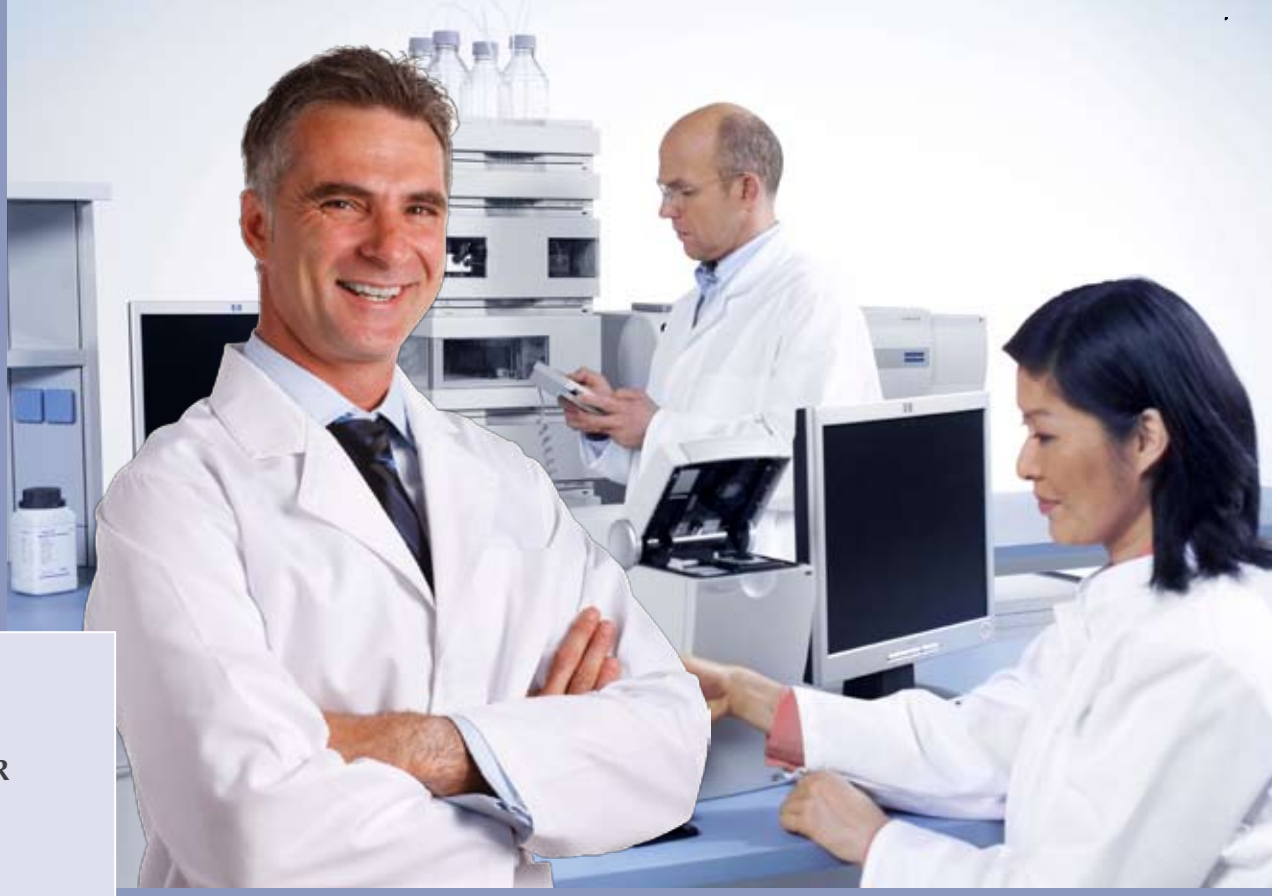

**Speakers:**

**DR CHRISTOPHER BURGESS**
Burgess Analytical Consultancy, UK

**DR BOB MCDOWALL**
McDowall Consulting, UK

**DR HOWARD HILL**
NDA Analytics, UK

**DR RETO THEISS**
Merck KGaA, Germany

**DR ULRICH WEBER**
Boehringer Ingelheim, Germany

# The Pharmaceutical Laboratory Manager 2010

## How to Efficiently Manage cGMP Compliance in Analytical Labs

- New cGMP Requirements for QC Labs
- Increasing Analytical Labs' Efficiency and Effectiveness

**11 - 12 October 2010, Berlin, Germany**

ECA
European Compliance Academy

This conference is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager"

## Objectives

The objectives of this conference are to provide guidance on ways of attaining best regulatory practice and to review the quality management tools available to increase laboratory throughput whilst maintaining data quality. This conference will address new GMP requirements for analytical laboratories and it will also present tools for an efficient and effective laboratory operation.

