



Every participant will get:

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

Improve your Quality Reviews

PQR, APR, Management Review

29-30 March 2012, Berlin, Germany

SPEAKERS:

Dr Christopher Burgess

Burgess Analytical Consultancy

Ian Holloway

*U.K. Medicines & Healthcare Products
Regulatory Agency (MHRA)*

Dr Andreas König

Aenova Holding, Germany

Dr Bernd Renger

European QP Association

HIGHLIGHTS:

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



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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 and KPIs, to define correct and efficient actions and to control their implementation.

Quality Reviews will help you with this approach and are necessary and compulsory quality management tools. Both the **FDA Guidance on Quality Systems Approach to Pharmaceutical cGMP Regulations and ICH Q10 Pharmaceutical Quality System** System (which will be implemented in the **EU-GMP Guide**) consider a Management Review to be an appropriate instrument to assess adequacy and effectiveness of quality systems.

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.

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

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

The System of Quality Reviews in internationally acting Companies

- 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 in the Light of Inspections - Expectations of the Agencies

- What does the inspector expect
- Internal and external responsibilities
- The PQR as an ideal starting point for an inspector
- Quality reviews – a good vehicle to demonstrate quality commitment and a systematic approach
- Quality reviews in the inspections – first experiences

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?

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

Social Event

On 29 March, you are cordially invited to a social event (city tour and dinner) in Berlin. 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 Christopher Burgess is Chartered Chemist with more than 30 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He is a Qualified Person and a qualified ISO Guide assessor and a member of the PDA (USA) Scientific Advisory Board on ‚OOS Task Force‘. He is also a member of the Qualified Person Association Advisory Board.

Ian Holloway

Medicines & Healthcare Products Regulatory Agency (MHRA), U.K.

Ian Holloway is Head of the Defective Medicines Report Centre at MHRA.

Dr Andreas König

Aenova Holding, Germany

Dr Andreas König is Director Quality Management 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 Fresenius Kabi and later Global Quality Director at Intervet.

Dr Bernd Renger

Bernd Renger Pharma Consulting GmbH, Germany

Dr Bernd Renger is a member of the ECA Advisory Board and Chairman of the European QP Association. Since 2011, he is running his own consultancy business. Before that he was Director of Quality Control at Vetter Pharma-Fertigung. He started his career at Hoechst AG as a research and development chemist. Since then, he has held several quality positions at Mundipharma, Altana Pharma and Baxter.



Easy Registration



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Reservation Form (Please complete in full)

Improve your Quality Reviews

29-30 March 2012, Berlin, Germany

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

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D-69007 Heidelberg
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E-Mail (please fill in)

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

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 %
 - until 1 weeks prior to the conference 50 %
 - 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 HEIDELBERG will 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).

Date

Thursday, 29 March 2012, 9.00 – 18.00 h
(Registration and coffee 8.30 – 9.00h)
Friday, 30 March 2012, 8.30 – 15.30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
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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
(does not include ECA Membership)
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 hotels. Reservation should be made directly with the hotels not later than 29 February 2012. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "VA 7213" to receive the specially negotiated rate (€ 125,-/€ 145,- single/double room per night, incl. breakfast and VAT) for the duration of your stay. 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

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