ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Cheryl Chia
Lotus Phoenix Consulting,
The Netherlands

Dr Rainer Gnibl
GMP Inspector for EMA, Germany

Dr Jean-Denis Mallet
NNE Pharmaplan, France

Dr Jens-Uwe Rengers
JeRo Consulting, Switzerland

Improve your Quality Reviews

PQR, APR, Management Review, Quality Metrics

Live Online Training on 10/11 April 2024

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
- Management Review SOP

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

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)

Set up of efficient PQRs and APRs

- How to use the data from existing systems (and vice-versa)
- Best practices / filtering the data
- Time/ efforts needed
- Ongoing (computerised) data collection
- Possible difficulties and redundancies
- 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 regulatory status of the expectations
- Key areas and data to be submitted
- The two communication levels: baseline and emergencies
- How to get ready to communicate upon request

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, The 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 Jean-Denis Mallet
NNE Pharmaplan, France

Jean-Denis Mallet is STP (Senior Technology Partner) GMP at NNE PHARMAPLAN. He was previously the Head of the Pharmaceutical Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM).

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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Reservation Form (Please complete in full)

Improve your Quality Reviews, Live Online Training on 10/11 April 2024

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of Live Online Training

Wednesday, 10 April 2024, 9.00 – 17.00 h CEST
Thursday, 11 April 2024, 9.00 – 16.00 h CEST

Technical Requirements

We use WebEx for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,690
QP Association Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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.
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