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GMP Webinar
Stratified Sampling – Update 2018
What is state of the art regarding the validation of blend uniformity for solids?

Date:
Friday, 23 November 2018, 11.30 - 13.00 h (CET)

Speaker:
Dr Gerrit Hauck, Basilea Pharmaceutica International AG, Basel

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

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Background
Validation of blend uniformity is one of the critical steps in process validation for solids. Whereas in Europe there is no regulatory requirement with regards to the validation of blend uniformity, this is different in the USA. The 21 Code of Federal Regulation (CFR) 211.110 requires pharmaceutical manufacturers to demonstrate the adequacy of their mixing operations on a routine basis. Due to issues with sampling of powder blends, this topic is under discussion since the early 90s. Based on a PQRI recommendation, FDA published in 2003 the Draft Guidance "Powder Blends and Finished Dosage Units - Stratified In-Process Dosage Unit Sampling and Assessment". This document described stratified sampling as method for the validation of the blend uniformity and proposed a sampling plan for final product testing. Although the guidance was never finalized, it represented the state of the art regarding blend uniformity testing until 2013 when it was withdrawn by FDA. Apart from sample size requirements the acceptance criteria for uniformity of dosage units no longer represented the agency's „current thinking".

What is today state of the art regarding the validation of blend uniformity? The webinar will provide an answer to this question.

Educational Objectives
Addressed are following topics regarding the validation of blend uniformity from solids

- PQRI proposal regarding Stratified Sampling
- The FDA draft Guidance for Industry „Powder Blends and Finished Dosage Units - Stratified In-Process Dosage Unit Sampling and Assessment"
- Why did FDA withdraw its draft guidance?
- How relevant are the ASTM standards 2709 and 2810 for the FDA?
- What is the impact of sample size on the test characteristic?
- Does ISPE´s proposal „Recommended Changes to Withdrawn FDA Draft Stratified Sampling Guidance Document" close the gap?
- What is accepted by the FDA today?

Target Audience
The webinar targets employees who are involved in the validation of solids and want to know what is state oft he art regarding the validation of blend uniformity, e.g. head of production, head of validation, members from Quality Assurance departments.

Speaker

Dr Gerrit Hauck, Basilea Pharmaceutica International AG, Basel
Dr Gerrit Hauck is Chief Technology Officer at Basilea overseeing the company's technical development and commercial manufacturing activities. Before that he hold different positions in technical development at Sanofi-Aventis Deutschland GmbH.

Fees (plus VAT)
Single participation: € 149.- for ECA Members
Single participation: € 199.- for non-ECA Members
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Participation of a Group
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. **Please contact Mr Rouwen Schopka, phone +49(0)6221-844413, schopka@concept-heidelberg.de** for details.

Group Participation (fee per person):
3-10 Persons € 169,15
11-20 Persons € 149,25
more than 20 Persons € 129,35

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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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For questions regarding technical aspects:
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Registration for the GMP Webinar "Stratified Sampling"
on Friday, 23 November 2018, 11.30 – 13.00 h (CET),
Speaker: Dr Gerrit Hauck, Basilea Pharmaceutica International
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 22 November 2018

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