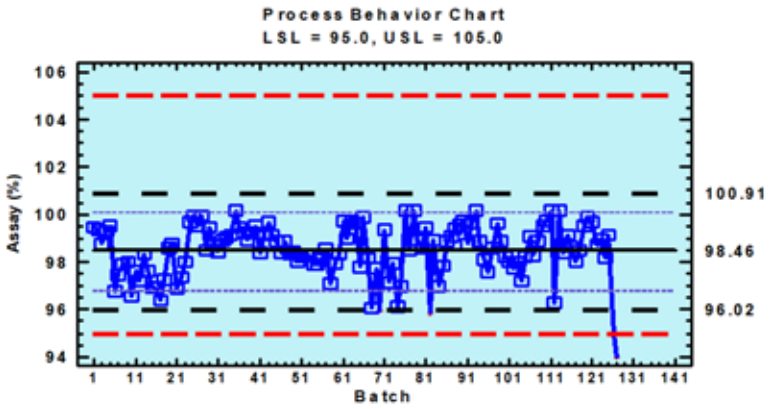
GMP Webinar

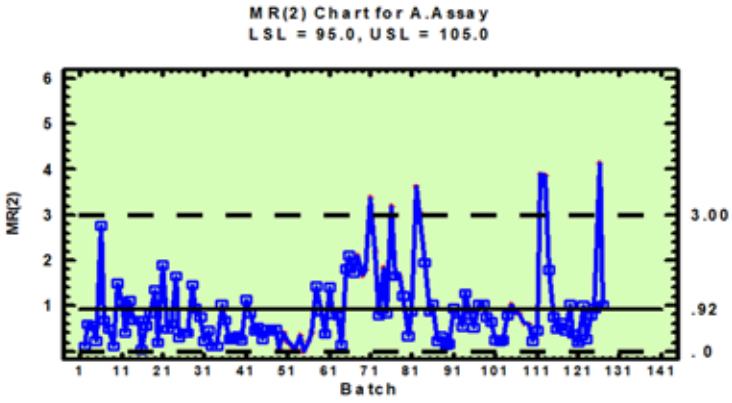
Ongoing/Continued Process Verification (Part 1)

Monitoring and Trending of Process Data with control charts – basic control charts

Date:
Tuesday, 12 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.

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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.

Statistical Process Control (SPC), whereby process data are plotted in process behavior charts and evaluated against statistically derived control, allows the detection of unusual variation, trends or shifts, that indicate, in turn, a deviation from a state of control.

Educational Objectives
The following issues will be discussed:

- What is Ongoing/Continued Process verification
- Run Chart versus Control chart
- Process Variation
- What is "state of statistical control"
- Control charts of grouped and individual data
- Computation of three-sigma Control limits
- Three-Way charts
- Examples of control charts
- Capability indices (Cp, Cpk, Pp and Pk)
- Stability and capability of a process

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.

Remark: Part 2 of this webinar on the following day deals with Monitoring and Trending of Process Data – SPC rules in the real world for a CPV/OPV plan

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
Single participation: € 299,- for non-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
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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
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Do you have any questions?
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Registration for the Webinar: "Ongoing/Continued Process Verification (Part 1)" on Tuesday, 12 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.

Please tick:
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Important: Deadline is 12 noon on 11 January 2021

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