



**2019 PharmaLab**  
Congress & Exhibition  
Analytics • Bioanalytics • Microbiology  
Düsseldorf, 12/13 November 2019

# Rapid and Real Time Methods Mycoplasma qPCR Endotoxin and Pyrogens

2nd International Mycoplasma qPCR Testing User Day

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Rapid Microbiological Methods

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Microbiological Real Time Counting and Testing

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Endotoxin and Pyrogen Testing

11-13 November 2019 | Düsseldorf/Neuss, Germany

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# 2nd International Mycoplasma qPCR Testing User Day

11 November 2019, Düsseldorf/Neuss, Germany

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## Objectives

Mycoplasma contamination of biopharmaceutical products (also known as biologics or large molecules) resulting from cell culture contamination in the manufacturing process poses a potential health risk to patients. Mycoplasmas can affect virtually every cell culture parameter with often only minor visible effects, creating an uncontrollable environment that is undesirable in the pharmaceutical industry. Therefore, regulatory agencies require manufacturers to test their biopharmaceutical products and to ensure the absence of mycoplasmas in released products. Most regulatory agencies have issued guidelines that provide protocols for mycoplasma testing, and some give recommendations for the validation of rapid NAT (nucleic acid amplification techniques) testing methods. This satellite symposium will give you a scientifically sound introduction into the field of Rapid Mycoplasma testing with a specific focus on NAT and more specifically on qPCR methods. It includes talks, case studies as well as interactive round table discussions from users to users.

## Target Audience

The satellite symposium is directed to responsible personnel involved in Quality Control testing of biopharmaceuticals and biologics, e.g.:

- QC Director, Manager, Scientists, Microbiologists, and Process Microbiologists
- Analytical Experts
- Biosafety and Pathogen Safety departments
- Bioassay Developer
- Regulatory departments

It is also useful for service providers, such as contract research organisations and contract manufacturers.

## Moderation

**DR PETER STEINHARDT**, Roche Diagnostics

## Speakers

**JAN-OLIVER KARO**, Paul-Ehrlich Institut (PEI), German Federal Agency for Vaccines and Biomedicines Division Microbial Safety. Quality assessor and national expert advisor for the microbial safety of ATMPs. Member of the "Cell Therapy Products" Working Party of the German Pharmacopoeia Commission.

**DR PHILIP KUHLMANN**, Reading Scientific Services Limited (RSSL), UK. Technical Specialist, Bio-Molecular Analysis Laboratory.

**DR FÉLIX A. MONTERO JULIAN**, bioMerieux, France. Scientific Director.

**DIANA PATZELT**, Sartorius Stedim Biotech, Germany. Scientist - Applications for Molecular Biology.

**DR CHRISTIANA SCHNITZLER**, Boehringer Ingelheim, Germany. Head Mycoplasma Laboratory.

**DR PETER STEINHARDT**, Roche Diagnostics, Germany. International Alliance Manager, Business Development Pharma & Biotech, EMEA LATAM.

**ANDREJ STEYER**, University of Ljubljana, Slovenia. Institute of Microbiology and Immunology Faculty of Medicine.

## Programme

### Pitfalls and Issues on Mycoplasma Testing according to Pharmacopoeial Requirements

Jan-Oliver Karo, Paul-Ehrlich Institut (PEI)

### MycotoOL – Method Development and Generic Validation Strategy

Dr Christiana Schnitzler, Boehringer Ingelheim

### Rapid Mycoplasma Detection – How Stochastics Can Help

- Expected sensitivity levels
- The need for detecting on low genome copy level
- The stochastic analytical approach of MycoTool

Dr Philip Kuhlmann, RSSL

### Automatization of Mycoplasma detection using a new fast and easy to use molecular method

- Architecture of the system with broad detection of Mollicutes with less than five minutes of hands-on time
- Sensitivity
- Application - screening at various stages of the manufacturing process for low level mycoplasma contamination in a wide range of possible sample types

Dr Félix A. Montero Julian, bioMerieux

### Comparability Study of a Real-time PCR-based Mycoplasma detection kit with the culture method according to EP 2.6.7

- For regulatory acceptance in several Asian countries, equivalency data are of crucial importance. In this study the equivalency of qPCR-based versus growth-based approach was investigated.

