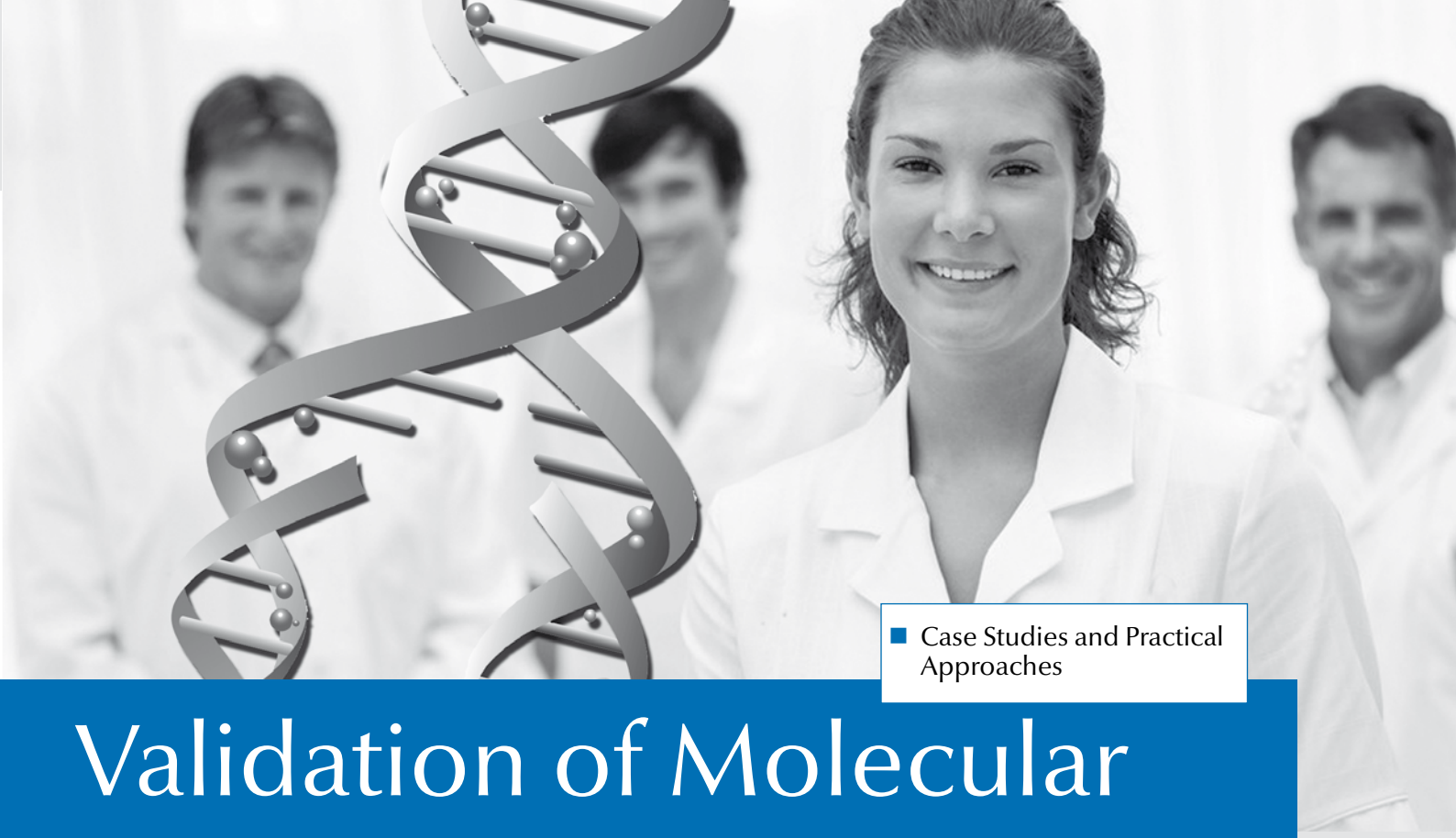

- Case Studies and Practical Approaches

Validation of Molecular Biological Methods

Requirements, Standards, Validation

14 – 15 February 2012, Prague, Czech Republic

SPEAKERS:

Eric Abachin
Sanofi Pasteur, France
Frederic Bar
Life Technologies, France
Christine Farrance
Accugenix, USA
Anna Gottlieb
NIBSC, UK
Holger Kavermann
Roche Diagnostics, Germany
Thomas Meindl
L+S AG, Germany
Michael Miller
Microbiology Consultants, USA
Dr Michael Nübling
Paul-Ehrlich-Institut
Melanie Störmer
Paul-Ehrlich-Institut, Germany
Emiliano Toso
Merck Serono, Italy
Geert Verdonk
MSD, The Netherlands
Dirk Vollenbroich
Minerva Biolabs, Germany

LEARNING GOALS:

- Regulatory Background
- Technologies
- Validation Strategies
- Validation and QA of methods used in clinical laboratories
- Virus Detection
- Mycoplasma Testing
- SLST and MLST in an Environmental Monitoring Programme
- Residual DNA Quantitation

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Validation of Molecular Biological Methods

14 – 15 February 2012, Prague, Czech Republic

Objectives

The great challenge for new industrial applications is the validation of the methods to achieve regulatory approval. One issue is that there are often no possibilities revert to previous experiences because the validation criteria in research applications are not the same than in industrial applications.
This two day education course provides you with an insight in the different methods available.

