Live Online Congress on 22-26 November 2021

PharmaLab

Regulatory and Methodological Developments

From Method Validation up to Optimisation and Automation in Analytical and Microbiological Laboratories

Highlights

- Laboratory and Method Optimisation
- Benefits of Modern and Alternative Methods
- Regulatory Developments
- Challenges on Method Validation
- Case Studies of Implementation and Use of Modern Methods

ECA Academy
Your GMP/GDP Information Source

All information can be found at: www.pharmalab-congress.com

The Congress Objective

Dear colleagues,

When we had to change the 8th PharmaLab Congress into an online event at short notice last year, no one would have thought how long the pandemic situation would last and affect our lives, private and business, for such a long period of time. Unfortunately, international on-site congresses will not be able to take place in the usual form this year either. Public restrictions, but also travel restrictions by the companies and reduced budgets do not allow this yet. Therefore, we will hold PharmaLab online again in 2021. Based on the feedback from 2020, we will make some significant optimisations:

The different lecture tracks will take place one after the other and not in parallel, so that every participant will have the opportunity to listen to every lecture.

More than 40 speakers from Europe and overseas will give comprehensive talks on current trends and changes in the field of pharmaceutical production, quality assurance and quality control - both regulatory and scientific - in around 50 presentations.

The following conference tracks are planned:

- Monday, 22 November: Laboratory Optimisation and Automation
- Tuesday, 23 November: Validation of Analytical Methods and Life Cycle Management of Analytical Procedures
- Wednesday, 24 November: Alternative- and Rapid Microbiological Methods
- Thursday and Friday, 25 and 26 November: Endotoxin and Pyrogen Testing

Particularities of the PharmaLab Congress:

- One-day and multi-day tickets offer you the opportunity to attend parts or even the entire congress, to compile the lectures of your choice
- You will receive all lectures of all conferences electronically as PDF files
- Use the PharmaLab to participate in the wealth of experience of the speakers

We look forward to welcoming you online at PharmaLab.

With best regards - and stay healthy!

Axel H. Schroeder
Administration Manager
Pharmaceutical Microbiology Working Group

Premium Sponsors 2021:

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ASSOCIATES OF CAPE COD EUROPE GmbH
Specialists in Endotoxin and Glucan Detection

Optimization and Automation

22 November 2021, 11.00 - 17.30 h CET

Track 1

Objectives

The aim of this Live Online Conference is to show possibilities to optimize the organization of a laboratory and to reduce costs. The topics LEAN, both for the laboratory and laboratory management and the optimization of structures and processes in the laboratory, are addressed. Furthermore, the possibilities of automation are presented and the benefits that can result from the optimization of the method portfolio. Equally modern approaches to cost savings through reduced testing and reduced sampling while maintaining GMP compliance will be presented.

Background

The pressure that the pharmaceutical industry is under today to reduce costs and increase efficiency and effectiveness applies equally to analytical laboratories. Often waiting for the results of quality control is still a speed-limiting step in the entire production process.

Many modern tools such as LEAN, Six Sigma, CIP, etc. are increasingly used to increase the efficiency (also) of analytical laboratories.

The correct recording and evaluation of the "Key Performance Indicators" (KPIs) plays a decisive role in this. Which of these factors are really "key", which ones can be dispensed with?

With this Live Online Conference, managers and employees in the laboratory learn tools for more effective and efficient control of laboratory activities.

Topics are:

- LEAN in QC
- Key Performance Indicators (KPIs)
- Optimization of laboratory processes - practical examples
- Cost-efficient design of a laboratory
- Case Studies for Laboratory Automation
- New analysis methods for the optimization of processes in the laboratory
- Reduced sampling and reduced scope of testing in the incoming goods inspection of active and auxiliary materials

Target Group

This Live Online Conference is aimed at laboratory managers and laboratory staff in the pharmaceutical industry who work in the areas of incoming goods inspection, finished goods inspection and analytical development. Also addressed are laboratory managers in the field of pharmaceutical active ingredient and excipient production and contract laboratories. The contents will also be of great interest to competent persons according to §14 AMG and to heads of quality control as well as to employees from the QA department

Programme

➲ Continous Improvement & Idea Management Process (CIP & IMP)
Dr Karl-Heinz Bauer, Boehringer Ingelheim

➲ Digitization of Workflows and Method Developments in a Pharmaceutical Testing Laboratory
Lars M.H. Reinders, IUTA

