

PharmaLab 2020

Congress for Analytics, Bioanalytics and Microbiology



Live Online Congress
on 10/11 November 2020



Regulatory and Methodological Developments

From the Analysis of Small and Large Molecules to Microbiological Methods
Implementation to Laboratory Automation and Digitalization

3 Conference Tracks with 6 Subsessions:

- Endotoxin Testing – LAL and rFC
- Pyrogen Testing – MAT and More
- Rapid Microbiological Methods
- Laboratory Optimization and Automation
- Bioanalytical Challenges
- Developments in classical Analytics

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

Official Media Partners 2020:



The Congress Objective

Dear colleagues,

We had actually been looking forward to the 8th PharmaLab Congress in Neuss Düsseldorf, especially as a whole series of competent speakers had again been confirmed and exciting topics were on the programme. But unfortunately, microbiology in the form of SARS-CoV-2 does not allow microbiology congresses with a face-to-face meeting this year. But we are not discouraged by this and we have to keep a close eye on current developments, in particular in the field of pharmaceutical development, production, quality assurance and quality control.

That is why we will not cancel PharmaLab 2020 but have converted it into an online congress. With 3 conference tracks and sessions on endotoxin and pyrogen testing, microbiological methods, bioanalytics, chemical analysis and laboratory optimization we offer a comprehensive congress again this year. As with the on-site congress, participants can book day tickets so that they can switch back and forth between the sessions and put together their own individual programme from the presentations. Are you interested in the rFC test in the pharmacopoeia, but also in the implementation of a mycoplasma test method? No problem - with PharmaLab you can see and hear both lectures and switch between the tracks.

More than 50 lectures by over 40 speakers from Europe and overseas will give you comprehensive information on current developments, both regulatory and scientific.

We look forward to welcoming you online at PharmaLab.

With best regards - and stay healthy!

Axel H. Schroeder
Administration Manager
Pharmaceutical Microbiology Working Group

PharmaLab Live Online 2020 Overview			
📌 Key Note 10 November Current European Pharmacopoeia Developments, with a Focus on Microbiology <i>Dr Emmanuelle Charton, EDQM, Head of Division B</i>			
📌 Key Note 11 November RTRT: A Reality Check in the Small and Large Molecule World <i>Dr Lorenz Liesum, F. Hoffmann-La Roche</i>			
	TRACK 1 Endotoxin and Pyrogen Testing	TRACK 2 Laboratory Optimization and Alternative Microbiological Methods	TRACK 3 Challenges in Bioanalytical and Analytical Laboratories
Day 1 - 10 Nov 2020	LAL and rFC – Current Developments	Laboratory Optimization	From Bioassays to ATMP Analytics
Day 2 - 11 Nov 2020	MAT Update and Endotoxin Thinking Out of the Box	Alternative Microbiological Methods	From Life Cycle Management to Real Time Measurements

*The conference language of all Live Online Conferences is English.
All times mentioned are CET.*

The Official Media Partners



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European Pharmaceutical Review is a leading free publication for information about technologies across all stages of drug development. Published bi-monthly, each issue offers technical and business contributions from the world's leading pharmaceutical companies and experts. Visit www.EuropeanPharmaceuticalReview.com for further information.

Key Note - Speakers (as of August 2020)

Dr Emmanuelle Charton	EDQM, Council of Europe, European Pharmacopoeia Department. Head of Division B.
Dr Lorenz Liesum	F. Hoffmann-La Roche

Speakers (as of August 2020)