## Background

The challenges laboratory managers are facing today is how to keep pace with rapidly changing regulatory needs and, at the same time, to increase analytical output with current resources.

Pharmaceutical laboratory managers must be familiar with many GMP-related topics, such as;

- Latest EU and US (FDA) GMP requirements
- Quality assurance systems and approaches,
- Pharmacopoeial requirements,
- Data integrity (paper and electronic records),
- Risk management,
- Change control,
- Auditing of analytical laboratories

and many more

On the other hand, management expects that laboratory managers operate their laboratory activities in an effective and efficient way. Laboratory managers must know how to manage costs in the analytical laboratory and must also know those Key Performance Indicators (KPIs), which are relevant for the performance of their labs and be aware of benchmarking against typical KPIs in their industry.

This also includes getting to know new tools as the introduction of "Quality by Design (QbD)". What does QbD mean for analytical methods? And how can QbD concepts being developed to enhance the robustness of manufacturing processes also be used to enhance the robustness of analytical methods?

This conference will explore concepts for increasing analytical lab's efficiency and effectiveness and will discuss potential benefits for QC labs.

## Target Audience

This conference will be of significant value to

- Laboratory managers
- Quality control managers
- Analytical scientist
- Senior laboratory staff

who are responsible for GMP compliance and Laboratory Organisation.

## Moderator

**Dr. Christopher Burgess**
Burgess Analytical Consultancy Limited, UK

## Social Event

On Monday evening, 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.

Programme

**Part I:**
**Compliance – New cGMP Requirements for QC Labs**

### Regulatory Update – Current Developments and Impact on Laboratory Operations
**DR. CHRISTOPHER BURGESS,** Burgess Analytical Consultancy, UK

### Data Integrity as a Key FDA Compliance Issue
- Predicate rules on laboratory data apply both to paper and electronic records
- Increased fraud observed in FDA 483 and warning letters
- Reviewing the audit trails of computerised systems
- Backing up electronic data
- GMP archiving of raw data: what does the predicate rule say and what should we do?

**DR BOB MCDOWALL,** McDowall Consulting, UK

### Roles and Relationship between QP and the Head of QC
- Defining the roles and responsibility
- Understanding requirements in the CRO – Client relationship
- Differing roles and expectations of QPs
- Building effective relationships

**DR HOWARD HILL,** NDA Analytics, UK

### Quality Control of Raw Materials
- Guideline requirements
- Roles and responsibilities of the raw material lab in the production chain
- Supplier qualification: A key issue in times of globalisation
- Reduced sampling and reduced testing: Strategies to avoid work

**DR RETO THEISS,** Merck KGaA, Germany

### Analysis of Metal Impurities According to the New USP Chapters
- Contents of the new USP chapters
- Comparsion with EMA´s „Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents“
- Choice of analytical methods

**DR ULRICH WEBER,** Boehringer Ingelheim, Germany

### Impact of the New EU Variation Regulations on QC Labs
- Principals of the new variation regulation
- Definitions of variations
- What has changed?
- Benefit for regulatory departments?

**DR RETO THEISS,** Merck KGaA, Germany

### Quality by Design for Analytical Methods
**DR. CHRISTOPHER BURGESS,** Burgess Analytical Consultancy, UK

### Auditing Analytical Laboratories – A Risk-based Approach
- What could you audit and which are the most important?
- One size fits all for laboratory audits or tailor to a specific laboratory?
- Principles and practice of auditing
- Facilitated discussion about findings from GMP laboratory audits with the emphasis is on what a laboratory manager would do, if anything, to correct each observation

**DR. CHRISTOPHER BURGESS,** Burgess Analytical Consultancy, UK
**DR BOB MCDOWALL,** McDowall Consulting, UK

Programme

**Part II:**
**Increasing Analytical Labs' Efficiency and Effectiveness**

### Managing Costs in the Analytical Laboratory

- Getting it right before you start
- Managing time, fit for purpose workforce
- Major "fixed" costs
- Cost base vs efficiencies
- Controlling variable costs
- Maximising use of resources
- Maximising throughput
- Monitoring financial and operational KPIs

**DR HOWARD HILL**, NDA Analytics, UK

### Typical KPIs in Analytical Laboratories

- Analytical turnround times
- Number of samples analysed
- Quality parameters – based on customer feed back
- Process improvements – real and perceived value
- Developing Budgetary KPIs

**DR HOWARD HILL**, NDA Analytics, UK

**WORKSHOP I**

### Performance Measurement and Key Performance Indicators (KPIs)

Part 1: Participants choose between a QC lab or a development lab and brainstorm performance measures and possible KPI metrics.

