

# Alternative and Rapid Microbiological Methods

 Live Online Conference  
on 24 November 2021

## Regulatory and Methodological Developments



This Live Online Conference is part of

**2021 PharmaLab**  
LIVE ONLINE  
Analytics • Bioanalytics • Microbiology  
22-26 November 2021

### Highlights

- Rapid Sterility Testing
- Evolution in Mycoplasma Detection
- Next generation Sequencing
- Modern Monitoring Methods
- Raman ID

### Speakers

Dr Hans-Joachim Anders, Novartis

Tara Cassidy, Charles River Laboratories

Brice Chasey,  
Charles River Laboratories

Stefan Gärtner, Labor LS

Dr Victoria Gerad, bioMérieux

Marleen Hoozemans, MSD

Dr David Jones, Rapid Micro Biosystems

Dr Prasanna Khot,  
Charles River Laboratories

Dr Denis Kiselev, Plair

Johannes Oberdörfer,  
Boehringer Ingelheim

Arnaud Paris, bioMérieux

Dr Jonas van den Berg, Roche

Alex van der Meer, Janssen Biologics

Dr Oliver Valet, mibiC

Ronny Zingre, MBV



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WITH  
CHAUDHREY



# Alternative and Rapid Microbiological Methods

24 November 2021, 09.00 - 17.30 h CET

## 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 mycoplasma 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

- Validation concept of the Celsis sterility test
- Submission strategy for pilot product and current approval status
- Method Transfer strategy
- Comprehensive implementation strategy for submission of subsequent products

*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 Cell containing Samples

- Current challenges of conventional methodologies
- Beta Testing of Celsis Adapt™ system at Boehringer Ingelheim and Labor LS
- Technology features and perspectives for the pharmaceutical industry

*Johannes Oberdörfer, Boehringer Ingelheim*

*Stefan Gärtner, Labor LS*

### BFPC Rapid-C Projekt

*Dr Denis Kiselev, Clair*

*Ronny Zingre, MBV*

### Mycoplasma Testing – Evolution towards RtR at Janssen Biologics BV

- Current situation of Mycoplasma testing: Compendial and CytolInspect methods
- New rapid Mycoplasma method: BioFire MYCOPLASMA - introduction cons/benefits evaluation
- Validation of Rapid Mycoplasma Testing at Janssen Biologics BV
- Preliminary validation results
- Current challenges and questions

*Alex van den Meer, Janssen*

### Updates in Rapid Hybrid Mycoplasma Testing

- Filing strategy and risk assessment
- Additional LOD study to fulfill criteria of all guidance's
- Outlook towards new generation hybrid Mycoplasma method

*Marleen Hoozemans, MSD*

### Application of Next Generation Sequencing for Microbial Identification, Typing and Profiling

- Overview of how NGS technology works for microbial identification, typing and profiling
- The regulatory landscape and the adoption of NGS applications in the industry
- Data from studies associated with strain typing for contamination tracking, microbial biodiversity profiling of water samples, and confirmation of microbial species in probiotic products

*Tara Cassidy/Dr Prasanna Khot, Charles River Laboratories*



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## Colony Counters: How to Evaluate Vision Algorithm Performance

- How to define critical parameters to test
- What is the best "control", human eye count or electronic image review?
- How to define acceptance criteria for the tests
- Performance data for example technology
- Robustness testing of the technology

*Dr David Jones, Rapid Micro Biosystems*

## Automation and digitalization of the Environmental Monitoring Manual Steps

- Analysis of the whole workflow of EM (real industry case) and the value brought by automation
- Different automation possibilities for EM (end-point reading, kinetic approaches, fluorescence...)
- Demonstration of an automated solution performance and value compared to the human analysis
- Presentation of the full validation results of an automated incubation & colony counting platform - the 3P Station - compared to the human counting performances
- Analysis of the whole value chain of automated EM, with data integrity software, and automatic reporting of results through an industrial partnership with different pharmaceutical companies

*Arnaud Paris, bioMérieux*

## Method Validation and Implementation of the GD for Performing of Environmental Controls in Sterile Production

- Presentation of the system - The detection of colonies with the Growth Direct
- Method validation for performing environmental controls with the Growth Direct
- Implementation of the Growth Direct for environmental controls in the production of sterile DP and ATMP

*Dr Hans-Joachim Anders, Novartis*

## Vitek MS Prime: Innovation in MALDI-TOF MS - Next level experiences

- Additional Features
- How to improve workflow, productivity and system uptime for routine use
- Range of species
- Identification rate

*Dr Victoria Gerad, bioMérieux*

## Two Hours T2R - From Complex Sample Matrix to Direct Viability Count & Identification, Typing and Profiling | Discussion of the GramRay Toolbox & Strategies

- Introduction of the robust cGMP compliant fully automated GramRay ultra-fast single microbe detection and probing innovation
  - Label-free detection of single microbes by means of dark field microscopy and/or Auto-fluorescence down to 350 nm
  - A variety of specific and un-specific dyes and up to 6 different filter combinations enhance the contrast between sample matrix particulates and the microbe's epi-fluorescence detection
  - Filter, Detect and Identify single microbes directly from the matrix to lower LOD below 10 CFU