Diana Patzelt, Sartorius Stedim Biotech

### Mycoplasma detection system and its verification

- Two commercial mycoplasma detection systems were compared, testing cell culture media with mycoplasma strains spiked at different concentrations
- The preferred system showed high reproducibility and sensitivity, with potential to reach the acceptability criteria to replace the culture method

Andrej Steyer, University of Ljubljana

### Summary

Dr Peter Steinhardt, Roche Diagnostics

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# Rapid Microbiological Methods

12 November 2019, Düsseldorf/Neuss, Germany

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## Objectives

This 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 meeting 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 mycoplasmaology 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 important. 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 Audience

This 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

## Social Event



On the evening of the first congress day, on 12 November 2019, all congress delegates and speakers are invited to a „Get together“ in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

## Moderation

**DR MICHAEL J. MILLER**, Microbiology Consultants

## Speakers

**DR ALEXANDER BARTES**, Roche Diagnostics, Germany  
Senior Quality Control Manager.

**DR SVEN M. DEUTSCHMANN**, Roche Diagnostics, Germany  
Head of Global ASAT "Adventitious Agents Testing and Alternative Microbiologica. Chairman of the Advisory Board of the ECA "Pharmaceutical Microbiology Interest Group", Member of PDA Task Forces.

**BARBARA GERTEN**, Merck, Germany  
Microbial Solutions R&D Senior Staff Scientist.

**DR DAVID JONES**, Rapid Micro Biosystems, USA  
Technical Services Director.

**DR PRASANNA KHOT**, Charles River Laboratories, USA  
Senior Research Scientist Microbial Solutions.

**DR MICHAEL J. MILLER**, Microbiology Consultants, USA  
Global expert in rapid methods, validation and pharmaceutical microbiology.

**KAI NESEMANN**, Sartorius Lab Instruments Germany  
Global Product Manager DNA-based rapid QC-testing.

**KHAM NGUYEN**, Rapid Micro Biosystems, USA  
QC Scientist.

**DR GEROLD SCHWARZ**, Bruker Daltronics, Germany  
Manager Application Support.

**JONAS VAN DEN BERG**, Roche Diagnostics, Germany  
Validation of the Celsis-based Alternative Sterility Test.

# Programme

12 November 2019

**New ICH Q14 and ICH Q2  
Revision – an industry view**

**DR JOACHIM ERMER**, Sanofi-Aventis Deutschland  
Head of QC Lifecycle Management Frankfurt Chemistry



**RMM Validation - ECA PMWG /  
PEI Activities**

**DR SVEN M. DEUTSCHMANN**, ECA Pharmaceutical Microbiology Interest Group

**RMM Validation Guide Food  
– A Look to the Neighbour-  
hood**

**BARBARA GERTEN**, Merck

**Evaluation and Optimization  
of MALDI-TOF for Identifica-  
tion of Filamentous Fungi**

- Background of identifying filamentous fungi by MALDI-TOF
- Cultivation and sample processing methods
- Adopting MALDI-TOF for identifying filamentous fungi found during Environmental Monitoring
- Workflow optimization, ID rate and accuracy, Impact of targeted library development

**DR GEROLD SCHWARZ**, Bruker Daltronics

**DR PRASANNA KHOT**, CRL

**Validation of the Celsis-based  
Alternative Sterility Test**

**JONAS VAN DEN BERG**, Roche Diagnostics

**Rapid Micro instruments:  
secure implementation to  
LIMS for data security**

**KHAM NGUYEN AND DR DAVID JONES**, Rapid Micro Biosystems



Picture: Labor LS

**A Practical Guide on how to  
demonstrate a significant  
return of investement when  
implementing Real-Time  
RMMs**

**DR MICHAEL MILLER**, Microbiology Consultants

**PCR - Rodent Parvo Virus  
Testing**

**DR ALEXANDER BARTES**, Roche Diagnostics

**Rapid detection of bacteria  
and fungi in ATMP prior  
treatment - Validation of a  
Real-time PCR-based test**

- Validation data according to international guidelines for the implementation of alternative methods
- Results about sensitivity, specificity, robustness and equivalency of a qPCR detection kit for total bacteria and fungi

**KAI NESEMANN**, Sartorius Labs Instruments

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# Microbiological Real Time Counting and Testing

13 November 2019, Düsseldorf/Neuss, Germany

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## Objectives

In this course we give an overview of the current requirements, available systems and methods and their areas of application. Speakers from industry, laboratories and manufacturers will report on their experiences and the challenges involved in introducing, establishing and validating real-time test systems.