➲ Efficient Cleaning Techniques: A Good Starting Point for a Successful Trace Metal Analysis
Fábio Brito, LEF - Infosaúde

➲ KPIs for Performance-Measurement
Dr Karl Heinz Bauer, Boehringer Ingelheim

➲ IT / Computers in the Lab
Ulla Bondegaard, NovoNordisk

➲ The Integrated, Automated Lab of the Future
Sinead Cowman, Lonza

➲ Accuracy of Human Visual Inspection in Pétri Dishes Enumeration
Laurent Leblanc, bioMérieux

➲ Microbial Identification: Maximising the Data Value of Pharmaceutical Flora
Miriam Guest, AstraZeneca

Validation of Analytical Methods and Life Cycle Management of Analytical Procedures

23 November 2021, 09.00 - 17.30 h CET

Track 2

Objectives

The Live Online Conference will present and highlight the current developments in the field of method validation and life cycle management. Experts from industry and laboratories will present the current status of the revision and the contents of the guidelines on the one hand; and their own experiences in the establishment and validation of methods and procedures on the other hand.

Background

On 14 November 2018, a final concept paper "ICH Q14: Analytical Procedure Development and Revision of Q2(R1) Analytical Validation" was published. It proposed to develop a new quality guideline for analytical procedure development and to revise the ICH Q2(R1) Guideline on Validation of Analytical Procedures: Text and Methodology. Meaning:

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Guideline Q14 Analytical Procedure Development
"The new guideline is proposed to harmonise the scientific approaches to analytical procedure development and to provide the principles for describing the process of analytical procedure development. The use of this guideline will improve communication between industry and regulatory authorities and facilitate more efficient, science-based and risk-based approval and post-approval change management of analytical procedures."

Q2(R1) Revision
"The scope of the revision will include validation principles covering the analytical use of spectroscopic or spectrometric data (e.g. NIR, Raman, NMR or MS), some of which often require multivariate statistical analyses. The guideline will continue to provide a general framework for the principles of analytical method validation applicable to products that fall primarily within the scope of Q6A and Q6B."

Unfortunately, development is currently treading water a bit, but nevertheless many laboratories are already running corresponding methods and procedures and report on their experiences here. Also the USP has published a corresponding document with Chapter <1229>, which will also be presented during this conference.

Target Group

The ECA Academy aims to actively engage analytical chemists, QC analysts, quality assurance staff and managers, R&D scientists, statisticians and managers, as well as production scientists and managers, regulatory affairs specialists and contract laboratories in this critical area for analytical science.
It is also useful for service providers, such as contract research organisations and contract manufacturers.

Programme

- New USP General Information Chapter <1220> Analytical Procedure Lifecycle
  Dr Joachim Ermer, Ermer Quality Consulting
- AQbD
  tba
- Transfer of Analytical Procedures, Bridging of Methods
  Ulla Bondegaard, NovoNordisk
- Established Conditions for Analytical Procedures & Application During the Analytical Life Cycle Management
  Isabelle Moineau, AKTEHOM, Jean-François Dierick, GSK
- How to Establish ATP for Small Molecules
  Patrick Jackson, GSK
- Update TMU
  Dr Xaver Schratt, GB Pharma
- Use of ATP to Guide Analytical Method Changes of Large Molecules
  Dr Gerald Gellermann, Novartis
- Analytical Procedure Lifecycle Management, Practical Implementation of Stage 3
  Ulla Bondegaard, Novo Nordisk
- Optimization, Qualification and Validation of FcgR binding using SPR
  Alexander Gill, Vela Labs
- Deriving Fit-to-Purpose Validation Acceptance Criteria Based on Actual Testing Procedures by HPLC
  Dr Pavel Parkhomyuk, Teva

Alternative and Rapid Microbiological Methods

24 November 2021, 09.00 - 17.30 h CET

Track 3

Objectives

This Live Online Conference will review the current knowledge about developments in modern microbiological methods and mycoplasma detection strategies for quality control in biopharmaceutical manufacturing.

This one-day Live Online Conference provides the opportunity to discuss the recent advances in the area of the newest technological developments as well as practical aspects and concerns of meeting the regulatory requirements. State-of-the-art presentations from authority speakers, as well as industrial and academic experts in the field of microbiological detection and identification and mycoplasmology with particular focus on the current methodologies their implementation and validation will provide an in-depth overview.

