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GMP Webinar *Recording*
Revised Annex 17 – What´s new?

Real Time Release Testing (RTRT) – Challenges and Opportunities

Date of the Recording: 05 December 2017

Speaker: Dr Rainer Gnibl (GMP Inspector for EMA)

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

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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)

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Group Participation (fee per person):

3-10 Persons EUR 211,15
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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

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Do you have any questions?

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Registration for the Webinar *Recording*: Revised Annex 17 – What´s new?
Speaker: Dr Rainer Gnibl
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