



GMP Webinar

The MRA with the U.S.

The End of FDA Inspections in the EU?

Date:

Wednesday, 03 May 2017, 15.00 – 16.30 h CEST

Speaker:

Dr Rainer Gnibl, GMP Inspector for EMA



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

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GMP-Webinar: 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: € 149.- for ECA Members

Single participation: € 199.- for non-ECA Members (This fee does not include the ECA Membership. You will find more about the ECA Membership at 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 € 169,15

11-20 Persons € 149,25

more than 20 Persons € 129,35

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

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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
2 May 2017**

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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 %.

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