Background

The scientific progress in the field of cellular and molecular biotechnology led to a fast development of biopharmaceuticals, tissue engineered applications and advanced therapy medicinal products (ATMPs). Against this background, the safety of such new technologies, products and applications becomes more importance. One important topic in the focus of risk assessment and safety is the contamination with microorganisms and mycoplasmas and their detection, prevention and control.

Target Group

This Live Online Conference is of interest to professionals from

- Biotechnological & Biopharmaceutical Companies
- Contract Service Laboratories
- Academic Research Institutions and Organizations
- Government Agencies
- Cell Culture Collections
- Supplier Detection Systems

with responsibilities in

- Manufacturing
- Quality Assurance
- Quality Control
- Regulatory Affairs
- Research & Development
- Process Development
- Validation

Programme

➲ The Journey of Implementing an Alternative Rapid Sterility Test
Dr Jonas van den Berg, Roche

➲ Demonstrating an Approach to Rapid Microbiological Testing for Cell-based Therapies
Brice Chasey, CRL

➲ A Look into Rapid Microbial Contamination Detection in Cellcontaining Samples
Johannes Oberdörfer, Boehringer Ingelheim
Stefan Gärtner, Labor LS

➲ BFPC Rapid-C Projekt
Dr Wolfgang Eder, Roche; Ronny Zingre, MBV

➲ Mycoplasma Testing – Evolution towards RtR at Janssen Biologics BV
Alex van den Meer, Janssen

➲ Updates in Rapid Hybrid Mycoplasma Testing
Marleen Hoozemanns, MSD

➲ Application of Next Generation Sequencing for Microbial Identification, Typing and Profiling
Tara Cassidy/Dr Prasanna Khot, Charles River Laboratories

➲ Colony Counters: How to Evaluate Vision Algorithm Performance, Rapid Microbio Systems
Dr David Jones, Rapid Micro Biosystems

➲ Method Validation and Implementation of the GD for Performing of Environmental Controls in Sterile Production
Dr Hans-Joachim Anders, Novartis

➲ Automation and Digitalization of the Environmental Monitoring Manual Steps
Arnaud Paris, bioMérieux

➲ Automated Environmental Monitoring: The Solution for the Next Decade
Niels Visschers, Merck

Endotoxin and Pyrogen Testing

25 November 2021, 09.00 - 17.30 h CET
26 November 2021, 09.00 - 13.30 h CET

Track 4

Objectives

This Live Online Conference will inform you about current developments in Endotoxin and Pyrogen testing as well as the practical use of established test methods like LAL for Endotoxin testing including:

- International regulatory developments
- Feasibility of new and innovative products and methods
- Special issues like masking/LER
- Testing of critical substances
- Application of alternative testing methods – MAT or RFC

Background

Testing for Endotoxins and Pyrogens is a critical in-process and final release test for parenteral products. Different approaches have been developed over the last few decades to provide solutions for the breadth of product range that is tested for endotoxins and pyrogens: RPT, LAL, MAT. With the LAL test method as the established, compendial methodology for bacterial endotoxins with harmonization of the EP, USP and JP. Due to the importance of these tests, they are under ongoing scrutiny by industry and regulators to ensure testing efficacy and safe manufacturing and release of products into the market.
Novel medicinal products such as cellular and gene therapies and combinations with medical devices as well as complex biopharma formulations pose testing challenges and require in-depth knowledge and expertise in the field of Endotoxins and Pyrogens. In addition, as the choice of solutions offered by suppliers for endotoxin testing becomes wider (e.g. recombinant factor C, ELISA-based test kits, automated LAL cartridge technology) it is important to get a data driven understanding of the advantages and limitations of each approach.
So not only the discussions on low endotoxin recovery and endotoxin masking are important. Additionally the need for future innovations within BET that provide solutions to current challenges with modern pharmaceutical and biopharmaceutical products for the day-to-day testing should be in our focus.
Enough reasons to attend this Endotoxin and Pyrogen Session at PharmaLab 2021.

Target Group

This Live Online Conference is addressed to all persons from

- Pharmaceutical manufacturers
- Biopharmaceutical companies
- Contract laboratories
- Tissue establishments
- Authorities who are involved in Endotoxin- and Pyrogen Testing.

