



EUROPEAN COMPLIANCE
ACADEMY

SPEAKERS:

Colin Booth
Oxoid

Dr Sven M. Deutschmann
Roche Diagnostics

Gordon Farquharson
*Bovis Lend Lease
Pharmaceutical*

Dr Robert Johnson
Dialogue

Thomas Mikosch
Centocor Europe

Dr. Thomas Montag
*Paul Ehrlich Institut, an
agency of the German
Federal Ministry of Health*

Dr Marion Pfohl
Novartis

Dr Barbara Potts
Genentech

Jolande Schoemaker
Schoemaker Consultancy

Dr Birgitta Steinborn
Cilag AG

Ian D. Symonds
GSK

Dr Britta Tofern-Reblin
*Federal Institute for Drugs
and Medical Devices
(BfArM)*

Dr Björn Wiese
Cilag, Johnson&Johnson



First European Microbiology Conference

**Berlin, Germany
22-23 April 2008**

Sessions

- Microbiology Laboratory
- Facilities and Utilities
- Risk Assessment and Continuous Improvement
- Product Development
- Biotechnology

Invitation to the First European Microbiology Conference 2008

Dear Colleague,



I would like to Invite you to the First annual European Microbiology Conference organised by the European Compliance Academy (ECA).

The conference is intended to provide microbiological updates and “real life” experiences to support the microbiologist in today’s Pharmaceutical development and manufacturing activities.

The Pharmaceutical microbiologist has a key role to play in all aspects of development, manufacture and control of medicinal products, and their components.

This first conference will focus on microbiological aspects of:

- Formulation development
- Design and control of facilities and utilities
- Best laboratory practices
- Handling microbiological deviations and continuous improvement
- Biotechnology

Experts from the pharmaceutical industry, regulatory authorities and international academia will present in different sessions covering various microbiological aspects of the above topics.

It is the aim of this conference to equip the pharmaceutical microbiologist with practical knowledge and “know how” which can be applied within the work place. In addition it will provide a forum for interesting and open discussion between presenters, regulators and your colleagues from the industry.

It would be great pleasure for me if you could join us in Berlin for what promises to be an exhilarating experience.



Dr Robert Johnson
Chairman, ECA RMM Working Group

Steering Committee

Colin Booth, *Oxoid, UK*

Dr Sven M. Deutschmann, *Roche Diagnostics, Germany*

Gordon Farquharson, *Bovis Lend Lease Pharmaceutical, UK*

Dr Ulrich Herber, *Concept Heidelberg, Germany*

Dr Robert Johnson, *Dialogue, Switzerland*

Jolande Schoemaker, *Schoemaker Consultancy, The Netherlands*

Tuesday, 22 April 2008

Two Parallel Sessions

Please choose the one you like to attend when you register for the conference.

Microbiology Laboratory

Objectives

The activities of the pharmaceutical microbiology laboratory are an area of focus for regulators during product submission and inspection, and also the organisation in support of products development and manufacture. The importance of microbiological laboratory best practice has recently been formally emphasised with the development of the USP chapter<1117> on “microbiological best laboratory practice”. But what is “best practice “ for the microbiological laboratory, and how can you achieve the requirements?

The quality control tests being used in microbiological laboratories are described in the different pharmacopoeias (EP, USP, JP etc) and are undergoing harmonisation. How does this impact upon your current “validated” microbiological methods ?, If and when should you implement the harmonised methods?

You are responsible for ensuring that the official methods function in your environment and with your products. Validation and implementation of microbiological test methods consumes time, money and resource. The challenge is therefore to satisfy regulatory requirements alongside financial expectations of your management.

During this one day session you will gain insight into “microbiological laboratory best practice” and see how the information can be used to help perform audits to assure compliance.

The session will also help you develop strategies for a sustainable approach to the validation of microbiological test methods. During interactive sessions you will create a test strategy for a pharmaceutical product formulation. The outcome will be that you be able to cope with the validation of microbiological test methods in a compliant and efficient manner.

Speaker

Dr Robert Johnson
Dialogue, Switzerland
Dr Christine Magin
Kwizda Pharma, Austria

First European Microbiology Conference

22-23 April 2008, Berlin, Germany

Agenda

- Best microbiological laboratory practice
- Breakout session e.g. using what you heard in 1st lecture to create a micro lab audit plan
- Harmonisation of pharmacopeial methods
- Objectionable organisms
- Practical applications for Water activity in Microbiology
- Breakout session devising a micro test regime for specified product
- Experiences in Microbiological Laboratory regulatory inspections

Facilities and Utilities

Objectives

2008 sees a new wave of regulatory initiatives, changes to GMP Guidance and business challenges to our industry. Everyone is struggling with applying the "risk-based" approach whilst often seeing specific unscientific regulatory demands impact facility and process designs and operations.