Ketan Agravat	rK3 Solutions, India, Chief Executive Officer.
Darren Bauer	Thermo Fisher Scientific, USA, Product Manager.
Dr Karl-Heinz Bauer	Boehringer Ingelheim, Germany, Head of Quality Unit DPI/MDI.
Ulla Bondegaard	Novo Nordisk, Denmark.
Dr Nicolas Brauckhoff	Protagen Protein Services, Germany, Head of Biotherapeutic Analytics.
Professor Guy C. Brown	University of Cambridge, Department of Biochemistry. Professor of Cellular Biochemistry.
Dr Marja Claassen	MSD, Senior microbiological specialist.
Laura-Felicia Cristescu	STADA Hemofarm SRL (STADA Group), Romania, QA and Local Pharmacovigilance Officer Deputy.
Dr Sven M. Deutschmann	Roche Diagnostics, Germany, Head of Global ASAT "Adventitious Agents Testing & Alternative Microbiologica. Chairman of the Advisory Board of the ECA "Pharmaceutical Microbiology Interest Group", Member of PDA Task Forces.
Dr Markus Fido	MFI Bio Consulting, Austria, Founder and CEO.
Dr Anja Fritsch	Confarma, France, Responsible for cell based bioassays (development and routine).
Stefan Gärtner	Labor LS, Germany, Head of Department - Sterile Products Rapid and Alternative Methods.
Dr Wolf-Christian Gerstner	Geniu, Germany, Managing Director.
Dr Viviane Grunert da Fonseca	Roche Diagnostics, Germany, Statistical support to the nonclinical areas of chemistry, manufacturing, and controls.
Gerd Heimlich	Yokogawa Deutschland, Germany, Senior Executive Sales - Life Innovation Business Europe.
Jordi Iglesias	Charles River Laboratories, Ireland, Technology Market and Development Manager.
Niek Janssen	Altran, The Netherlands, Advanced Expert Life Sciences.
Judith Kernbichler	Takeda, Austria, Head of Analytical Sciences Knowledge Management.
Roland Koch	Gasporox AB, Sweden, Senior Application and Sales.
Kai Kottwitz	Rentschler Biopharma, Germany, Quality Control Manager.
Timo Kretschmar	Anapur, Austria, Senior Consultant.
Dr Marijke Molenaar-de Backer	Sanquin, The Netherlands, Manager MAT services.
Dr Michael J. Miller	Microbiology Consultants, USA, President.
Kai Neemann	Sartorius Labs Instruments, Germany, Global Product Manager DNA-based rapid QC-testing.
Dr Jörg Neumann	Jörg Neumann Beratung, Germany, Founder and CEO.
Johannes Oberdörfer	Boehringer Ingelheim, Germany, Quality Biopharmaceuticals.
René Ørving	Novo Nordisk, Denmark.
Dr Kent Persson	Octapharma, Sweden.
Nicola Reid	Charles River Laboratories, UK, Associate Director Product Management.
Johannes Repellnig	VelaLabs – A Tentamus Company, Austria, Application Specialist.
Markus Roucka	VelaLabs – A Tentamus Company, Austria, Managing Director.
Sabrina Rottal	VelaLabs – A Tentamus Company, Austria, Application Specialist - R&D and Analytical Development.
Dr Wolfgang Rudy	TentaMedix, Germany, Chief Scientific Officer.
Shabnam Solatil	CTL-MAT, USA, Chief Executive Officer.
Jacob G. Tesdorpf	PerkinElmer Life Sciences & Technology, Germany, Senior Director Life Science Markets.
Dr Franz Tüchler	VelaLabs – A Tentamus Company, Austria, Validation Consultant.
Dr Daniel M. Waldera-Lupa	Protagen Protein Services, Germany, Application Specialist Mass Spectrometry.
Melanie Wallisch	Rentschler Biopharma, Germany, Quality Control Manager.
Veronika Wills	Associates of Cape Cod, USA, Manager Technical Services.
Kevin Williams	bioMérieux, USA, Senior Scientist.
Alireza Zarei	Zamann Pharma Support, Germany, Chief Executive Officer.
Dr Christian Zeine	USP, Senior Scientific Affairs Manager EMEA.

Key Note Presentation ⌚09.30 – 10.15 h
**Current European Pharmacopoeia Developments,
with a Focus on Microbiology**

Dr Emanuelle Charton, EDQM, Head of Division B



ECA Live Online Conference: ⌚09.00 – 17.00 h
Endotoxin and Pyrogen Testing (Day 1)

TRACK 1

Introduction and Organisationals 09.00 – 09.30 h

Break 10.15 – 10.45 h

Invention of rFC 10.45 – 11.15 h

➔ *Speaker invited*

Evaluation of rFC 11.15 – 11.45 h

➔ *Speaker Boehringer Ingelheim invited*

The changing BET Landscape and the Recombinant Alternative 11.45 – 12.45 h

➔ *Veronika Wills, Associates of Cape Cod.*

Questions and Answers 12.15 – 12.45 h

Break 12.45 – 13.45 h

Data as clean as Water:

