Workshops on:
- Process Analysis and Failure Investigation
- Evaluating and Monitoring

Deviation Management and CAPA

25-26 June 2015, Barcelona, Spain

SPEAKERS:

Dr Martin M. Appel
Cilag AG, Switzerland

Marcus Heinbuch
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Mick Hopper
GxPpro, U.K.

Dr Bob McDowall
R.D. McDowall Limited, UK

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GMP-Inspectorate, Germany

LEARNING OBJECTIVES:

- Rules and Regulations
  - EU
  - FDA
  - What the Inspector is looking for
- Deviations and CAPA
  - Deviations
  - CAPA
  - Classification
  - Failure Investigation
  - Risk Management
  - Root Cause
  - Human Error
- Evaluating and Monitoring
  - Effectiveness of CAPAs
  - KPIs

ECA ACADEMY

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

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Learning Objectives

During this course, you will learn all relevant aspects to **implement and/ or improve your Deviation Management and CAPA System** to fulfil regulatory GMP requirements. Furthermore, you will get to know possibilities and tools to **monitor and evaluate your CAPAs.**

Background

Things will go wrong from time to time. In the world of pharmaceuticals, we need to ensure that we have robust processes and procedure in place to deal with such situations. When an unplanned event arises it must be handled accordingly.

FDA's **Quality System Guide, recent Warning Letters** and EU-GMP Chapter 1 clearly emphasise the increasing relevance of a proper deviation management and CAPAs. ICH Q9 on Quality Risk Management and ICH Q10 on Pharmaceutical Quality Systems empower us to handle issues that arise in our daily work on the basis of risk analysis.

In any case a sound failure investigation is the key. Here it is also important to know how to deal with human error based and non-human error based non-conformances. Effective root cause analysis is the key to identifying appropriate CAPAs.

Independent from that, it needs to be pointed out that **CAPA is an excellent Quality Management tool** to continuously improve processes and avoid future failures. All personnel involved in the management of deviations and in CAPAs should aim to identify opportunities for further improvement.

Target Audience

This course is designed for all personnel involved in Deviation Management and CAPA activities at their company and decision makers who want to improve the existing process. It is addressed to persons from Quality Assurance and Control, Manufacturing and R&D.

Programme

International Requirements – Rules and Regulations

- European requirements
- The expectations of the FDA
- GMP and documentation issues
- Harmonisation in sight?

Excerpt from FDA Warning Letter

"...the investigation failed to establish a root cause and your quality unit failed to ensure the implementation of adequate corrective actions to prevent future recurrence."

Deviation Handling

- How to document deviations
- Information and Data Management
- Critical/ major/ minor
- CAPA or not?

CAPA: Principles, System, Implementation and Process Improvements and the use of Risk Management Techniques

- Tools
- Quality Risk Management
- Human Error Overview
- Monitoring & Evaluation Overview

Workshop:

An interactive exercise on scenarios with a focus on using the tools from the presentation

- Human Error based
- Non-human error based

Deviations in the Light of Inspections

- Focus in inspection
- Trends, Product Quality Review and Product Review
- The FDA approach
- Self-inspection as an important tool

Case Study: how to implement a CAPA-System

- How to integrate existing QM-Systems (OOS, Complaint Handling, Deviations)
- Examples and lessons learned

Software tools for CAPA management as part of a QMS

- Understanding your paper workflows and processes
- Can you improve the current process using electronic workflows?
- An overview of some of the main software applications for CAPA
- Efficient validation of a CAPA application

Evaluating and Monitoring Effectiveness

As part of the periodic quality review programme, Quality Management should routinely analyse reports of deviations and CAPAs to determine KPIs, trends, recurrence of non-conformances and effectiveness of CAPAs. A summary overview should be reported to the Senior Management team. ICH Q10 identifies this as best practice - but are we doing this as well as we could or should? We will discuss Quality Metrics as well as which are the important ones that will show you have a good Pharmaceutical Quality System.

Workshop on Evaluating and Monitoring Effectiveness

An interactive session with a focus on enhancing the knowledge gained in the presentation.

Social Event

On 25 June, 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 Martin M. Appel, *Cilag AG, Johnson & Johnson, Switzerland*
Dr Appel holds a Master Degree in chemistry and a PhD from the University of Hohenheim, Stuttgart and a Master Degree of Business Administration from the GSBA Zurich and State University of New York. Martin Appel has more than 25 years experience in several manager positions in the pharmaceutical industry. He was Quality System Director at Cilag AG and since 2008 he is Director QA for the Global API External Manufacturing and Supplier Quality of Janssen Supply Chain.

Michael Hopper, *GxPpro, U.K.*
Michael (Mick) Hopper set-up GxPpro after leaving Pfizer. Mick has over 30 years experience of working in the pharmaceutical Industry, where he held several Technical, Management and QA roles. He also gained a green belt accreditation and led the implementation of several improvement initiatives including Human Error management, Quality Risk Management and yellow belt development.

Dr Bob McDowall, *R.D.McDowall Limited, UK*
Analytical Chemist with over 40 years experience including 15 years working in the pharmaceutical industry; Director of R.D. McDowall Limited, UK. He has been involved with the validation of computerised systems for over 20 years and is the author of a book on the validation of chromatography data systems. Bob is the writer of the Questions of Quality (LC-GC Europe) and Focus on Quality (Spectroscopy) columns and is a member of the Editorial Advisory Boards of several Journals.

Marcus Heinbuch
B. Braun Melsungen AG, Germany
Marcus Heinbuch is Project Manager and Deputy of Vice President Quality Management CoE Pharmaceuticals at B.Braun Melsungen AG. He holds a Diploma in Chemical Engineering (FH Fresenius and California State University) and a Master of Sciences from Cardiff University.

Rico Schulze, *GMP Inspectorate, Local Authorities Dresden, Germany*
Rico Schulze is a Pharmacist and holds a degree in Economics. Since 2003, he is GMP and GDP Inspector at the Local Inspectorate in Dresden. From 2008 to 2011 he was working at the Saxon State Ministry of Social affaires. He is also the Head of the German Authorities' Radiopharmaceuticals Working Group.

Easy Registration

Reservation Form:
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69007 Heidelberg
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Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

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Reservation Form (Please complete in full)

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☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number Purchase Order No, if applicable

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Date

Thursday, 25 June 2015, 09.00 – 17.45 h
(Registration and coffee 08.30 – 09.00 h)
Friday, 26 June 2015, 08.30 – 16.00 h

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
PHone +34 (93) 503 53 00
Fax +34 (93) 490 60 45

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The course 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 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.

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