ECA Academy
Your GMP/GDP Information Source

GMP Webinar *Recording*
The MRA with the U.S.

The End of FDA Inspections in the EU?

Date of the recording: 03 May 2017
Speaker: Dr Rainer Gnibl, GMP Inspector for EMA

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

GMP-Webinar *Recording*: The MRA with the U.S.

Background:
On 2nd March 2017, the U.S. Food and Drug Administration FDA and the European Medicines Agency EMA informed that they concluded a so-called MRA (Mutual Recognition Agreement). Such agreements are intended to mutually recognise GMP inspection systems and accept the respective inspections. The agreement shall cover both medicinal products and APIs. Some CBER regulated products like human blood, human plasma, human tissues and organs, and veterinary immunologicals are excluded from the scope of the agreement. The new agreement should come into force on 1st November 2017. Until then, the FDA wants to review the authorities of further EU countries.

Educational Objectives:
This webinar aims at giving you a comprehensive overview about the agreement and to explain the details. Furthermore, ambiguities, possible consequences and open questions are discussed:

- Scope, exceptions, particularities
- Specifics with investigational medicinal products (IMPs)
- Interfaces with Annex 16 and the planned Annex 21 of the EU-GMP Guidelines
- Control of imported materials, testing and batch release
- The future of GMP certificates
- Quality Metrics: still needed?

Target Audience
The webinar targets executives and staff in the pharmaceutical industry, who want to get a comprehensive overview of the agreement and its consequences.

Speaker

Dr Rainer Gnibl,GMP Inspector, District Government of Upper Bavaria, Germany
Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

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 http://www.gmp-compliance.org/eca_about.html.

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 EUR 211,15
11-20 Persons EUR 186,75
more than 20 Persons EUR 161,85

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. You will find the detailed system requirements here:
http://www.gmp-compliance.org/webinar/webinar_requirements.htm

Registration
By mail, fax, e-mail or online on the Internet at www.gmp-compliance.com. 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.

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:
Mr Wolfgang Schmitt, phone +49 62 21 - 84 44 39,
email: w.schmitt@concept-heidelberg.de.

For questions regarding technical aspects:
Mr Rouwen Schopka, phone +49 62 21 - 84 44 13
email: schopka@concept-heidelberg.de

Registration for the recorded Webinar: The MRA with the U.S. of 03 May 2017, Speaker: Dr Rainer Gnibl, GMP Inspector for EMA 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

Date on which you want to watch the recording online _____

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)!