Every participant will get:
- an example for a PQR SOP with Annexes
- an example for a Management Review SOP
- real PQR examples
- extracts from real Management Reviews

Improve your Quality Reviews

PQR, APR, Management Review

27-28 May 2014, Barcelona, Spain

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy

Dr Rainer Gnibl
GMP Inspector for EMA

Dr Andreas König
Aenova Holding

Katja Kotter
Vetter Pharma-Fertigung

HIGHLIGHTS:

- Quality Reviews in the Context of FDA, EU and ICH
- Expectations of the Agencies
- How to set up efficient PQRs and APRs
- Management Review
- Statistical Tools
- Two Workshops

ECA
EUROPEAN COMPLIANCE ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager". Please find details at www.gmp-certification.eu

Improve your Quality Reviews

27-28 May 2014, Barcelona, Spain

Objectives

Based on real examples you will learn how you can implement and improve your Quality Reviews and use them more efficiently.
Use this opportunity to discuss the challenges with your colleagues and the speakers and learn how you can work successfully with these useful tools.

Background

In times of **permanent change, increasing complexity and pressure for permanent improvement**, it becomes more and more important to meet internal and external **GMP requirements and expectations** fast and smoothly while keeping an eye on the economic and operational situation. It is of utmost importance to collect and evaluate the right data, to define correct and efficient actions and to control their implementation.

Both parts of the **EU-GMP Guideline require the Product Quality Review (PQR)**. The aim of this requirement is to verify

- the consistency and appropriateness of the existing process,
- the adequacy of current specifications for starting material and finished product
- and to identify product and process improvements.

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

Quality Reviews will help you with this approach and are necessary and compulsory quality management tools. 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 industry who are involved in preparing and compiling Quality Reviews.

Programme

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

- EU-GMP Guide
- ICH Q10 and FDA Quality System Guide
- The role of ICH Q9
- Harmonisation and ISO 9001:2008
- Regulatory expectations
- The role of the Qualified Person
- Are PQR and APR the same or different?
- Are the requirements the same for APIs & drug products?

Quality Review Management

- Reviews of individual Quality Systems (Deviations, Complaints, Changes...)
- Quality Management Review
- Scope, Participants, and Frequency
- Planning and Execution
- Content, Results, and Actions, Follow-up

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?

The application of statistical tools in data review

- 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?

Workshop: What are the data telling us?

A step wise case study on analysing and interpreting process performance data

Quality Reviews from an Inspector's View

- Regulatory frame for EU-PQR
- Technical terms and aims of EU-PQR
- Critical technical terms of EU-PQR
- Comparison EU-PQR and US-APQR (Annual Product Quality Review)
- Practical implementation and inspection
- PQR and contract manufacturing

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?

Every participant will get:

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

Social Event

On 27 May, you are cordially invited to a social event (city tour and dinner) in Barcelona. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

Dr Christopher Burgess

Burgess Analytical Consultancy, U.K.

Dr Burgess is a Chartered Chemist and has more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R&D. He is a "Qualified Person" and a member of the European QP Association Advisory Board. He has been appointed to the United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the Chairman of the ECA Analytical Quality Control Group.

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 also working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Andreas König

Aenova Holding, Germany

Dr Andreas König is Director Manufacturing & Quality at Aenova Holding GmbH. Until 2009 he was Vice President Global Quality Operations Animal Health at Schering Plough. Before that he was Head of QC and QA at Fresenius Kabi. and later Global Quality Director at Intervet.

Katja Kotter

Vetter Pharma-Fertigung GmbH & Co. KG, Germany

Katja Kotter is Director Quality Assurance (Regulatory Affaires and Compliance). She studied Pharmaceutical Technology and Business Engineering and has brought experience in managing authority inspections and customer audits, supplier qualification and Quality Management Reviews.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Improve your Quality Reviews
27-28 May 2014, Barcelona, Spain
☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (if applicable)**

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

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If the bill-to-address deviates from the specifications on the right, please fill out here:

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Fax +49 (0) 62 21/84 44 34

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

Date

Tuesday, 27 May 2014, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00h)
Wednesday, 28 May 2014, 8.30 – 15.30 h

Venue

Barceló Sants
Placa dels Paisos Catalans, s/n
Estació de Sants
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 490 60 45

Fees

ECA Members € 1,490.- per delegate plus VAT
QP Association Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
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.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. 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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany,
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 84
info@concept-heidelberg.de
www.concept-heidelberg.de

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