Well-experienced speakers will share their know-how on how to implement and validate these methods successfully in industrial daily business.

Background

The Development of Molecular Biological Methods has made a rapid progress during the last years. Being primarily science based, they found their way more and more to industrial applications. Especially in the food and pharmaceutical industry, Molecular Biological Methods for the detection of adventitious biological agents and impurities gained importance in process control strategies and release testing.

Target Audience

This course is addressed to employees from
- Quality Assurance
- Microbiological Quality Control Laboratory
- Viral Quality Control Laboratory
- Analytical Laboratory

which are involved or interested in molecular biological methods and their validation

Moderator

Axel H. Schroeder, Concept Heidelberg

Social Event

On 14 February 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

The future of Rapid Molecular and Microbiological Methods: A Review of Technologies, Validation Strategies and Regulatory Expectations

- A review of existing rapid method technologies and insights into future detection platforms
- Validation strategies for the detection, enumeration and identification of microorganisms
- FDA, EMA, PMDA and TGA expectations for validation and implementation
- The role of PAT and Quality by Design
- Dispelling the myths surrounding rapid methods and their use

Perception of molecular biology methods for viral safety

- My 12 years experience to develop tools and resources to apply molecular biology methods to Biotech Quality Control
- How to deal with Regulatory Requirement vs Cost Saving
- Case studies: examples of successful method implementations
- Old and new in Viral safety: next generation techniques

Tracking the Untrackable Microbes – The use of SLST and MLST in environmental monitoring programs

- Combining an accurate method of genotypic identification with multi or single-locus sequence typing (M/SLST), to resolve difficult organisms
- MLST and SLST to distinguish closely-related microorganisms to the subspecies or strain level by analyzing essential protein coding or housekeeping genes which are hypervariable
- MLST and SLST for determination of gene combinations that give high level of variability to differentiate to the strain or subspecies level even in situations where the organisms are closely related
- Case studies: Propionibacterium acnes and Ralstonia pickettii

Quality Control reagents for clinical microbiological diagnostic nucleic acid amplification assays

- Clinical diagnostic microbiology – the current standard of Quality Control
- Identification and production of required QC materials for clinical microbiological diagnostics
- Singleplex collaborative studies – large and small studies on singleplex reagents
- Multiplex collaborative studies – small studies on multiplex reagents
- Development and use of an on-line QC programme

Design of screening NATs – Implications for variable pathogen targets

- NAT- Sub/Underdetermination (e.g. HIV-1 NATs)
- Possibilities of Optimising

Challenges in Validation of Molecular Biological Methods for Microbiological Control of Advanced Therapy Medicinal Products (ATMPs)

- Validation of Mycoplasma Detection according to European Pharmacopeia
  - Regulatory Considerations
  - International Microbiological Reference Preparations

Real Time PCR for MVM Testing in unprocessesd Bulks of Biotech API

- Test and control concept
- Validation strategy
- Points to consider
- Influence of the sample matrix

Q-PCR Mycoplasma testing : choosing the right thing

- DNA recovery study
- MPL method for determination of the LOD
- Comparability testing

Validation of a MALDI-TOF system in a contract laboratory

- Definition of specific validation parameters
- How to define acceptance criteria in a microbiological approach

Applied Mycoplasma PCR Testing - Manufacturer´s validation burden

- Case studies: sample specific validation strategies
- Results from an international collaborative study

Residual Host Cell DNA Quantitation – Implementation and Validation

- Assay and sample preparation strategy
- Aifferences in validation strategies between quantitative tests and limit tests
- Validation guidelines
- Exemplary validation studies

Validation of mycoplasma detection method

- Evaluation of alternative Mycoplasma assay for Mycoplasma contamination detection on our vaccine matrices
- Prevalidation study carried out 9 Mycoplasma strains
- Validation of an alternative Mycoplasma test by following regulatory requirements

Speakers

Eric Abacin,
Analytical R&D Department, Sanofi Pasteur, France
Eric works as analytical scientist in sanofi pasteur R&D department. His research is focused on developing and validation of molecular biology methods and bacteriology methods in order to control vaccines.

Frederic Bar, *Life Technologies, France*

Christine Farrance, Ph.D.,
Marketing Applications Specialist, Accugenix, Inc.
Dr. Farrance has 16 years of experience conducting both applied and basic research using molecular, microbial, genetic and biochemical techniques.

