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

This education course is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager”. Please find details at www.gmp-certification.eu
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 to 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.
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 unprocessed 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
- Differences 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 Biomedicines in 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.
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.

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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Mr Axel Schroeder (Operations Director) at +49-(0)6221/84 44 10,
or by 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 by e-mail at strohwald@concept-heidelberg.de.

Lufthansa is Mobility Partner for all ECA Events

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

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 – otherwise the booking platform window will not open.

GMP Certification Programme

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

ECA 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

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.
Reservation Form (Please complete in full)

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

☐ Mr.       ☐ Ms.

---

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number   PO Number if applicable

Street/P.O. Box

City       Zip Code       Country

Phone/Fax

E-Mail (please fill in)

---

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

D-69007 Heidelberg
GERMANY

---

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:
   - until 2 weeks prior to the conference: 10%,
   - until 1 week 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).