- Morphology & fluorescence color directed Raman spectroscopy on individual microbes:

° Without Stable Isotope labeling for accurate viability detection and differentiation between VBNC / viable / non-viable and non-biologic

° Examples of USP<71> microorganism identification, typing and differentiation

- Several short application examples:

- Detection & identification of < 1000 microbes in 1 ml ATMP [2 E6 mammalian cells]

- Detection & identification of < 100 microbes in 1g tomato product'

- Detection & identification of < 10 microbes in 200 ml WFI

- Statistically meaningful differentiation of VBNC and viable lactobacillus mixtures

*Dr Oliver Valet, mibiC*

## Speakers

### Dr Hans-Joachim Anders, Novartis, Switzerland

Microbiologist and team leader in Analytical Science & Technology in the field of microbiological quality control at Novartis in Stein. Several years of experiences in water testing, validation of Rapid Micro Methods up to contamination control issues.

### Tara Cassidy, Charles River Laboratories, Australia

Expert in animal sciences and NGS studies. Actively involved in research and development projects with a wide interest in animal health studies and utilizing new technologies to find solutions for industry.

### Brice Chasey, Charles River Laboratories, USA

Since 2012 primary focus on the validation and implementation of Celsis rapid detection systems. Now manages the Celsis rapid microbial detection product portfolio at Charles River.

### Stefan Gärtner, Labor LS, Germany

Head of Department for "Sterile Products" with regard to Bacterial Endotoxin, Pyrogen and Sterility Testing as well as rapid and alternative microbial methods.

### Dr Victoria Gerad, bioMérieux

Victoria holds an engineer degree in food sciences and a PhD in microbiology from the university of Montreal. She has been working in bioMérieux since 2008 as R&D microbiology director and identification expert.

### Marleen Hoozemans, MSD, The Netherlands

Specialist Microbiology. Development and validation of molecular methods in the Centre of Expertise for Microbiology within MSD.

### Dr David Jones, Rapid Micro Biosystems, USA

Director Industry Affairs. Experience in product development for the diagnostics industry specializing in tangential flow technology and instrument wet chemistry interaction and in rapid micro with Chemunex, Wyeth Biopharma, Rapid Micro Biosystems.

### Dr Prasanna Khot, Charles River Laboratories, USA

Research and Development Manager. Extensive experience spanning environmental monitoring and clinical microbiology.



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## **Dr Denis Kiselev, Plair SA, Switzerland**

Denis Kiselev studied at the Moscow State University and University of Geneva. In 2014 he spent two years as Scientific collaborator at Geneva University, he started with Plair as CEO and CTO/Engineering.

## **Johannes Oberdörfer, Boehringer Ingelheim, Germany**

Scientist. Responsible for Rapid Microbiology Methods.

## **Arnaud Paris, bioMérieux, France**

Prior to the Direction of the Healthcare Scientific Affairs for Microbiology at bioMérieux, Arnaud was the R&D Director for 3 years of all the microbiological detection solutions for the healthcare industries. From traditional culture media solutions to fully automated and ultra-rapid detection technologies, Arnaud helped develop a wide portfolio of solutions for the healthcare industries. With over 13 years of pharmaceutical microbiology experience, Arnaud has an extensive knowledge of all the quality control of Biotechnology drugs and Cell & Gene Therapies (ATMPs).

## **Dr Oliver Valet, mibiC, Germany**

Co-founder and Managing Director.

## **Dr Jonas van den Berg, Roche Diagnostics, Germany**

Global Quality Control at Roche. Project lead for the implementation of a rapid sterility test at Roche.

## **Alex van der Meer, Janssen Biologics, Netherlands**

QC Technical Specialist at Janssen since 2019, mainly responsible for the introduction of (Mycoplasma) PCR methods.

## **Ronny Zingre, MBV, Switzerland**

Owner and CEO of MBV, specialised in Microbial Air Samplers.

## 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  
www.pharmalab-kongress.de



### Date of the Live Online Conference

Wednesday, 23 November 2021, 09.00 – 17.30 h CET

### Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <https://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.

### Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.pharmalab-congress.com](http://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.

### 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](http://www.concept-heidelberg.de)

For questions regarding content please contact:

Mr Axel H. Schroeder (Operations Director) at +49(0)62 21/84 44 10, or per e-mail at [schroeder@concept-heidelberg.de](mailto:schroeder@concept-heidelberg.de)

For questions regarding organisation please contact:

Mr Ronny Strohwald (Organisation Manager) at +49(0)62 21/84 44 51, or at [strohwald@concept-heidelberg.de](mailto:strohwald@concept-heidelberg.de)

### Registration Options

I want 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.

Please mark your ticket:

- 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: 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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GERMANY

### Reservation Form (Please complete in full)

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Company

Department

Important: Please indicate your company's VAT ID Number

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City Zip Code

Country

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E-Mail (please fill in)

#### 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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German law shall apply. Court of jurisdiction is Heidelberg.

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