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)
If you cannot attend the conference you have two options:

1. **General Terms and Conditions**
   - Cancel an event. If you have to cancel entirely we must charge the following processing fees:
     - 1 week prior to the conference: 100%.
     - 2 weeks prior to the conference: 10%.
     - Within 1 week: 50%.

2. We are happy to welcome a substitute colleague at any time.

**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. 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.

**Technical Requirements**

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**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.

**Registration for the Webinar Recording: Revised Annex 17 – What’s new?**

**Speaker**: Dr. Rainer Gnibl

Please fax to CONCEPT HEIDELBERG, +49 (0)6221 / 84 44 34 or you register online at www.gmp-compliance.org.

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**German law shall apply. Court of jurisdiction is Heidelberg.**