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

Dr Andreas König
Quality König

Dr Jens-Uwe Rengers
JeRo Consulting

Aline Zillig
Kite Pharma

Improve your Quality Reviews

PQR, APR, Management Review, Quality Metrics

Live Online Training on 17/18 March 2022

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 16 March: 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 16 March: 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 Education Course

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?

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

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.

Programme pre-course Session **Statistical Process Evaluation and Reporting** on 16 March 2022

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
- Case study on analysing and interpreting process performance data

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).

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.

Aline Zillig
Kite Pharma EU B.V., Netherlands

Aline Zillig is Senior Quality Specialist at Kite Pharma. She is a Chemical Engineer, with various experience from pharmaceutical companies, currently focused on the areas of quality and compliance for the production of vaccines and other biotechnology products.

Date of Live Online Training

Pre-course Session
Statistical Process Evaluation and Reporting
Wednesday, 16 March 2022, 10.30 – 17.00 h CET

Education Course
Improve your Quality Reviews
Thursday, 17 March 2022, 9.00 – 17.00 h CET
Friday, 18 March 2022, 8.30 – 15.30 h CET

Technical Requirements
For our online training, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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

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

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

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.

Ordering Recordings
Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

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

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Mr Wolfgang Schmitt (Operations Director) at
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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

Your Benefits:

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires:
„... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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This Training Course is recognized for the Quality Assurance Manager Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. 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. Please find more information at www.gmp-certification.org

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GERMANY

Reservation Form (Please complete in full)

☐ Live Online Training: Pre-course Session: Statistical Process Evaluation and Reporting, 16 March 2022
☐ Live Online Training: Improve your Quality Reviews, 17/18 March 2022

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.