The Criticality of Detecting Relevant Endotoxins in Global Pharmaceutical Water Samples 13.45 – 14.15 h

➔ *Nicola Reid, Charles River Laboratories*

Symbols of Infection 14.15 – 14.45 h

➔ *Kevin Williams, BioMerieux*

Impact of Sample Preparation on Endotoxin Detection 14.45 – 15.15 h

➔ *Speaker invited*

Break 15.15 – 15.30 h

Masking of Endotoxin during Sample Hold Time 15.30 – 15.45 h

➔ *René Ørving, Novo Nordisk*

FDA's Thinking on current Developments in Endotoxin and Pyrogen Testing 15.45 – 16.15 h

➔ *Speaker FDA invited*

Questions and Answers 16.15 – 17.00 h

ECA Live Online Conference: ⌚09.00 – 17.00 h
Laboratory Optimization and Automation

TRACK 2

Introduction and Organisationals 09.00 – 09.30 h

Break 10.15 – 10.45 h

The Future Laboratory beyond Digitization 10.45 – 11.15 h

➔ *Niek Janssen, Altran*

Reversed Phase HPLC Method Optimization for a Contrast Agent containing Drug Product 11.15 – 11.45 h

➔ *Johannes Repellnig, VelaLabs - A Tentamus Company*

LIMS Systems and Segregation of Duties 11.45 – 12.15 h

➔ *Alireza Zarei, Zamann Pharma Support*

Questions and Answers 12.15 – 12.45 h

Break 12.45 – 13.45 h

Data Integrity critically examined in the Laboratory - Ubiquitous Traps in a Hybrid Environment

13.45 – 14.15 h

➔ *Timo Kretzschmar, Anapur*

Lean Lab Design: Laboratory Planning for new Buildings and Refurbishments 14.15 – 14.45 h

➔ *Dr Wolf-Christian Gerstner, Geniu*

Practical Handling of Laboratory Computerised Systems 14.45 – 15.15 h

➔ *Ulla Bondegaard, Novonordisk*

Break 15.15 – 15.30 h

Ideation Management & Continuous Improvement Processes - A sustainable Contribution to Laboratory Optimizations 15.30 – 16.00 h

➔ *Dr Karl-Heinz Bauer, Boehringer Ingelheim*

Fusion of a Microbiological with a Chemical / Analytical Laboratory 16.00 – 16.30 h

➔ *Dr Franz Tüchler, VelaLabs - A Tentamus Company*

Questions and Answers 16.30 – 17.00 h

ECA Live Online Conference: ⌚ 09.00 – 17.00 h
Challenges in Bioanalytical and Analytical Laboratories
Day 1 - from Bioassays to ATMP Analytics

TRACK 3

Introduction and Organisations 09.00 – 09.30 h

Break 10.15 – 10.45 h

A Journey beyond Automation in High-Content Analysis for Live-cell Imaging Research and Drug Discovery

10.45 – 11.15 h

➔ Gerd Heimlich, Yokogawa

A complex Cell-based Bioassay for efficient Lifecycle Management of Analytical Procedures

11.15 – 11.45 h

➔ Melanie Wallisch, Rentschler

Development of a Cell-based Binding Assay according to QbD 11.45 – 12.15 h

➔ Sabrina Rottal, *VelaLabs - A Tentamus Company*

Questions and Answers 12.15 – 12.45 h

Break 12.45 – 13.45 h

Mass Spectrometric Evaluation of Host Cell Protein Patterns in Downstream Process and Biopharmaceutical Product 13.45 – 14.15 h

➔ Dr Daniel M. Waldera-Lupa, Protagen

Simultaneous Bioanalytical Monitoring of Cytotoxicity and Biomarker Release via Higher Throughput Assays 14.15 – 14.45 h

➔ Jacob G. Tesdorpf, Perkin Elmer

Validation of Bioanalytical Testing for a Therapeutic mAb using MesoScaleDiscovery 14.45 – 15.15 h