## Background

Microbiological control, whether for environmental monitoring, in-process control or release testing, is mandatory in many cases. In order to be able to react quickly to deviations or to achieve the greatest possible safety for products with a short shelf life, be it ATMP or radiopharmaceuticals, methods for real-time measurement would be desirable. Some of these methods are already available on the market, but they present us with a number of challenges during implementation, e.g.:

- Comparability with Compendial Methods
- Greater sensitivity than previous methods (limit conflict with current requirements)
- Possibility of further cultivation
- Differentiation live/dead

## Moderator

**DR SVEN M. DEUTSCHMANN**, Roche Diagnostics

## Target Group

All employees who have to deal with real-time systems, i.e.

- in the laboratory
- in quality control
- during validation
- in the context of inspections or audits
- at a regulatory level

## Social Event

On the evening of the first congress day, on 12 November 2019, all congress delegates and speakers are invited to a „Get together“ in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

## Speakers

**DR MARJA CLAASSEN-WILLEMSE**, MSD, The Netherlands

Senior microbiological specialist, Microbiology Center of Excellence.

**DR SUNNIVA FÖRSTER**, Lonza, Switzerland

**ANNETTE KUNZ**, CSL Behring, Switzerland.

Manager Monitoring.

**DR MICHAEL J. MILLER**, Microbiology Consultants, USA

Global expert in rapid methods, validation and pharmaceutical microbiology.

**DIARMAID O'RIORDAN**, Pfizer, Ireland.

QC Microbiologist.

**JOSEPH PIERQUIN**, Redberry, France

Chief Technical Officer.

**DR DAVID ROESTI**, Novartis Pharma Stein, Switzerland

Technical Steward Microbiology, Manufacturing Science & Technology.

**NATASCHA STAUB**, Mibelle, Switzerland

Microbiological QC.

**DR ULRICH ZUBER**, Hofmann La-Roche, Switzerland

Head of mEMT Parenteral Manufacturing Kaiseraugst.

# Programme

13 November 2019, Düsseldorf/Neuss, Germany

**Laboratory Services - from Outsourcing to a strategic partnership**

**DR JÜRGEN BALLES, DR THOMAS MEINDL AND INGO GRIMM, Labor LS**



**Different Measurement Methods/Systems - Pros and Cons**

**ANNETTE KUNZ, CSL**

**Implementation of a Microbial Detection Analyzer For Real-Time Monitoring of Microbial Contamination for Purified Water**

- Implementation of the Mettler 7000RMS Bioburden Analyzer for Purified Water
- How do you implement a new technology and set limits for which there are no official regulations?
- Find out how Mibelle Group Buchs faced this challenge

**NATASCHA STAUB, Mibelle**

**Biofluorescent Particle Counting (BFPC) for continuous monitoring in aseptic manufacturing**

- Auto Fluorescent Units and traditional CFU's are difficult to correlate
- For setting environmental monitoring limits a correlation is not relevant
- BFPC has great value for process understanding and investigations
- Data shows a clear correlation with cleanliness of rooms and activities

**DR MARJA CLAASSEN-WILLEMSE, MSD**

**Automated Colony Counting**

**DR SUNNIVA FÖRSTER, Lonza**

**Evaluation of the Scanstation 100 system for the automated incubation and analysis of pharmaceutical environmental monitoring samples using standard Petri plates**

**DIARMAID O'RIORDAN, Pfizer**



Picture: Labor LS

**Case Study: Using continuous Real-Time intrinsic Fluorescence Techniques for EM in Isolators**

**DR MICHAEL MILLER, Microbiology Consultants**

**Experiences at Roche – Water/EM?**

**DR ULRICH ZUBER, Hofmann La-Roche**

**Calculating alert levels and trending of microbiological data**

- Challenges with microbiological data
- Parametric percentile ranking method
- Defining and investigating adverse trends

**DR DAVID ROESTI, Novartis Stein Pharma**

**New Generation of Solid Phase Cytometry for Rapid Detection of Microbiological Contaminants in Water Samples**

**JOSEPH PIERQUIN, Redberry**

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# Endotoxin and Pyrogen Testing

12/13 November 2019, Düsseldorf/Neuss, Germany

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## Objectives

This 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.

