ECA Certified Quality Control Manager Course*

- Participate in 6 Workshops!

Best Practices for Auditing GMP Laboratories

For Qualified Persons, QA Personnel and Laboratory Managers

20 – 21 October 2011, Heidelberg, Germany

SPEAKERS:

Dr Christopher Burgess
Burgess Analytical Consultancy Ltd., UK

Dr Bob McDowall
McDowall Consulting, UK

PROGRAMME:

- The Role of Auditing in Analytical Laboratories
- What is an Audit?
- Internal Versus External Laboratory Auditing
- Types of Audit
  - System Audit
  - Functional Audit
  - Regulatory Audit
- Regulatory Standards and Expectations
- FDA Key Laboratory Concerns
- Workshops Based on Actual Laboratory Audit Observations and Findings:
  - Audit Scope
  - Preparing for the Audit
  - Risk Assessment and Prioritisation
  - Key Areas of the Laboratory to be Audited
  - Observations and Findings
  - Closing Meeting and How to Present the Findings

ECA
EUROPEAN COMPLIANCE ACADEMY

* This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager"

Best Practices for Auditing GMP Laboratories

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Objectives

The two specific learning objectives of this new course are firstly, how to audit GMP labs in Pharma organisations and contract labs and secondly, how laboratory personnel can ensure compliance and be able to defend their positions.
The scope of auditing a GMP laboratory will be developed during the course along with a **risk-based prioritisation** of the key areas to focus audit attention on. The attendees will develop and review an auditing check list template to facilitate best audit practices.

Background

How do you know that the laboratories providing you with analytical data and results on which product release or stability studies rely are scientifically sound and regulatory compliant?
The announcement by the FDA of their post inspection response programme with a 15 day response requirement in August 2009 means that it is always cheaper to be compliant than to receive a warning letter with the attendant bad publicity. In addition there is urgent need to obtain a letter from the FDA that the company has effectively put in place remedial actions and is compliant again.
The regulatory requirements for analytical laboratories are to be found in:

- FDA GMP Sub Part I on Laboratory Controls
- EU GMP Guide Part I / Chapter 7
- EU GMP Guide Part II (APIs) / Section 16
- EU GMP Annex 11 **(new)**

In addition there are regulatory guidances from the FDA and PIC/S:

- Quality System Review according to FDA's Quality System Guidance
- PIC/S Aide Memoire on the Inspection of Pharmaceutical Quality Control Laboratories
- FDA Compliance Program 7346.832 Chapter 46 – New Drug Evaluation Pre-Approval Inspections / Investigations
- FDA Guide to Inspection of Pharmaceutical Quality Control Laboratories

In addition, ICH Q10 pharmaceutical quality systems (PQS) provides a FDA & EU regulatory acceptable basis for the establishment of pharmaceutical quality systems based on ISO 9000 quality management systems and the need for continual improvement.
The need for auditing to ensure that the elements of the PQS are in place is critical and is one mechanism for establishing that laboratory operations are efficient and effective in meeting the regulatory requirements.
This educational course is intended to focus on the quality system as it pertains to auditing GMP laboratories as well as the expected controls that need to be in place.
The course will be relevant to laboratories that are both internal and external to an organisation to ensure that the essential compliance elements are in place and that they work.

Target Group

This course will be of significant value to:

- Managers and scientists from Quality Control and Analytical Development Laboratories wanting to understand the audit process and to ensure quality
- Quality Assurance personnel
- Contract Research Organisation and Contract - Manufacturing Organisation laboratory and QA personnel
- Regulatory Affairs personnel with responsibility for the laboratory submissions and variations
- Auditors (internal and external) responsible for assessing laboratory QMS elements

Programme

Day 1 – Principles

Introduction to the Course

- Introduction to the teaching team
- Scope of GMP laboratories: internal and external to an organisation
- Inspection ready is redefined in light of the 483 Observation Post-Response Program
- Aims & objectives for the two day course

Trust but Verify – The Role of Auditing in GMP Laboratories

- Roles and responsibilities of the QP and QA in compliance
- Types of audits:
  - 1: System audit – is it there?
  - 2: Functional audit – are we in control?
  - 3: Regulatory audit – are we in compliance?
- Importance of walking through the laboratory to observe versus sitting in a room reading paper!