➔ Max Roucka, *VelaLabs - A Tentamus Company*

Break 15.15 – 15.30 h

New Approaches for Analyzing ATMPs in GMP Environment 15.30 – 16.00 h

➔ Dr Markus Fido, MFI Bio Consulting

Advanced Analytical Approaches for accelerated Development of Gene Therapy Products

16.00 – 16.30 h

➔ Dr Nicolas Brauckhoff, Protagen Protein Services

Questions and Answers 16.30 – 17.00 h

Key Note Presentation ⌚ 09.00 – 09.45 h
TRTR: A Reality Check in the Small and Large Molecule World

Dr Lorenz Liesum, F. Hoffmann-La Roche



The Live Online
Conferences on
11 November 2020

ECA Live Online Conference: ⌚ 09.45 – 17.00 h
Endotoxin and Pyrogen Testing (Day 2)

TRACK 1

Overcoming technical Issues with Assays to assess Innate Immune Response Modulating Impurities

09.45 – 10.30 h

➔ *Speaker FDA invited*

The Endotoxin Hypothesis of Neurodegeneration 10.30 – 11.00 h

➔ Professor Guy C. Brown, Department of Biochemistry, University of Cambridge

Break 11.00 – 11.15 h

Use of Monocyte Activation Test for Evaluation of Pyrogenicity associated with typical Environmental Contaminants 11.15 – 11.45 h

➔ Dr Anja Fritsch, Confarma

Pyrogen Detection on Cellular Preparations and other Short Shelf Life Pharmaceuticals 11.45 – 12.15 h

➔ Stefan Gärtner, Labor LS

Questions and Answers 12.15 – 12.45 h

Break 12.45 – 13.45 h

Determination of Pyrogens from Medical Devices/MAT Multiplexing 13.45 – 14.15 h

➔ Dr Wolfgang Rudy, Tentamedix

Using the Monocyte Activation Test to determine the Pyrogenicity of an OMV Vaccine 14.15 – 14.45 h

➔ Dr Marijke Molenaar-de Backer, Sanquin

The Monocyte Activation Test (MAT): The Road forward for Pyrogen Testing 14.45 – 15.15 h

➔ Shabnam Solati, CTL-MAT

Break 15.15 – 15.30 h

Industrials Experiences with MAT 15.30 – 16.00 h

➔ *Speaker invited*

How to handle Endotoxin OOS, OOT and Atypic Results – the ECA Guide on Microbiological Deviation Chapter 2 16.00 – 16.30 h

➔ Jordi Iglesias, Charles River Laboratories

Questions and Answers 16.30 – 17.00 h

ECA Live Online Conference: ⌚09.45 – 17.00 h
Rapid Microbiological Methods and Mycoplasma Testing

TRACK 2

Validation of Alternative Methods: the Perspective from the European Pharmacopoeia

09.45 – 10.30 h

➔ Dr Emmanuelle Charton, EDQM

Development and Validation of a Rapid Sterility Test using BacT/ALERT Dual T

10.30 – 11.00 h

➔ Dr Marja Claassen, MSD

Break 11.00 – 11.15 h

Validation and Implementation of an Automated Colony Counter for Product Bioburden Testing

11.15 – 11.45 h

➔ Dr Sven M. Deutschmann, Roche Diagnostics

Non-inferiority Testing for RMM Validation: Two Use Cases 11.45 – 12.15 h

➔ Dr Viviane Grunert da Fonseca, Roche Diagnostics

Questions and Answers 12.15 – 12.45 h

Break 12.45 – 13.45 h

From Visual Counting to Automation of Water Monitoring with the Growth Direct

13.45 – 14.15 h

➔ Johannes Oberdörfer, Boehringer Ingelheim

Validating a Rapid Sterility Test: Practical Strategies to ensure Regulatory Compliance

14.15 – 14.45 h

➔ Dr Michael Miller, Microbiology Consultants

Rapid Microbial Test for Short Shelf Life Pharmaceuticals 14.45 – 15.15 h

➔ Kai Neseemann, Sartorius

Break 15.15 – 15.30 h

A Real-time PCR Assay designed to fulfill Mycoplasma Detection Regulatory Requirements

15.30 – 15.45 h

➔ Darren Bauer, Thermo Fisher Scientific

Making the Switch: the Evaluation, Implementation and Validation of bringing Rapid Mycoplasma

