The GMP Webinar Series on "Basics of EU GMP-/FDA-compliant Sampling"

ECA has set up a series of three webinars to discuss principles and relevant aspects of EU GMP-/FDA-compliant sampling. Each webinar can be attended as a single event, allowing participants to combine the webinars according to their individual demands.

Regulatory and Quality related Aspects – Monday, 15 June 2020, 14:00 - 15:30 h CEST
Statistical Aspects – Monday, 22 June 2020, 14:00 - 15:30 h CEST
Practical Aspects – Monday, 29 June 2020, 14:00 - 15:30 h CEST

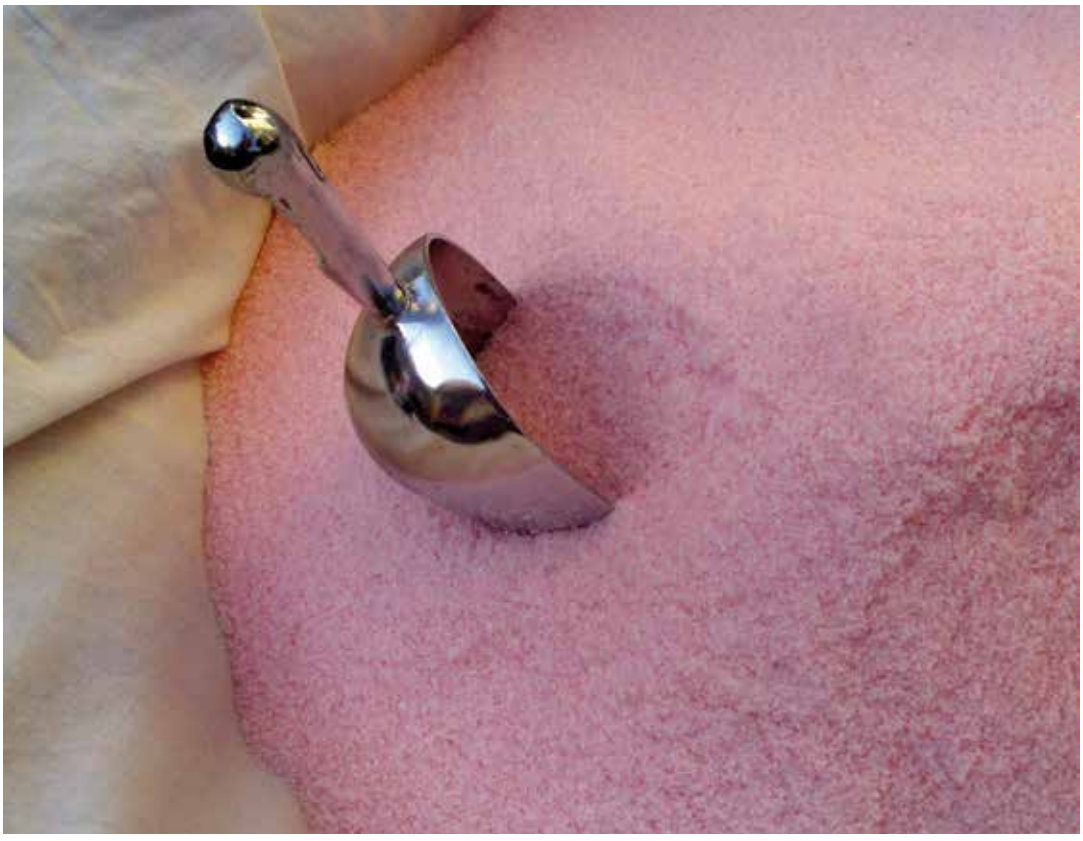
ECA Academy
Your GMP/GDP Information Source

GMP Webinar Series on "Basics of EU GMP-/FDA-compliant Sampling"

Regulatory and Quality related Aspects

Date:
Monday, 15 June 2020, 14:00 - 15:30 h CEST

Speaker:
Philip Lienbacher, Takeda



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

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Background
Sampling of materials is one of the most important processes in pharmaceutical companies. Regulatory agencies require a sampling plan that utilizes basic elements of statistical analysis or provides a scientific rationale for taking a representative sample according to the lot size. According to the revised Chapter 6 of EU GMP Guide, the sampling plan used should be appropriately justified and based on a risk management approach. Representative samples should be taken and recorded in accordance with approved written procedures. FDA requires as well in the Code of Federal Regulations (21 CFR Part 211.84) that sampling should be done upon statistical criteria.

Educational Objectives
This webinar will give you a comprehensive overview of the regulatory and quality related aspects of sampling.

The following topics will be covered:
- Regulations: US GMPs, EU GMPs, WHO, PIC/S
- Sampling plans
- Articles sampled in pharma and bio-tech (discrete units vs. granular or liquid materials)
- Good quality practice around sampling (documentation, incorporation into the LIMS system)

Target Audience
This webinar is directed at all those employees from quality control units and production units in the pharmaceutical industry who are competent or responsible for sampling, testing and release of starting materials (APIs and excipients), packaging materials (primary and secondary) as well as finished pharmaceutical products. This course is also of interest to personnel from quality assurance and to those employees from API, excipient or packaging material suppliers who want to get a comprehensive yet compact overview of the requirements on sampling.

Speaker

Philip Lienbacher, Takeda, Austria
Mr Lienbacher is Manager Global Material Lifecycle Management Systems and is responsible for a team of process experts and project managers. His responsibility includes the global ownership for Receiving & Inspection as well as the general testing and method deployment-strategy in the company.

Fees (plus VAT)
Single participation: € 199.- for ECA Members
Single participation: € 249,- for non-ECA Members
(This fee does not include the ECA Membership. You will find more about the ECA Membership at https://www.gmp-compliance.org/about-the-academy).

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.

Group Participation (fee per person):
3-10 Persons € 211,15
11-20 Persons € 186,75
more than 20 Persons € 161,85

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.

Technical Requirements
For our 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 email 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.

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.

Do you have any questions?
For questions regarding content please contact:
Dr Markus Funk, phone +49(0)62 21 - 84 44 40
email: funk@concept-heidelberg.de

For questions regarding technical aspects please contact:
Mr Niklaus Thiel, phone +49(0)62 21 - 84 44 43
email: thiel@concept-heidelberg.de

Registration for the Webinar "Regulatory and Quality related Aspects"
on Monday, 15 June 2020, 14:00 - 15:30 h CEST
Speaker: Philip Lienbacher, Takeda
Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

Please tick:
☐ **Single Participation**
☐ **Group Participation**
  ☐ 3-10 Persons
  ☐ 11-20 Persons
  ☐ more than 20 Persons

Important: Deadline is 09.00 am on 15 June 2020

Title, First Name, Last Name

Company | Department | VAT ID No. (mandatory)

Street | Postal Code/City

Phone | Fax

E-Mail (mandatory for your registration)

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 2 weeks prior to the conference 10 %, until 1 week prior to the conference 50 %, within 1 week 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.
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)!