



Speakers



Cheryl Chia
Lotus Phoenix Consulting,
The Netherlands



Dr Rainer Gnihl
GMP Inspector for EMA, Germany



Dr Andreas König
Quality König, Germany



Dr Jens-Uwe Rengers
JeRo Consulting, Switzerland

Improve your Quality Reviews

PQR, APR, Management Review, Quality Metrics



Live Online Training on 29/30 March 2023



Highlights

- Quality Reviews in the Context of FDA, EU and ICH
- Expectations of the Agencies
- How to set up efficient
 - PQRs and APRs
 - Management Reviews
 - Quality Metrics

Every participant will get examples for

- PQR SOP Annexes
- A Management Review SOP
- PQRs
- Management Review extracts

Objectives

This Live Online Training examines regulatory requirements, provides insight into inspectors' expectations and explains tools for improving your documented review processes.

Based on real examples you will learn how you can implement and improve your Quality Reviews and use them more efficiently.

Background

Quality Reviews and Metrics are critical GMP elements. They are an integral part of a pharmaceutical quality system and provide an opportunity to assess and control relevant processes.

Both parts of the EU-GMP Guidelines require the Product Quality Review (PQR) to verify the consistency and appropriateness of existing processes, but also to identify product and process improvement opportunities.

The FDA 21CFR 211 requires an Annual Product Review (APR) to evaluate annually the quality standards of each drug product.

All relevant guidance does also consider a Management Review to be an appropriate instrument to assess adequacy and effectiveness of quality systems.

All these different reviews could result in a tremendous work load or they can be performed in an efficient way with useful results – depending on how they are organised. Therefore, it is very important to understand the requirements and the idea behind it and to see how these tools can be used more efficiently.

Target Audience

This Live Online Training is designed for managers, supervisors and all other staff members in the pharmaceutical and API industry who are involved in preparing and compiling Quality Reviews and Metrics.

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg (on behalf of ECA)

Every participant will get:

- an example for PQR SOP Annexes
- an example for a Management Review SOP
- real PQR examples
- extracts from real Management Reviews

Programme

Quality Reviews in the Context of FDA, EU and ICH Requirements and Expectations

- EU-GMP: which types of Quality Reviews are required?
- EU Quality System Review (overview)
- How to achieve EU-GMP compliance
- ICH/US-FDA view on the situation (overview)
- EU Product Quality Review (PQR)
 - Technical terms and aims of PQR
 - What documents and data should be reviewed?
 - Are EU-requirements the same for APIs & medicinal products?
 - What about US-FDA and ICH?

PQR and APR

- How to combine PQR and APR in an efficient way
- Well-proven PQR/APR designs
- Interface to Regulatory Affairs
- Certainties (PQR/APR in Custom Manufacturing, how to deal with limited numbers of batches ...)

EU Product Quality Reviews in the Light of Inspections – Expectations of the Agencies

- Inspectors view on critical parts of EU-PQR
- Practical implementation and inspection
- PQR and contract manufacturing
- Comparison EU-PQR and US-APQR (inspectors point of view)

Discussion of given PQR-Examples

Based on real examples, the speaker will discuss the content and lay-out of PQRs:

- What is useful?
- What is ambiguous?
- What could be improved?

Set up of efficient PQRs and APRs

- How to profit from existing QA Systems in PQR/APR and vice versa
- Best practices
- Time/efforts needed
- Ongoing data collection
- Foreseeable complications/advantages
- Well-proven examples

Management Review

- Definition, scope, objectives
- Organisation
- Participants, responsibilities
- Topics to be presented: input and output
- KPIs per system
- Examples and experience

Using KPI in Quality Reviews and in Communication with Authorities

- Current status of the requirements
- Key areas and data to be submitted
- How industry can prepare to meet the expectations

Quality Reviews in Contract Manufacturing

- Customer QMRs - content, scope, frequency, organisation
- Interface with Business Management Reviews
- Assessment of data, trending and decision making
- Actions, follow-up
- „Face to Face“ or telecon?

Management Review - from Data Collection to Evaluation and Reporting

- Collection and preparation of data: time/efforts needed, automatic vs. manual data capture
- Evaluation of deviations and changes
- Interpretation of data: what is the data telling us?
- How to report the data and information gained

Review Management: Bringing them all together in an efficient Way

- How to set up an integrated data, review and report management
- How to avoid double work

Question and Answer Sessions

A set of live Q&A Sessions will give you the possibility to interact with the speakers and get answers to your questions.

Speakers



Cheryl Chia
Lotus Phoenix Consulting, Netherlands

Cheryl Chia is an independent consultant for GMP and GDP compliance in the pharmaceutical supply chain. Before starting her consultancy business, she worked at Organon and Amgen.



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.



Dr Andreas König
Quality König GmbH, Germany

Dr Andreas König is General Manager of Quality König GmbH. Before that he was amongst others Senior Vice President Corporate Quality & HSE at Aenova Holding GmbH and Vice President Global Quality Operations Animal Health at Schering Plough.



Dr Jens-Uwe Rengers
JeRo Consulting GmbH, Switzerland

Dr Jens-Uwe Rengers is CEO and Managing Consultant. Prior to the funding of his consultancy business, Jens-Uwe Rengers acted as General Manager at Akorn AG. Before that he was Director Quality and QP and held different other roles at Byk Gulden (now Takeda), Cytos Biotechnology AG and Siegfried Ltd.

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Improve your Quality Reviews, Live Online Training on 29/30 March 2023

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of Live Online Training

Wednesday, 29 March 2023, 9.00 – 17.15 h CEST
Thursday, 30 March 2023, 8.30 – 15.45 h CEST

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members € 1,490
QP Association Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
All fees are payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Phone: +49(0) 62 21/84 44-0
Fax: +49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content, please contact:

Mr Wolfgang Schmitt (Operations Director) at
+49(0) 62 21/84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de

For questions regarding organisation please contact:

Ms Nicole Bach (Organisation Manager) at
+49(0) 62 21/84 44 22, or per e-mail at
bach@concept-heidelberg.de