Programme

➲ The New Strategy of Ph. Eur. on Pyrogen/Endotoxin Testing
Dr Ingo Spreitzer, Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines

➲ Inspection Experiences
Dr Rainer Gallitzendörfer, GMP Inpector, Government of Upper Bavaria

➲ Regulatory Perspectives in Europe, USA and Japan on the Validation and Industrial Implementation of the rFC Method
Arnaud Paris, bioMérieux

➲ Sustainability in Bacterial Endotoxin Testing – A Holistic Approach
Veronika Wills, ACC

➲ Endotoxin testing with rFC, Not Only From a Performance Point of View, but also Covering the Automation of the Assay and the Lab Optimization
tba

➲ The Journey of LER
Dr Michael Kracklauer, Microcoat

➲ BET and MAT in the US
Speaker FDA Invited

➲ Fully Automated, High Speed & High Throughput Endotoxin Testing with the Fluent Gx and rFC
Dr Stefan Haberstock, Tecan

➲ Centripetal Microfluidic Automation for Optimized Endotoxin Testing
David Wadsworth, Suez

➲ Error-Proofing and Futureproofing: Part Deux
Ruth Noe, Lonza

➲ Scalable Generation of Fully Defined Monocyte/Macrophages from Human iPSC to Assess Pyrogens in Parenteral drugs and Medical Products
Prof. Dr. Nico Lachmann, Medical University Hannover

➲ The Monocyte Activation Test (MAT) Can Predict Reactions to Medical Devices in Contact with Blood
Dr Sandra Stoppelkamp, University Tübingen

- Waive and Replace the Rabbit Pyrogen Test in Lifecycle Vaccine Release
  Dr Shahjahan Shaid, GSK Vaccines

- Method Validation Strategy for Endotoxin Testing of Water Samples with Recombinant Factor C in Adherence to 3R Principle for Animal Welfare
  Carmen Marín Delgado de Robles, Roche Diagnostics

- From Cell Preparation to ELISA Execution: Key Aspects for a Successful Implementation of the MAT
  Dr Eelo Gitz, Sanquin

- MAT - Identifying Innate Immune Response Modulating Impurities
  Sophia Pfeiffer, Boehringer Ingelheim

- Feasibility of the Monocyte Activation Test for Cell-Based Samples
  Anne-Clair Erba, Merck

- Monocyte Activation Test: Understanding and Mitigating Patient Safety Risks Arising from the Synergistic Effects of Mixed Pyrogens
  Shabnam Solati, CTL-MAT

- Next-generation Monocyte Activation Test: Increasing Accuracy/Reliability for High Throughput Sample Testing
  Dr Koen Marijt, MAT-Research

Speakers

Dr Hans-Joachim Anders, *Novartis, Switzerland*
Teamlead Analytical Science and Technology Microbiology.

Dr Karl-Heinz Bauer, *Boehringer Ingelheim, Germany*
Head of Strategic Quality Management & Culture.

Ulla Bondegaard, *NovoNordisk, Denmark*
Responsible for maintaining cross-organisational (and cross-country) laboratory processes.

Fábio Brito, *LEF - Infosaúde, Portugal*
Trace Metal Laboratory, ICP-MS technique.

Tara Cassidy, *Charles River Laboratories, Australia*
Applications Development Specialist.

Brice Chasey, *Charles River Laboratories, USA*
Associate Director Product Management.

Sinead Cowman, *Lonza, Ireland*
Global BD and Marketing Manager - Informatics.

Carmen Marín Delgado de Robles, *Roche Diagnostics, Spain*
Quality Control Scientist Endotoxins.

Jean-François Dierick, *GSK Vaccines, Belgium*
Global Subject Matter Expert Analytical Validation & Lifecycle.

Dr Wolfgang Eder, *Roche Diagnostics, Germany*
Head of Global Functions Supply Chain IT.

Anne-Claire Erba, *Merck, France*
Senior R&D Scientist.

Dr Joachim Ermer, *Ermer Quality Consulting, Germany*
CEO & Founder.

Dr Rainer Gallitzendörfer, *Government of Upper Bavaria, Germany*
GMP Inspector.

Stefan Gärtner, *Labor LS, Germany*
Head of Department - Sterile Products Rapid and Alternative Methods.

Dr Gerald Gellermann, *Novatis, Switzerland*
Analytical Lead at Novartis Biologics Development.

Alexander Gill, *VelaLabs, Austria*
Lab Technician.

Dr Eelo Gitz, Sanquin Reagents, *The Netherlands*
Head Product Development.

Miriam Guest, *AstraZeneca, UK*
New Modalities & Parenteral Development, Pharmaceutical Technology & Development, Operations.

Dr Stefan Haberstock, *Tecan, Germany*
Senior Market Manager Detection & Liquid Handling EMEA.

