ECA Academy
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GMP Webinar
Update IMPs
Impact of the new Regulation (EU) 536/2014 on clinical trials

Date:
Wednesday, 13 November 2019, 14.00 -15:30 h CET

Speaker:
Dr Rango Dietrich, PharmDev Innovations

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

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Objective

You will learn about the new requirements for manufacturing, labelling, testing, release and distribution of investigational medicinal products (IMPs) and get to know different aspects of the outstanding changes in the EU and in Germany.

Background

The Clinical Trials Regulation No 536/2014 (CTR) entered into force in 2014. The date of its initial application depends on the full functionality of the Clinical Trials Information System (CTIS) being established by an independent audit. Right now, preparations for the CTIS' audit are being made. The CTR will become applicable six month after the publication of this confirmation by the European Commission.

With the coming into force of the CTR, the currently valid GMP guidelines for IMPs as well as the current Annex 13 will be repealed. Various customary provisions for IMPs (e.g. Labelling, import, sponsor responsibility, safety reporting) have been revised, partly with considerable consequences regarding the time and budget for clinical trial supplying. The resulting changes in the handling of IMPs will be introduced in this webinar. It will also throw light on the newly regulated comparator products and non-IMPs (NIMPs) which are used as background therapy in clinical trials.

Target Audience

This training is aimed at all workers in the pharmaceutical industry involved in the development, manufacturing, quality control, packaging, quality assurance, release and distribution of IMPS, as well as persons from authorities and associations. It also addresses employees of IMP contract manufacturers and staff at CROs who are involved in the project planning for provisioning IMPs.

Topics overview:

Changes of regulatory requirements due to Regulation (EU) No 536/2014 on clinical trials for human medicines (CTR) and the repealing of Directive 2001/20/EC

- Regulation (EU) 536/2014 (CTR) and associated Delegated Regulations and guidelines
- Major changes in comparison with GMP Directive 2003/94/EC, Annex 13 of the EU GMP Guidelines and Directive 2001/20/EC
- Sponsor responsibility in IMP release, distribution and agreements on limitations of liability
- Perceived loopholes and pain points

Labelling according to Annex VI of the CTR

- Major changes in comparison with Annex 13 and challenges of Annex VI
- Possible solutions to the challenges of Annex VI

Comparators and auxiliary medicinal products (AxMPs)

- Use of comparators and AxMPs in clinical trials
- Changes due to Regulation (EU) 536/2014 (CTR)

Imports from third countries

- Imports from third countries (i.e. drug substance, drug product, IMP); changes due to Regulation (EU) 536/2014 (CTR)
- Mutual recognition agreement (MRA)
- Qualifying suppliers in the supply chain
- The role of the QP

Speaker

Dr Rango Dietrich, PharmDev Innovations

Dr Rango Dietrich is CEO of PharmDev Innovations and Qualified Person as per §14 AMG. He has worked in the pharmaceutical industry, at Byk Gulden GmbH (later Altana Pharma AG), for over twenty years. As a company executive, he had full responsibility for the global pharmaceutical development there. Since 2007, he has been working as a consultant for the pharmaceutical industry, covering the topics pharmaceutical development and investigational medicinal products.

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 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 € 169,15
11-20 Persons € 149,25
more than 20 Persons € 129,35

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.

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:
Dr Andrea Kühn-Hebecker, phone +49 62 21 - 84 44 35,
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For questions regarding technical aspects:
Mr Rouwen Schopka, phone +49 62 21 - 84 44 13
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Registration for the GMP-Webinar: Update IMPs on Wednesday, 13 November 2019, 14.00 -15:30 h CET, Speaker: Dr Rango Dietrich, PharmDev Innovations
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 12 noon on 12 November

Title, First Name, Last Name

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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
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