What is an Audit?

- First party, second party and third party audits
- Importance of auditor independence
- The audit process – from plan to report
- Approaches to auditing a GMP laboratory
- Open and closed questions and where to use them
- The role of a checklist in an audit
- Documented and photographic evidence
- Audit terminology: observations, findings and recommendations
- How to grade findings
- The corrective action plan and responses to it

What Will We Audit Against?

- Regulations: are your practices scientifically sound?
- Pharmacopoeial requirements
- Regulatory guidance for Industry from FDA and PIC/S
- Industry guidance e.g. ICH, AAPS, ISPE, APIC
- Site Master File
- Quality and technical agreements
- Corporate guidelines and laboratory SOPs
- Laboratory process flow and interactions
- Laboratory 483 observations and warning letters

Workshop 1: Identifying the Audit Scope of Laboratory Controls

- Group work with facilitated discussion to establish the potential scope and boundaries for a laboratory audit. This establishes what could be audited
- Inputs: laboratory process flows and a summary of the EU & FDA regulatory requirements for quality control
- Output: listing of the laboratory controls that could be audited

Workshop 2: So Much We Could Do But So Little Time to Do it! (Risk Assessment and Prioritisation of Audit Elements)

- Group work to take the output list from Workshop 1 and identify the key elements that must be audited based on risk assessment and prioritization
- Facilitated discussion of the different controls and approaches required for different types of laboratory e.g. secondary manufacturing, excipients, APIs, contract labs etc?
- Output: prioritised listing of the laboratory controls that should be in the audit scope

Workshop 3: FDA Key Laboratory Concerns

- Using some real 483 observations and warning letters the teams will cross check that the output of workshop 2 is congruent with the FDA concerns around laboratory
- Attendee validation of an updated audit list

Pulling it All Together

- Based on many years of the teaching team's laboratory experience, presentation of their top 10 non-compliances based on FDA and EU regulations and audit experience will be given.
- There will be an opportunity to discuss and compare the output from Workshop 3 against this knowledge base and experience.

Day 2 - Practice

Introduction to the Workshops on the Laboratory Audit

- Description of the laboratory scenario for day 2 workshops
- Identification of the key areas of the laboratory quality system to be audited:
  - Sampling and sample management
  - Method validation
  - Instrument qualification and computerised system validation
  - Primary record review
  - OOS and atypical results
  - Observations during a laboratory tour: reference standards, calibration of balances, reagent preparation and use
  - CAPA
  - Change control
  - Stability samples
- The workshop will focus on one or more of these as time permits
- Aim to identify specific non-compliances and any systematic issues
- Recommend changes where not a non-compliance but where working practices if not controlled could develop into compliance problems in the future

Workshop 4: Preparing for the Audit

- Based on the selected scenario the attendees will determine the preparation needed for a laboratory audit
- Feedback and discussion with the teaching team

Workshop 5: Observations and Findings During a Laboratory Audit

- Scenario descriptions of key areas described above will be provided along with observations for the attendees to determine if there are any non-compliance with the regulations and laboratory procedures
- Teams will determine if any observations are findings (non-compliances) and grade the severity of each one
- Discussion and feedback with the rest of the course and the teaching team

Workshop 6: Planning Closing Meeting and Informing the Auditees

- Teams will plan the closing meeting and how to present the audit conclusions and the findings
- Presentation of the findings to the course

Review of the Course and Key Learning Points

- Key learning points of the course presented
- Final discussions and close of the meeting

Laboratory Audit Checklist
Every participant will receive a checklist for the auditing of analytical laboratories.

Speakers

Dr Christopher Burgess,
Burgess Analytical Consultancy, UK
Dr Burgess has over 35 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He has MSc and PhD degrees from Loughborough University in Analytical Chemistry. He is a qualified ISO 17025 assessor. Dr Burgess has published over 70 papers and books in analytical science. He is also a Qualified Person and a member of the European QP Association Advisory Board.

