ECA Academy
Your GMP/GDP Information Source

GMP Webinar
Revised Annex 17 – What´s new?

Real Time Release Testing (RTRT) – Challenges and Opportunities

Date:
Tuesday, 05 December 2017, 14.00 -15.30 h CET

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

Background

The revised Annex 17 of Eudralex volume 4 is intended to outline the requirements for application of a *Real Time Release Testing (RTRT)* approach in manufacturing, where the control of critical process parameters and relevant critical quality attributes may be used as an alternative to routine finished product testing of medicinal products. The previous Annex 17 only focused on the application of Parametric Release for the routine release of terminally sterilized products waiving the performance of a test for sterility on the basis of successful demonstration that predetermined and validated sterilizing conditions have been achieved. Recent advances in the application of process analytical technology (PAT), quality by design (QbD) and quality risk management (QRM) principles to pharmaceutical development and manufacturing have shown that the appropriate combination of process controls together with timely monitoring and verification of pre-established critical quality attributes provides greater assurance of product quality than finished product testing alone. The revised Annex 17 is brought into line with ICH Q8- Q12 documents and will detail regulatory expectations for a batch release system based on the information collected during the manufacturing process, through product knowledge and process understanding and control.

Educational Objectives

The control of critical process parameters (CPPs) and relevant critical quality attributes (CQAs) may be used as an alternative to routine finished product testing of medicinal products. Therefore, the following topics are discussed during the webinar:

- Which are the requirements for application of a Real Time Release Testing (RTRT) approach in manufacturing?
- How are CPPs and relevant CQAs controlled?
- Can the Qualified Person (QP) certify batches based on the compliance of the process data to the approved release criteria together with appropriate GMP compliance?
- Are active substances and intermediates included in this new approach?
- What are the expected benefits and hurdles?

Target Audience

The webinar targets executives and staff from development, production and quality units, as well as quality assurance, who are in charge of being compliant with specifications regarding critical quality parameters of pharmaceutical products which have been determined during development phase. But also Qualified Persons responsible for the review and release of products are within the target group of this webinar.

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 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.

Organisation/Contact

CONCEPT HEIDELBERG, P.O. Box 10 17 64, D-69007 Heidelberg,
Tel. 0 62 21/84 44-0, Telefax 0 62 21/84 44 34
info@concept-heidelberg.de, www.gmp-navigator.com

Do you have any questions?

For questions regarding content:
Dr Andrea Kühn-Hebecker, phone +49 62 21 - 84 44 35,
email: kuehn@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: Revised Annex 17 – What´s new?
05 December 2017, 14.00 – 15.30 h CET, Speaker: Dr Rainer Gnibl
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 4 December

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.
f 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)!
German law shall apply. Court of jurisdiction is Heidelberg.