Testing in-house to expedite Lot Release of Recombinant Protein Product 15.45 – 16.15 h

➔ Dr Kent Persson, Octapharma

Questions and Answers 16.15 – 17.00 h

ECA Live Online Conference: ⌚09.45 – 17.00 h
Challenges in Bioanalytical and Analytical Laboratories
Day 2 - Analytics - From Life Cycle Management to Real Time

TRACK 3

Analytical Procedure Lifecycle Management, practical Implementation of Routine for Process Verification

09.45 – 10.30 h

➔ Ulla Bondegaard, Novo Nordisk

Life Cycle Management of Analytical Procedures - Regulatory Perspective 10.30 – 11.00 h

➔ Ketan Agravat, rK3 Solutions

Break 11.00 – 11.15 h

Key Performance Indicators in Pharmaceutical Quality Control Laboratories - Tools to measure and monitor Optimizations 11.15 – 11.45 h

➔ Dr Karl-Heinz Bauer, Boehringer Ingelheim

The Value of Pharmacopeial RS: A Story about Uncertainties, associated Guard Bands and Secondary RS

11.45 – 12.15 h

➔ Dr Christian Zeine, USP

Questions and Answers 12.15 – 12.45 h

Break 12.45 – 13.45 h

Small Molecule Drugs & Analytics - SWOT Analysis on the OOS/OOT/OOE established System

13.45 – 14.15 h

➔ Laura-Felicia Cristescu, STADA Hemofarm SRL (STADA Group)

Validation of Analytical Methods 14.15 – 14.45 h

➔ Judith Kernbichler, Takeda

OOS, OOT, OOE – Update from practical Experiences 14.45 – 15.15 h

➔ Dr Jörg Neumann, Jörg Neumann Beratung

Break 15.15 – 15.30 h

Strategic Design of HCP Analysis during Clinical Phases 15.30 – 15.45 h


➔ Kai Kottwitz, Rentschler

Real-time Measurements of Starting Materials used in Tablet Production 15.45 – 16.15 h

➔ Roland Koch, Gasporox

Questions and Answers 16.15 – 17.00 h

Organisation

Date of the Live Online Conferences	Tuesday, 10 November 2020, 09.00 – 17.00 h CET Wednesday, 11 November 2020, 09.00 – 17.00 h CET 
Technical Requirements	You will receive the access data together with the technical requirements in time.
Fees (per delegate, plus VAT)	The registration allows access to all three lecture tracks and the change between the tracks at will. 1-day ticket 690.- € 2-day ticket 1380.- € 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. 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) at +49 6221/84 44 10, or per e-mail at schroeder@concept-heidelberg.de For questions regarding organisation please contact: Mr Ronny Strohwalde (Organisation Manager) at +49 6221/84 44 51, or per e-mail at strohwalde@concept-heidelberg.de

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Registration Options PharmaLab Live Online 2020

I want to take part in:

- PharmaLab Live Online Conferences on 10 November 2020 – € 690,- plus VAT
- PharmaLab Live Online Conferences on 11 November 2020 – € 690,- plus VAT

With a one day ticket/two days ticket for the PharmaLab Live Online Conferences (10 Nov/11 Nov 2020) you can attend any Live Online Conference offered that day/both days..

We would appreciate it if you marked the conference you are interested in.
 Please also mark the day you plan on attending the Congress.

Please mark only one Live Online Conference per day.

- I would like to attend on **day 1 (10 November 2020)** and I'm primarily interested in:
 - ECA Live Online Conference: Endotoxin and Pyrogen Testing (Day 1)
 - ECA Live Online Conference: Laboratory Optimization
 - ECA Live Online Conference: Challenges in Bioanalytical and Analytical Laboratories Day 1 - from Bioassays to ATMP Analytics
- I would like to attend on **day 2 (11 November 2020)** and I'm primarily interested in:
 - ECA Live Online Conference: Endotoxin and Pyrogen Testing (Day 2)
 - ECA Live Online Conference: Rapid Microbiological Methods and Mycoplasma Testing
 - ECA Live Online Conference: Challenges in Bioanalytical and Analytical Laboratories Day 2 - Analytics - From Life Cycle Management to Real Time

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