Dr Anna Gottlieb,
NIBSC, United Kingdom
Since joining NIBSC Anna has worked to produce NIBSC's first QC reagents for clinical diagnostic microbiology, from the scientific and technical development to documentation covering all of the quality aspects required by the EU In Vitro Diagnostics Directive.

Holger Kavermann,
Roche Diagnostics GmbH, Germany
In 2003 Mr Kavermann joined Roche Diagnostics GmbH, as Manager QC. He is responsible for the microbiological and cell biological analytics of QC and In-Process-Control samples in the production of biotechnological derived active pharmaceutical ingredients.

Dr Thomas Meindl,
L+S AG, Bad Bocklett, Germany
From 2000 to 2003 he was Project Manager for development of new and modified drugs at Sympore. 2003 – 2005 he researched in Oncology at SKM Oncology GmbH. Since 2005 he is Division Manager at L+S AG .

Dr Michael Miller,
Microbiology Consultants, LLC, United States
For more than 22 years, Michael has held numerous R&D, manufacturing, quality, and consulting and business development leadership roles. In his current role, Dr Miller consults with multinational companies in providing technical, quality and regulatory solutions for pharmaceutical manufacturing, contamination control, QC, barrier isolator technology and microbiological PAT.

Priv.-Doz. Dr Claudius Micha Nübling,
Paul-Ehrlich-Institut, Langen (Germany)
Dr Nübing is employed since 1990 at the Paul-Ehrlich-Institut, the German Federal Institute for Vaccines and Biomedicinesin Langen. Since 1996, he is Deputy Head of Virology Division. He is a Member of different committees like the Biological Reference Preparations (BRP) Program of the European Pharmacopeia,, the OMCL Proficiency

Testing Program of the EDQM, the WHO Working Group on Hepatitis and HIV Diagnostic Kits, and the EU Working Group on Common Technical Specifications (CTS) for in vitro diagnostic (IVD) medical devices

Dr Melanie Störmer,
Paul Ehrlich Institute, Federal Institute for Vaccines and Biomedicines, Division of Microbial Safety, Germany
Since April 2008 she is employed at the Paul Ehrlich Institut at the microbiological research group of the division of microbial safety, working on novel principles in microbial detection in advanced products and the establishment of the first international WHO Transfusion-Relevant Bacteria Reference Strain Repository for validation and development of new technologies.

Emiliano Toso, PhD,
Merck Serono Ivrea (Turin), Italy.
He is head of the Molecular Biology group in the GMP Biological Quality Control department. Since 2000 he has set up and validated PCR and qPCR detection of viruses, retroviruses and mycoplasma in cell banks and bulk harvests, as well as genotypic characterization tests of recombinant cell lines, microbial identification with genotypic methods, residual DNA detection by qPCR, and human cell line DNA profiling.

Geert Verdonk,
Senior Scientist Quality, MSD, Oss, The Netherlands
Mr Verdonk has been with MSD (formerly Organon Oss and Schering Plough) since 1996. For the past 5 years he managed the microbiological development group in Oss, the Netherlands. He is responsible for validation activities, development of new microbiological technologies (rapid microbiological methods) and troubleshooting microbiological contaminations in pharmaceutical production processes

Dr Dirk Vollenbroich,
Minerva Biolabs GmbH, CEO, Germany
At the German Federal Institute for Health, the Robert Koch Institute, he gained invaluable experience within the field of virus safety of blood products, virus inactivation in biopharmaceutical processes and mycoplasma contamination control of cell culture derived materials. 1999 he founded Minerva Biolabs GmbH providing products and services for mycoplasma safety and pathogen.

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

Tuesday, 14 February 2012, 09.30 – 17.30 h
(Registration and coffee 09.00 – 09.30 h)
Wednesday, 15 February 2012, 09.00 - 16.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Praha 4, Czech Republic
Phone +420 (261) 191 111
Fax +420 (261) 225 011

Fees

ECA-Members: € 1,590.– per delegate + VAT
APIC Members: € 1,690.- per delegate + VAT (does not include ECA Membership)
Non-Members: € 1,790.– per delegate + VAT
EU GMP Inspectorates: € 895.– per delegate + VAT
Including: Conference documentation, lunch on both days, all refreshments, dinner on the first day. The registration fee is payable in advance after receipt of invoice. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. Reservation should be made directly with the hotel not later than 13 January 2012. 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 "XCON130212" to receive the specially negotiated rate (single/double room € 95,- per night, incl. breakfast) for the duration of your stay. 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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For questions regarding content:
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or per e-mail at schroeder@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at
+49-62 21/84 44 51 or per e-mail at
strohwald@concept-heidelberg.de.

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And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager

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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

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

Reservation Form (Please complete in full)

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Validation of Molecular Biological Methods, 14 – 15 February 2012, Prague, Czech Republic

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Title, first name, surname

Company Department

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P.O. Box 101764
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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 %
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