GMP Webinar

APIs & Excipients: Handling and Life Cycle Management in times of Covid-19

Date:
Tuesday, 03 November 2020, 14.00 – 15.30 h CET

Speaker:
Manfred Karner, Takeda, Vienna, Austria

Background
Especially, in times of the Covid-19 pandemic, GMP Compliance and Life Cycle Management of APIs & Excipients are of high importance. For ensuring the GMP-compliant handling new strategies as well as risk-based approaches need to be evaluated and established.

Educational Objectives
This GMP webinar will give you a comprehensive overview of the regulatory requirements and GMP-compliant handling of APIs & Excipients. Despite the topics like processing and qualification, risk-based approaches and new strategies will be discussed and explained:

– Regulatory requirements
– Handling and procurement
– Supplier qualification and evaluation
– Life Cycle Management and maintenance
– Risk-based approaches and strategies
– GMP compliance

Target Audience
This webinar is designed for persons working in the Quality Assurance, Quality Control, Production, Regulatory Affairs and Development departments. It will also be of interest for personnel from suppliers, contract manufacturing companies and consultants.

Speaker

Manfred Karner, Takeda, Vienna, Austria
Mr Karner has been working for Takeda (former Baxter / Baxalta / Shire) in Vienna since 1996. After various management functions in Local Quality (including Head Receiving & Inspection + Product Release) he switched in 2014 to Global Quality Management and had there different management roles. Currently he is leading the Direct & Indirect Material department in Global Quality Auditing & Supplier Management. His responsibilities currently are qualifying suppliers and creating quality agreements and material specifications for Takeda.

Fees (plus VAT)
Single participation: € 249.- for ECA Members
Single participation: € 299,- 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 EUR 254,15
11-20 Persons EUR 224,25
from 21 Persons EUR 194,35

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.

Organisation/Contact
CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg, Tel. +49(0)6221/84 44-0, Telefax +49(0)6221/84 44 34
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?
For questions regarding content please contact:
Ms Anne Günster, phone +49(0)6221/ 84 44 50
Email: guenster@concept-heidelberg.de

For questions regarding organisational aspects please contact:
Mxxxxxx, phone +49(0)6221/84 44 xxxxx
Email: xxxxxxx@concept-heidelberg.de

Registration for the Webinar "APIs & Excipients: Handling and Life Cycle Management in times of Covid-19" on Tuesday, 03 November 2020, 14.00 – 15.30 h CET
Speaker: Manfred Karner, Takeda, Vienna, Austria
Please fax to CONCEPT HEIDELBERG, +49 (0)6221/84 44 34 or you register online at www.gmp-compliance.org.

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

**Important:
Deadline is 12 noon on
02 November 2020**

Title, First Name, Last Name

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