Dr BOB MCDOWALL,
McDowall Consulting, UK
Analytical chemist with over 35 years experience including 15 years working in the pharmaceutical industry and 18 years working for the industry as a consultant. He is Principal of McDowall Consulting, UK. Bob is an ISO 17025 assessor and 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 also 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.

Efficient and Effective Quality Management in the Analytical Laboratory
On 18 - 19 October 2011, i.e. on Tuesday and Wednesday of the same week, there will be another ECA GMP Education Course in Heidelberg about **Efficient and Effective Quality Management in the Analytical Laboratory** . This course is intended to outline the roles of ICH Q9 (Quality Risk Management) and Q8 (Pharmaceutical Development) as toolboxes for ICH Q10 as part of the overall Laboratory Quality Matrix approach. The course is designed to take the contents of ICH Q10 and provide through the use of a simple tool, the Laboratory Quality Matrix, the means to interpret the ICH Q10 document to enable attendees to implement the laboratory elements of a Pharmaceutical Quality System.

The course is an **ideal precursor** to the ECA Education Course **Best Practices for Auditing GMP Laboratories** (20.-21. Oct. 2011). Further information about this course can be received at www.gmp-compliance.org.

Participants who register simultaneously for both courses will receive **a 300€ discount** (not valid for EU GMP Inspectorates).

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

Date

Thursday, 20 October 2011, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Friday, 21 October 2011, 08.30 - 16.00 h

Venue

Crowne Plaza Hotel Heidelberg
Kurfürstenanlage 1
69115 Heidelberg, Germany
Phone + 49 / (0) 6221 917 0
Fax + 49 / (0) 6221 917 100

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.

Do you want to save money?
If you register for the ECA Education Course "Efficient and Effective Quality Management in the Analytical Laboratory" from 18 to 19 October 2011 at the same time, you will receive a 300€ discount. This is not valid for EU GMP Inspectorates.

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 Booking code "ECA 6853" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 20 September 2011. 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.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Günter Brendelberger (Operations Director) at
+49-62 21 / 84 44 40, or per e-mail at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager)
at +49-62 21 / 84 44 46, or per e-mail at
weidemaier@concept-heidelberg.de.

Conference language

The official conference language will be English.

GMP Certification Programme

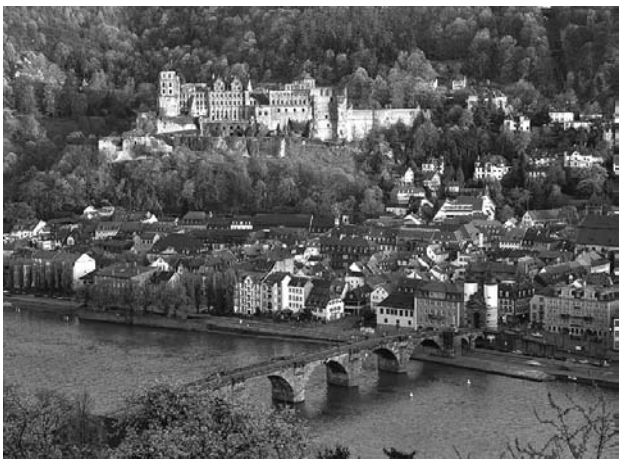
This course is recognised within the GMP Certification Programme Module „Quality Control Manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- Certified Validation Manager (ECA)
- Certified QA Manager (ECA)
- Certified API Production Manager (ECA)
- Certified Quality Control Manager (ECA)
- Certified Technical Operations Manager (ECA)
- Certified Computer Validation Manager (ECA)
- Certified Regulatory Affairs Manager (ECA)
- Certified Microbiological Laboratory Manager (ECA)
- Certified Sterile Production Manager (ECA)
- Certified Biotech Manager (ECA)
- Certified Pharmaceutical Development Manager (ECA)

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Social Event

On 20 October 2011, 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.



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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

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☐ I would also like to register for the Course **Efficient and Effective Quality Management in the Analytical Laboratory**, 18 - 19 October 2011, Heidelberg, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

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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)!