You become informed about

- 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 2019.

## Moderator

**DR JOHANNES REICH, Microcoat Biotechnologie**

## Target Audience

This Conference is addressed to all persons of

- pharmaceutical manufacturers
- biopharmaceutical companies
- contract laboratories
- tissue establishments
- authorities

who are involved in Endotoxin and Pyrogen Testing.

## Social Event

On the evening of the first congress day, on 12 November 2019 all congress delegates and speakers are invited to a „Get together“ in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

## Speakers

**CHIARA CELLI, Merck, Italy.** Scientist Microbiological ID.

**DR SVEN DEUTSCHMANN, Roche Diagnostics, Germany.** Head of Global ASAT "Adventitious Agents Testing and Alternative Microbiologica. Chairman of the Advisory Board of the ECA "Pharmaceutical Microbiology Interest Group", Member of PDA Task Forces.

**DR ANJA FRITSCH, Confarma, France.** Responsible for cell based bioassays (development and routine).

**DR EELO GITZ, Sanquin Reagents, The Netherlands.** Project manager product development.

**DR JESSICA HANKINS, U.S. Food and Drug Administration**

**DR QING HE, Chinese National Institutes for Food and Drug Control. Pharmacology Division.**

**CHRISTIANE HÖFNER, Labor LS, Germany.** Senior Expert Microbiological Testing.

**MARINE MARIUS, Sanofi Pasteur, France.** Scientist in Analytical R&D Microbiology.

**DR HIKARU MIZUMURA, Seikagaku, Japan.**

**ALEXANDER NEGWER, Paul-Ehrlich-Institut (PEI) - German Federal Agency for Vaccines and Biomedicines** Scientist Section 1/3, "Microbial Safety and Parasitology".

**DR JELENA NOVAKOVIC, Galenika, Serbia.** Senior Expert Associate.

**KATRIN PAULS, Lonza, Germany.** Market Development and Scientific Affairs Manager.

**DR JOHANNES REICH, Microcoat Biotechnologie, Germany.** General Manager.

**NICOLE REID, Charles River Laboratories, UK.** Senior Product Manager.

**DR RUTH RÖDER, Microcoat Biotechnologie, Germany.** Project Manager Endotoxin Services.

**STÉPHANIE RICHARD, Sanofi Pasteur, France.** Scientist-Analytical Sciences Department-Immunology platform.

**DR MILANKA SETINA, National Control Laboratory Medicines and Medical Devices Agency of Serbia.** Scientist.

**DR INGO SPREITZER, Paul-Ehrlich-Institut (PEI) - German Federal Agency for Vaccines and Biomedicines** Deputy Head of Section 1/3, "Microbial Safety and Parasitology".

**VERONIKA WILLS, Associates of Cape Cod., USA.** Assistant Manager of Technical Services.

**KEVIN WILLIAMS, bioMérieux, USA.** Endotoxin Expert.

# Programme

12 November 2019, Düsseldorf/Neuss, Germany

## New ICH Q14 and ICH Q2 Revision – an industry view

**DR JOACHIM ERMER**, Sanofi-Aventis Deutschland  
Head of QC Lifecycle Management Frankfurt Chemistry



## MAT Task Force

- Kick-off Meeting
- Milestones and Deliverables

**DR SVEN DEUTSCHMANN**, Roche Diagnostics

## Validation of MAT – Regulatory Experiences

- Feedback from users during validations
- MAT Task Force: relation to BET-Working Party
- Putative modifications on Methods A and B
- Which NEP to choose?