Marleen Hoozemanns, *MSD, The Netherlands*
Specialist New Technologies for Microbial Testing in a GMP environment.

Patrick Jackson, *GSK, UK*
Investigator in Chemistry, Manufacturing and Controls - Analytical.

Dr David Jones, *Rapid Micro Biosystems, USA*
Director Industry Affairs.

Dr Prasanna Khot, *Charles River Laboratories, USA*
Research and Development Manager.

Dr Michael Kracklauer, *Microcoat Biotechnologie, Germany*
Manager Endotoxin Services.

Prof. Dr. Nico Lachmann, *Medical University Hannover, Germany*
Group leader at the "REBIRTH Research center for translational and regenerative medicine".

Laurent Leblanc, *bioMérieux, France*
Microbiology R&D Manager.

Dr Koen Marijt, *MAT Research, The Netherlands*
Co-founder.

Isabelle Moineau, *AKTEHOM, France*
Analytical Expert.

Ruth Noe, *Lonza Bioscience, UK*
Senior Product Manager.

Johannes Oberdörfer, *Boehringer Ingelheim, Germany*
Scientist Rapid Microbiology Methods.

Arnaud Paris, *bioMérieux, France*
Director of Scientific Affairs.

Dr Pavel Parkhomyuk, *Teva Pharmaceutical Industries, Israel*
Teva API Analytical R&D Manager.

Sophia Pfeiffer, *Boehringer Ingelheim, Germany*
Expert Rapid Microbiological Methods.

Lars M. H. Reinders, *University Duisburg, Germany*
Scientist / PhD student at Institute of Energy and Environmental Technology (IUTA).

Dr Xaver Schratt, *GB Pharma, Germany*
Head of Global Quality Management.

Dr Shahjahan Shaid, *GSK Vaccines, Germany*
Senior Manager.

Shabnam Solati, *CTL-MAT, The Netherlands*
CEO.

Dr Ingo Spreitzer, *Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines*
Deputy Head at PEI and Chair EDQM Working Party "Bacterial Endotoxin Test.

Dr Sandra Stoppelkamp, *University Tübingen, Germany*
Expert MAT Medical Devices.

Dr Jonas van den Berg, *Roche Diagnostics, Germany*
Global Quality Control.

Alex van der Meer, *Janssen Biologics, Netherlands*
QC Technical Specialist Mycoplasma & PCR.

Niels Visschers, *MSD, The Netherlands*
Senior Specialist Microbiology.

David Wadsworth, *Suez Water Technologies & Solutions, Analytical Instruments, USA*
Product Management.

Veronika Wills, *Associates of Cape Cod, USA*
Manager Technical Services.

Ronny Zingre, *MBV, Switzerland*
CEO.

Organisational Details

Date of the Live Online Training
22-26 November 2021
All times mentioned are CET.

Technical Requirements
For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)
The registration allows access to all lecture tracks and the change between the tracks at will.
1-day ticket 690.- €
2-day ticket 990.- €
5-day ticket 1,990.- €

The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.pharmalab-congress.com.

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

ECA Academy
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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 please contact:
Mr Axel H Schroeder (Operations Director)
Phone: +49 6221/84 44 10
E-mail: schroeder@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager)
Phone: +49 6221/84 44 51
E-mail: strohwald@concept-heidelberg.de

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Telefax:
+49 (0) 6221 84 44 34

E-Mail:
info@concept-heidelberg.de

Internet:
www.pharmalab-congress.com
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Registration Options PharmaLab Live Online 2021

I want to take part in:

With a one day/two day/five day ticket for the PharmaLab Live Online Conferences you can attend the Live Online Conference offered that day/s.

- ❑ One-Day Ticket (€ 690 + VAT)
- ❑ Two-Day Ticket (€ 990 + VAT)
- ❑ Five-Day Ticket (€ 1,990 + VAT)

Please mark the days you want to attend:

- ❑ 22 November: Laboratory Optimisation and Automation
- ❑ 23 November: Validation of Analytical Methods and Life Cycle Management of Analytical Procedure
- ❑ 24 November: Alternative- and Rapid Microbiological Methods
- ❑ 25 November: Endotoxin and Pyrogen Testing (Day 1)
- ❑ 26 November: Endotoxin and Pyrogen Testing (Day 2)

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

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

Reservation Form (Please complete in full)

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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 %.

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CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without dedution-swithin 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)!

German law shall apply. Court of jurisdiction is Heidelberg.

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