This one day seminar and workshop provides the ideal platform to hear learn about regulatory updates as well as opinion and current practice from professionals in the field. The seminar sessions will explore the changes to the EU/PIC-S Annex 1 for sterile products, the application of RABS (Restricted Access Barrier Systems) and Isolators, cleaning & bio-decontamination and regulatory expectations.

The workshop sessions will provide an excellent opportunity to consolidate the regulatory expectations by exploring the issues that should influence the choice of RABS or Isolators and considerations for effective environmental monitoring in isolator systems for sterile products manufacture.

Speakers

Gordon Farquharson, B.Sc.(Hons); C.Eng.
Bovis Lend Lease Technology Consulting
Björn Wiese
Cilag AG Johnson & Johnson, Switzerland

Agenda

- Annex 1 EU GMP – The new requirements in practice
- Bio-contamination control in Isolators and RABS
- Trends in Aseptic processing – beyond Annex 1

Workshop 1:

- Evaluation of best options for Aseptic Processing Isolators vs RABS

Workshop 2:

- Environmental Monitoring in Isolators – Microbiological and Particulate Contamination

Wednesday, 23 April 2008

Three Parallel Sessions

Please choose the one you like to attend when you register for the conference.

Risk Assessment and Continuous Improvement

Objectives

Risk Management has received a lot of attention in the last few years. The appearance of the ICH guidance documents has significantly increased the interest of industry in this area. However, risk management is not a stand alone activity, and should always be linked to process understanding and overall quality management. Thus the ICH guidance documents Q8 (Development), Q9 (Risk Management) and Q10 (Quality Management) are inter-linked. This session aims to give an understanding of Risk Management, specifically in relation to pharmaceutical microbiology and the risk of product contamination. The risk assessment tools most suitable to contamination control are discussed, and the principles are applied in an interactive session using real life examples.

Speakers

Dr Marion Pfohl
Novartis, Switzerland
Jolande Schoemaker
Schoemaker Consultancy, The Netherlands
Dr Brigitta Steinborn
Cilag AG Johnson & Johnson, Switzerland

Agenda

- Introduction to Q8, Q9 and Q10: Risk Management and Quality Management in relation to Development and Continuous improvement
- Out-of-specification results: root cause analysis and risk assessment
- Microbial specifications: product use and process capabilities
- Risk Management in clean rooms
- Workshop in which to apply the principles of risk management to a case study
- Risk Assessment- - Reduced Testing Frequencies for Raw Materials and Finished Products a case study
- Regulatory views on Risk Management in microbiology

Product Development

Objectives

The development of new Pharmaceutical formulations requires the input of Microbiologists to assess the microbiological risk to the product during all stages of manufacture, and to help establish robust control processes ensuring that the new product will always be of appropriate quality. Regulatory guides and Pharmaceutical microbiology text books explain in some detail how to validate methods for existing products. Hardly any deal with the special subject of developmental microbiology associated with bringing a new formulation to the market. In this section we use real world examples, the challenges faced and the processes used to evaluate the microbiological risk to the product, the process and the patient.

Speakers

Colin Booth

Oxoid, UK

Dr Britta Tofern-Reblin

Federal Institute for Drugs and Medical Devices (BfArM), Germany

Ian D. Symonds

GSK, UK

Dr Brigitta Steinborn

Cilag AG Johnson & Johnson, Switzerland

Agenda

- How to choose a preservative for your formulation and validate the preservative efficacy test
- Case Study: In-use test for preserved medicinal products
- Case Study: Reduced validation Activities during product development
- Developing a terminal sterilisation process for a new formulation
- Workshop: Validating compendial microbiological methods for new products
- Pharmaceutical development in quality dossiers: microbiological requirements from the European point of view

Biotechnology

Objectives

Microbiological safety of biopharmaceuticals requires special attention. Due to the nature of the processes, biopharmaceutical API manufacturing often provides optimal growth conditions for microbial contaminants. An additional danger is their poor stability towards steam and heat sterilisation, increasing the potential for microbial contamination. To ensure microbiological safety, two complementary approaches are applied:

Pro-active: control of starting materials, equipment and facilities, cleaning validations, in-process controls ...