**DR INGO SPREITZER**, Paul-Ehrlich-Institut (PEI), German Federal Agency for Vaccines and Biomedicines

## Development of the Monocyte Activation Test on vaccines containing inherently pyrogenic component

- The issue: inherently pyrogenic components
- Embedded TLR agonists such as endotoxin (liposaccharide) and non-endotoxin (lipoprotein)
- Pyrogen test to be used to monitor process consistency
- Evaluation of different Human Peripheral Blood Mononuclear Cells (PBMCs) and read out systems
- PBMC pool (8 donors) and IL6 cytokine quantification by HTRF technology

**STÉPHANIE RICHARD**, Sanofi Pasteur

## Comparison of a Monocyte Activation Test based on fetal bovine serum and on human AB serum

- Performance of a cryopreserved PBMC-based Monocyte Activation Test (MAT) using fetal bovine serum (FBS) or human AB serum as cell culture supplement
- Case studies of analyzing drug products using FBS and human AB serum as supplement for the MAT assay
- Advantages and disadvantages of using FBS and human AB serum as supplement for the MAT assay
- Critical aspects for performing the MAT assay

**DR EELO GITZ**, Sanquin Reagents

## Pyrogenicity associated with heat-inactivated microorgan- isms isolated in our laboratory from actual samples

- Microorganisms found in bioburdens or environmental monitoring
- Evaluating the pyrogenicity associated with heat-inactivated microorganisms
- Evaluated and compiled data
- Possible approach to risk-based management of pyrogenicity during production

**DR ANJA FRITSCH**, Confarma

## MAT implementation: from validation to use in routine in a GMP QC Lab

- Monocyte Activation Test: a pyrogen test to replace animal-based tests for batch release
- Implementing MAT in a GMP QC lab, what should be considered?
- Product Specific Validation: example of hormone-based drugs

**CHIARA CELLI**, Merck

## MAT - Ready for GMP Routine?

- MAT - Advantages and disadvantages of the respective methods from the point of view of a contract laboratory
- Selection of suitable sources for monocytes
- Critical aspects of the test
- Comparison with other test methods

**CHRISTIANE HÖFNER**, Labor LS

## The Monocyte Activation Test: Validation & Analysis

- Establishing a cryo-preserved, PBMC-based Monocyte Activation Test (MAT) in a new laboratory
- Characterization of MAT response towards Non-Endotoxin Pyrogens (NEP) and Toll-like Receptor (TLR) Ligands
- Comparison of MAT and Bacterial Endotoxin Test (BET, various methods)
- Selected MAT Case Studies with different product types
- Analysis of the MAT – Development of a complete FDA 21 CFR Part 11 MAT analysis software solution

**KATRIN PAULS**, Lonza

## Endotoxin, ten misconcep- tions around detection and control

- Detection depends upon the definition of endotoxin
- Control versus detection (i.e. detection is confirmation of control)
- Recombinant factor C comparability

**KEVIN WILLIAMS**, bioMérieux



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# Programme

13 November 2019, Düsseldorf/Neuss, Germany

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## Laboratory Services - from Outsourcing to a strategic partnership

DR JÜRGEN BALLES, DR THOMAS MEINDL AND INGO GRIMM, Labor LS



## Current development in Endotoxin and Pyrogen Testing – FDA Point of View

DR JESSICA HANKINS, U.S. Food and Drug Administration

## Putting Patient Safety First, View from the other side

- Recent Regulatory Development Concerning Bacterial Endotoxin Testing
- Regulatory requirements – an overview in QC of Endotoxin Testing
- Routine BET testing, usage of well established LAL test method in Official Medicine Control Laboratorie (OMCL) of Serbia
- Validation/Verification of compedial method- compedial/test depending criteria

MILANKA SETINA, Medicines and Medical Devices Agency of Serbia

## Implementing PDA Technical Report on LER in an analytical control strategy

SPEAKER T.B.A.

## Endotoxin and Pyrogen detection of LER Samples

PAUL NEGWER, Paul-Ehrlich-Institut (PEI), German Federal Agency for Vaccines and Biomedicines

## Endotoxins – Requirements of CP

- Development of pyrogen detection methods in Chinese pharmacopoeia
- Development of a reporter gene assay for pyrogen detection

DR QING HE, Chinese National Institutes for Food and Drug Control

## Practical Insights in BET

- Structure and characteristics of endotoxins
- Most common sources of endotoxins
- History of BET testing
- Endotoxin potency vs bacterial numbers
- Calculation of the BET limit

DR JELENA NOVAKOVIC, Galenika

## A Global Perspective for Quantifying All Endotoxins within Pharmaceutical Water Systems

NICOLA REID, CRL

## 4 Factors affecting the recovery of endotoxin

- Interference of LAL test reaction
- Inadequate interpretation of raw data
- Masking of endotoxin
- Depletion of endotoxin