Part 2: Participants are given some historical data from a laboratory and asked to construct a KPI metric and assess how the laboratory is performing.

Moderators:
**DR CHRIS BURGESS, DR HOWARD HILL**

### Sample Management for an Efficient and Effective Laboratory Operation

- Overview of regulations impacting sample management covering raw materials, in process samples, finished products plus retained and stability samples
- Analytical approaches to improving operational efficiency in the laboratory
- Informatics solutions to aid sample management and laboratory effectiveness

**DR BOB MCDOWALL**, McDowall Consulting, UK

**WORKSHOP II**

### Efficient and Effective Sample Management

Working in groups, the attendees will be presented with scenarios containing issues covering sample management. Each group will propose solutions to overcome the problems and these will be discussed with the course and the presenter.

Moderator: **DR BOB MCDOWALL**

### Integrated Dissolution Testing: A Case Study in Laboratory Automation

- Custom or commercial options for laboratory automation?
- Case study laboratory description
- Why select the commercial option?
- Rapid Implementation and validation of the system
- Benefits of the approach
- Lessons to be applied to any laboratory automation project

**DR BOB MCDOWALL**, McDowall Consulting, UK

## Speakers

**DR CHRISTOPHER BURGESS,**
**Burgess Analytical Consultancy Limited, UK**
Dr Burgess is a Chartered Chemist and has 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 was a member of the PDA (USA) Scientific Advisory Board on 'OOS Task Force'.

**DR HOWARD HILL,**
**Director of NDA Analytics, Alconbury, UK**
Howard Hill spent over 30 years in the pharmaceutical industry, 29 of those in contract research in the UK, Germany, Spain and Canada.

**DR BOB MCDOWALL,**
**McDowall Consulting, Bromley, Kent, UK**
Analytical chemist with over 30 years experience including 15 years working in the pharmaceutical industry; Principal of McDowall Consulting, UK.

**DR RETO THEISS,**
**Merck KGaA, Darmstadt, Germany**
Dr. Reto Theiss started in 1997 at Temmler Pharma in Marburg. In 1999 he became deputy Head of Temmler's Quality Control department. In 2002 he changed to Merck in Darmstadt serving as QP responsible for releasing products of the generic branch for the market. Since January 2005 his duties include the QA supervision of solid dosage forms during the whole production chain.

**DR ULRICH WEBER,**
**Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany**
Dr. Ulrich Weber was responsible for Quality Control Labs and for development of analytical methods for quality control of APIs, synthetic intermediates and raw materials for more than 15 years. Currently he is in charge of the lab for the control of metal catalyst residues in drug substances at Boehringer Ingelheim in Ingelheim.

## What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

## How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses, you will automatically become a member of ECA for two years - free of charge. More information about ECA can be obtained on the Website **www.gmp-compliance.org**

## What Are the Benefits of ECA?

During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

## About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

## 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
Monday, 11 October 2010, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Tuesday, 12 October 2010, 8.30 h – 16.30 h

### Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Phone + 49 / (0) 30 / 21 27 0
Fax + 49 / (0) 30 / 21 27 117

### Conference fees
Non-ECA Members EUR 1,690.- per delegate plus VAT
ECA Members EUR 1,521.- per delegate plus VAT
APIC Members EUR 1,605.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates EUR 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.

### Registration
Via attached reservation form, by mail or by fax message.
Or you register online at **www.gmp-compliance.org.**

### Accommodation
CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the conference. Please use this form for your room reservation or be sure to mention "VA 6393 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 10 September 2010. Early reservation is recommended.

### 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 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.:
Marion Grimm (Organisation Manager) at
+49-62 21/84 44 18, or per e-mail at grimm@concept-heidelberg.de.

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CONCEPT HEIDELBERG
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Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

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**The Pharmaceutical Laboratory Manager 2010**
11 - 12 October 2010, Berlin, Germany

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Department

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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)!