Re-active: removal of microbial contaminants, extensive testing of the finished product ...

Considering the financial and ethical value of most biopharmaceuticals, it is worth spending a lot of thoughts, efforts and resources for enhancing the microbiological safety of these products.

It is the aim of this session to provide you with up-to-date information about current developments and guidance on implementing state-of-the art techniques.

Speakers

Dr Sven M. Deutschmann

Roche Diagnostics, Germany

Thomas Mikosch

Centocor Europe, The Netherlands

Dr Thomas Montag

Paul Ehrlich Institut, an agency of the German Federal Ministry of Health, Germany

Dr Barbara Potts

Genentech, USA

Agenda

- Adventitious agents in Biopharmaceutical Processes
- Cleaning Validation
- Alternative Test for the Presence or Absence of Micro-Organisms
- Workshop:
Contamination control of Biopharmaceutical processes

Speakers

Colin Booth, *Oxoid, UK*

Colin was the manager of pharmaceutical microbiology of Glaxo Wellcome Research and Development based in the UK where he was responsible for the microbiology associated with the development of all Glaxo Wellcome new products. In 2002 he joined Oxoid Limited where he is now Vice President Science and Technology. Colin is an ECA Advisory Board Member covering the field of Development Microbiology.

Dr Sven M. Deutschmann, *Roche Diagnostics, Germany*

Sven studied biology at the University of Braunschweig where he obtained his PhD in cell culture technology. In 1995 he joined Boehringer Mannheim GmbH, now Roche Diagnostics GmbH, as Manager QC. He was responsible for the microbiological and cell biological analytics of QC- and In-Process-Control-samples in the production of biotechnological derived active pharmaceutical ingredients and for the environmental monitoring program in the production areas. Since 2001 he is Director of the Microbiology QC Department. Sven M. Deutschmann is member of the microbiology commission of the German Pharmacopoeia Commissions and specialist in the Working Party "Monocyte Activation Test" of the European Pharmacopoeia Commissions.

Gordon Farquharson, *Bovis Lend Lease Pharmaceutical, UK*

Gordon is a chartered consulting engineer with 30 years experience of quality & safety critical processes and facilities used by industries such as healthcare, life science, micro-electronics, etc. He is principal consultant with Bovis Lend Lease Technology Division's global operation. In recent years he has focused on technologies such as isolators, barrier technology, and mini-environments, critical utility systems and has been responsible for the development of technical solutions in product development, primary manufacturing and device and dosage form manufacturing. In recent years, he has been heavily involved in the development of the new regulatory guidance and standards. He is a founding member, management committee member, past chairman, and honorary member of the UK Parenteral Society, and is active in ISPE, the R3 Nordic Association, and PDA. He is a member of the PDA Science Advisory Board (SAB) and is an honorary senior lecturer at UCL (London).

Dr Robert Johnson, *Dialogue, Switzerland*

Robert is currently the CEO of Dialogue, a consultancy operation providing a range of activities to support pharmaceutical companies. Previous to his current role he was head of Global Quality at PLIVA, Croatia. Before joining PLIVA Robert held different senior positions at GSK in the UK (e.g. Area Director, Global Quality and Senior Global Quality Manager Microbiology). He has been involved in multiple inspections from the MHRA, FDA, EMEA and other authorities. Robert is a Registered Qualified Person as well as Expert of British Pharmacopoeia.

Thomas Mikosch, *Centocor Europe, The Netherlands*
Manager Microbiology, QO Cell Culture Quality

Dr Christine Magin, *Kwizda Pharma, Austria*

Dr. Thomas Montag, *Paul Ehrlich Institut, an agency of the German Federal Ministry of Health, Germany*
Thomas studied medicine at the Humboldt-University Berlin and specialised in medicinal microbiology. After spending some years in research work at the Charité in Berlin he has been employed at the Paul-Ehrlich-Institut since 1990. At present Thomas is heading the department of parasitology, diagnostics und microbial safety.

Dr Marion Pfohl, *Novartis, Switzerland*

After studying Microbiology at the universities of Frankfurt/Main and Ulm, Marion started her industry career as head of microbiology at Degussa in Konstanz, Germany. In 1990 she moved to Sandoz, Basel, Switzerland, where she was in charge of environmental monitoring, preservative efficacy testing and training of operators. After the merger of Sandoz and Ciba-Ceigy in 1998 Marion became team leader Quality Assurance - Pharmaceutical Operations Switzerland/Microbiology at the Stein production site of Novartis. Since 2005 she has been the leader of the QA/QC Team Process Unit Ampoules. Marion is responsible for product release and liaison with inspectorates.