DR JOHANNES REICH, Microcoat Biotechnologie

## Recombinant Factor

DR HIKARU MIZUMURA, Seikagak

VERONIKA WILLS, Associates of Cape Cod

## Implementation of rFC for product testing


- Background on rFC - rationale for implementation in Pharma industry
- Implementation of rFC for product testing
- ROE on rFC

MARINE MARIUS, Sanofi Pasteur

## Easy Registration

 **Reservation Form:**  
**CONCEPT HEIDELBERG**  
P.O. Box 10 17 64  
69007 Heidelberg  
Germany

 **Reservation Form:**  
+ 49 (0) 6221  
84 44 34

 **e-mail:**  
info@concept-heidelberg.de

 **Internet:**  
www.pharmalab-congress.com

### Dates

Monday, 11 November 2019, 12.30 – 17.45 h  
Tuesday, 12 November 2019, 09.00 – 18.00 h  
Wednesday, 13 November 2019, 09.00 – 18.00 h  
(Registration Monday, 11 November, 11.30 – 12.30 h and  
Tuesday, 12 November/Wednesday, 13 November 08.00 – 09.00 h)

### Venue

Crowne Plaza Düsseldorf / Neuss  
Rheinallee 1  
41460 Neuss, Germany  
Tel.: +49 (0) 2131 77 - 00  
Fax: +49 (0) 2131 77 - 1367  
emailus@cphotelduesseldorfneuss.com



### Fees (per delegate plus VAT)

11 November 2019: Pre-Conference „1st International Mycoplasma qPCR Testing User Day“ € 490,- (until 31 August 2019 only € 440,-)  
12 November 2019 € 690,- (until 31 August 2019 only € 590,-)  
13 November 2019 € 690,- (until 31 August 2019 only € 590,-)

The conference fee is payable in advance after receipt of invoice and includes lunch on that day/on both days as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day. VAT is reclaimable.

Your registration also entitles you to participate in all other PharmaLab Congress conferences during the day of your conference/during the two days. For information on all PharmaLab conferences please visit [www.pharmalab-congress.com](http://www.pharmalab-congress.com).

### 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)

### PLEASE NOTE

Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center. Please further note that there will be no room reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice!

### Organisation & Contact

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
D-69007 Heidelberg  
Phone +49 (0) 62 21/84 44-0; Fax +49 (0) 62 21/84 44 34  
E-mail: info@concept-heidelberg.de; [www.concept-heidelberg.de](http://www.concept-heidelberg.de)

### For questions regarding content:


Mr Axel H Schroeder (Operations Director) at +49 6221/84 44 10, or per e-mail at [schroeder@concept-heidelberg.de](mailto:schroeder@concept-heidelberg.de)

### For questions regarding reservation, hotel, organisation etc.:

Mr Ronny Strohwald (Organisation Manager) at +49 6221/84 44 51, or per e-mail at [strohwald@concept-heidelberg.de](mailto:strohwald@concept-heidelberg.de)

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

### Reservation Form (Please complete in full)

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#### Part of PharmaLab 2019, Düsseldorf/Neuss, Germany, 12-13 November 2019

- Pre-Conference „2nd International Mycoplasma qPCR Testing User Day“ (11.11.2019) – € 490,- (until 31 August 2019 only € 440,-) plus VAT  
 Conferences on 12.11.2019 – € 690,- (until 31 August 2019 only € 590,-) plus VAT  
 Conferences on 13.11.2019 – € 690,- (until 31 August 2019 only € 590,-) plus VAT

I would like to attend the following conference(s):

- Rapid Microbiological Methods and Mycoplasma Testing** (12 November 2019)  
 **Microbiological Real Time Counting and Testing** (13 November 2019)  
 **Endotoxin and Pyrogen Testing** (12/13 November 2019)

- Yes, I will participate in the Social Event on 12 November.  
 Mr  Ms

Title, first name, surname

Company

Department

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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 %.

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)!

**Privacy Policy:** By registering for this event, I accept the processing of my Personal Data. CONCEPT HEIDELBERG will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. CONCEPT HEIDELBERG will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at <https://www.pharmalab-congress.com/privacy-policy.html>). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.