ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Dr Rainer Gnibl
GMP Inspector for EMA

Prof Edwin van den Heuvel
University of Technology Eindhoven

Arno Hoekstra
Kite Pharma

Dr Andreas König
Fidelio Healthcare

Dr Jens-Uwe Rengers
Consultant

Improve your Quality Reviews

PQR, APR, Management Review, Quality Metrics

03/04 September 2020 | Berlin, Germany

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

- **Optional pre-course Session on 02 September: Statistical Process Evaluation and Reporting**

- Every participant will get examples for
  - PQR SOP Annexes
  - A Management Review SOP
  - PQRs
  - Management Review extracts

With an optional pre-course Session on 02 September: Statistical Process Evaluation and Reporting

Objectives

This course 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 do 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 Education Course 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)

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?

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)

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 ...)

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

Workshop: Evaluation of given PQR-Examples

Evaluate with other delegates the content and lay-out of given PQR-examples and discuss it with the speakers:

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

Management Review

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

Kite Pharma Case Study: 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

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?

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

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

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 pre-course Session
Statistical Process Evaluation and Reporting
on 02 September 2020

This pre-course session will provide you with recommendations, tools and examples to apply statistical principles in your day-to-day business and it will help you to meet future challenges.

You will gain understanding of the consequences of appropriate and inappropriate performance parameters and a sound evaluation of data also by working with statistical simulation tools.

The Application of statistical Tools in Data Review

- Introduction
  - Ongoing/data collection and management
  - Interpretation, comparison and presentation of data
  - Describing process capability and performance
  - Control Charts; what is a trend and how to deal with it?
  - Quality Metrics
  - Documenting the outcomes; are we in control?
- Quality Review Summary Report
  - Descriptive statistics
  - Outlier detection
  - Normality testing
- Quality Review Performance
  - Control Charts
  - Capability indices

The Session includes a Workshop with a statistical software to explain and understand: What are the Data telling us?

A case study on analysing and interpreting process performance data.

Social Event

In the evening of 03 September, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

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.

Prof Edwin van den Heuvel
University of Technology Eindhoven, Netherlands

Prof van den Heuvel is fulltime professor Statistics at the TU/e department of Mathematics and Computer Science. Before, he was head of the statistics department at the pharmaceutical company MSD and fulltime professor Medical Statistics at the UMCG (University Medical Center Groningen).

Arno Hoekstra
Kite Pharma EU B.V., Netherlands

Arno Hoekstra is Senior Manager Quality Systems and Chair of the Quality Management Review Board, Change Control Board and Deviation Board. He has more than 20 years QA experience within different pharmaceutical companies.

Dr Andreas König
Fidelio Healthcare Limburg GmbH, Germany

Dr Andreas König is General Manager of Fidelio Healthcare Limburg 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
Consultant, Switzerland

Dr Jens-Uwe Rengers was 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.

Dates
Pre-course Session
Statistical Process Evaluation and Reporting
Wednesday, 02 September 2020, 11.00 – 17.30 h
(Registration and coffee 10.30 – 11.00 h)

Education Course
Improve your Quality Reviews
Thursday, 03 September2020, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Friday, 04 September 2020, 8.30 – 15.15 h

Venue for both events
HYPERION Hotel
Prager Straße 12
10779 Berlin, Germany
Phone +49 (0)30/236250 0
Email: hyperion.berlin@h-hotels.com

Fees (per delegate, plus VAT)
Pre-course Session Statistical Process Evaluation and Reporting
ECA Members € 890
QP Association Members € 890
APIC Members € 945
Non-ECA Members € 990
EU GMP Inspectorates € 495
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and coffee/refreshments. VAT is reclaimable.

Education Course Improve your Quality Reviews
ECA Members € 1,490
QP Association Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable

Save money when booking both events
If you book the Education Course "Improve your Quality Reviews" TOGETHER WITH the Pre-course Session "Statistical Process Evaluation and Reporting", the fee will be as follows:
ECA Members € 1,990
QP Association Members € 1,990
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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

Conference language
The official conference language will be English.

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
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E-Mail: info@concept-heidelberg.de
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For questions regarding content:
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 reservation, hotel, organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at
+49(0) 62 21/84 44 22, or per e-mail at
bach@concept-heidelberg.de

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Pre-course Session: Statistical Process Evaluation and Reporting, 02 September 2020, Berlin, Germany
☐ Improve your Quality Reviews, 03/04 September 2020, Berlin, Germany

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)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
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)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.