Dr Barbara Potts, *Genentech, USA*

Jolande Schoemaker, *Schoemaker Consultancy, The Netherlands*

Jolande is currently located in The Netherlands and works as a consultant to the pharmaceutical industry. Previous to her current role she was the Director Quality Affairs at Crucell. Jolande gained a wide field of experience in many aspects of the pharmaceutical and biotechnology industry, including formulation of drugs, manufacturing of sterile pharmaceutical products, hospital care and clinical trials, Regulatory Affairs, Quality Control and Quality Assurance. Furthermore, she was involved in many regulatory inspections, including some conducted by the US FDA, the Canadian and the British Inspectorate.

Dr Birgitta Steinborn, *Cilag AG, Schaffhausen, Switzerland*

Birgitta Steinborn gained her PhD in Microbiology in D-Freiburg. In 1993-1999 she headed the microbiology laboratory at Roche AG in CH-Sisseln and was responsible for the microbiological support to all non-sterile facilities and the aseptic bulk powder filling. Since 2000, she was Global Head of Microbiology for the Johnson & Johnson Pharmaceutical R&D sites in the United States, Belgium and Cilag AG in Switzerland and started a new position in Pharmaceutical R&D Quality Assurance at Cilag AG in 2005 with a focus on aseptic manufacturing support.

Ian D. Symonds, *GSK, UK*

Director Aseptic Quality Assurance

Dr Britta Tofern-Reblin, *Federal Institute for Drugs and Medical Devices (BfArM), Germany*
Assessor Pharmaceutical Quality

Dr Björn Wiese, *Cilag, Johnson&Johnson, Switzerland*

From 1996 to 2000 Björn Wiese worked as project manager in R&D of Danisco Ingredients, Niebüll, Germany, and developed start up cultures. Since November 2000, he had been head of the microbiology department of Hameln Pharmaceuticals, Hameln, Germany. From 2005 - 2007 Björn worked in the QA Department of Cilag as Person in the Plant at one of Cilag's contract manufacturers. Starting in 2007 Björn is now responsible for all Environmental Monitoring activities at the pharmaceutical production site of Cilag in Schaffhausen, Switzerland.

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

First European Microbiology Conference
22-23 April 2008, Berlin, Germany
Please choose one of the sessions per day:

- 22 April 2008**
- Microbiology Laboratory
 - Facilities and Utilities
- 23 April 2008**
- Risk Assessment and Continuous Improvement
 - Product Development
 - Biotechnology

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

General Terms of Business

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 % of the registration fee.
 - until 1 week prior to the conference 50 % of the registration fee.
 - within 1 week prior to the conference 100 % of the registration fee.

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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**

GMP Certification Programme

This conference is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- Certified Quality Assurance Manager – Pharmaceutical Production (ECA)
- Certified Quality Assurance Manager – API Production (ECA)
- Certified Quality Control Manager (ECA)
- Certified Pharmaceutical Engineering Manager (ECA)
- Certified Computer Validation Manager (ECA)
- Certified Regulatory Affairs Manager (ECA)
- Certified Validation 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.



Date

Tuesday, 22 April 2008, 9.00 – 18.00
(Registration and coffee: 8.30 – 9.00)
Wednesday, 23 April 2008, 9.00 – 18.00

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin
Germany
Tel +49 (0)30 2127 0
Fax +49 (0)30 2127 117

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the Steigenberger Hotel. Reservation should be made directly with the hotel not later than 7 March 2008. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention "VA 5489 ECA Course" to receive the specially negotiated rate for the duration of your stay. Early reservation is recommended.

Fees

Non-ECA Members EUR 1,790.- per delegate plus VAT
ECA Members EUR 1,611.- per delegate plus VAT
APIC Members EUR 1,700.- per delegate plus VAT
(does not include ECA membership)
EU GMP Inspectorates EUR 895.- 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.

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 the attached reservation form, by e-mail or by fax message. Or you register online at www.microbiology-conference.org

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
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herber@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Jessica Stürmer (Organisation Manager)
at +49-6221/84 44 43, or per e-mail at
stuermer@concept-heidelberg.de.

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.

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.

What Are the Benefits of ECA?

First benefit: 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.

Second benefit: The GMP Guidelines Manager CD ROM 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.



How Do You Become Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. There are no obligations for the member! Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website <http://www.gmp-compliance.org>.