



Workshops on:

- Failure Investigation and Root Cause Analysis
- Classification of Deviations

Deviation Management and CAPA

3 - 4 May 2012, Barcelona, Spain

SPEAKERS:

Dr Martin M. Appel
Cilag AG, Switzerland

Richard M. Bonner
*ECA Regulatory Affairs Director
formerly Eli Lilly, UK*

Dr Christopher Burgess
Burgess Consultancy, UK

Dr Bob McDowall
McDowall Consulting, UK

Rico Schulze
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 Assessment
 - Root Cause
- Atypical and aberrant results
 - OOS, OOT and OOE
 - Statistical Aspects



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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** which fulfils regulatory GMP requirements. Furthermore, you will get to know possibilities and tools to **successfully investigate failures and OOS results**.

Background

FDA's **Quality System Guide** and **ICH Q10** clearly emphasise the increasing relevance of a proper deviation management and CAPA.

As indicated in ECA's Warning Letter Report, production record review is one of the most frequent **GMP deviations observed by the FDA**. In the fiscal years 2008, 2007 and 2005, observations regarding this subject were No. 1 in the ranking of cited GMP deficiencies. After a closer look at these citations, it becomes obvious that most observations are caused **by failures in deviation management and CAPA**. In most cases, deviations were noticed by the pharmaceutical company but no sound investigation was performed and no consequences were defined.

But also OOS results are deviations and need to be thoroughly investigated as well as OOT and OOE results. Independent from that, it needs to be pointed out that **CAPA is an excellent Quality Management Tool** to continuously improve your processes and avoid future failures.

Target Group

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.

Moderator

Dr Christopher Burgess

Programme

International Requirements – Rules and Regulations

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

2008 Warning Letter

“Failure of your Quality Control Unit to investigate thoroughly any unexplained discrepancy ..., and failure to ensure that written records of investigations are made and include conclusions and follow-up.”

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

- Should a CAPA approach be used for all deviation investigations?
- Root cause or just the causal factor?
- What, if root cause can not be detected?
- Organisational aspects of CAPAs
- How to set timelines
- How to use an ICH Q9 approach to CAPAs
- Consequences of CAPA failures
- Monitoring/ measurement of CAPA

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

OOS, OOT, OOE and a correct Decision making

- OOS, OOT and OOE results
- Statistical aspects
- Failure investigation
- Responsibilities

Workshops:

An interactive exercise to examine some deviations associated with a batch of manufactured product and their impact on the batch disposition decision

- Part 1 : Process Analysis and Tools for Failure Investigation
- Part 2: Practical Failure Investigation and Risk Assessment

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 process using electronic workflows?
- A review of the main software applications for CAPA
- Approaches to the validation of these applications

Workshop on classification of deviations and the quality impact assessment

Typical examples from the analytical laboratory will be presented and discussed

Social Event

On 3 May, you are cordially invited to a social event in Barcelona. 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 20 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 External Manufacturing.

Richard M. Bonner

Pharmaceutical Consultant, formerly with Eli Lilly, UK

Dick Bonner is Regulatory Affairs Director at the ECA and also works as a consultant to the Pharmaceutical Industry. Previous to his current role he was a Senior Quality Adviser for Eli Lilly and Company. He had 31 years experience within the pharmaceutical industry working in production, technical services and both Quality Control and Quality Assurance functions. Dick Bonner is a Qualified Person in Europe.

Dr Christopher Burgess

Burgess Analytical Consultancy, UK

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 and a member of the Executive committee of European Compliance Academy.

Dr Bob McDowall

McDowall Consulting, UK

Analytical Chemist with over 30 years experience including 15 years working in the pharmaceutical industry; Principal of McDowall Consulting, 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.

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 Affairs. He is also the Head of the German Authorities' Radiopharmaceuticals Working Group, and a member of the Expert Group on Medicinal Gases.

Easy Registration



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Reservation Form (Please complete in full)

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Company

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1. We are happy to welcome a substitute colleague at any time.
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 - until 2 weeks prior to the conference 10 %
 - until 1 weeks prior to the conference 50 %
 - within 1 week prior to the conference 100 %.

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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, 3 May 2012, 9.00 - 18.00 h
(Registration and coffee 8.30 - 9.00 h)
Friday, 4 May 2012, 8.30 - 16.15 h

Venue

nh-Hotel Constanza
C/Deu i Mata, 69-99
08029 Barcelona, Spain
Phone +34 (0)93 2811500
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Fees

ECA 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 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 event. Please use this form for your room reservation or be sure to mention "7212" to receive the specially negotiated rate (€ 143,-/€ 158,- single/double room per night, incl. breakfast, excl. VAT) for the duration of your stay. Reservation should be made directly with the hotel not later than 4 April 2012. 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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