The conferences are part of 2022 PharmaLab
Congress & Exhibition
Analytics•Bioanalytics•Microbiology
Düsseldorf, 21-23 November 2022

Analytical Method Validation, Laboratory Optimization and ATMPs

Highlights

- ICH Q2(R2)/Q14: Mission accomplished?
- USP <1220> and the Proposed Revision of <1058>
- Next Steps of Practical Life Cycle Management in Laboratories
- From Vision to Validation: The Method Live Cycle explained by the Example of a HPLC Method
- Operation of PCs & Networks in GMP Labs
- Implementation of a LIMS integrated with the ERP
- Laboratory Control from the Cloud, SaaS and Data Integrity – an Excurse
- Analysis Strategies for Cell and Gene Therapy Products
- Bioactivity Testing for Cell and Gene Therapy Products

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Analytical Procedure Life Cycle Management - ICH Q14/ICH Q2(R2) | 22 November 2022

Background & Objectives

The 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.

The previous harmonised guideline Q2(R1) has been in force in its current form since 2005. At that time, it combined the two guidelines Q2A, which contained analytical methods for required validation parameters, and Q2B, the methodology guideline. In 2018, it was decided to develop a new ICH quality guideline on analytical method development (ICH Q14) and to revise the ICH Q2(R1) guideline on analytical method validation to potentially combine both documents into one document for simplification and clarity. In parallel, the USP also developed the <1220> Analytical Procedure Life Cycle chapter, which was published in October 2021. On 14 November 2018, a Final Concept Paper "ICH Q14: Analytical Procedure Development and Revision of Q2(R1) Analytical Validation" was published. It was proposed to develop a new quality guideline on Analytical Procedure Development and to revise the ICH Q2(R1) Guideline on Validation of Analytical Procedures: Text and Methodology.

After an extended processing time, the two documents on ICH Q14 and ICH Q2(R2) were published on the 24 March for consultation by the ICH regulatory members. The goal is to finalize by Step 4 by May 2023. Together, ICH Q14 and ICH Q2(R2) describe the development and validation activities proposed during the life cycle of an analytical method to assess the quality of medicinal products and medical devices.

- ICH Q14 addresses the scientific basis for the development, change management, and submission requirements of analytical methods for a minimal as well as an extended approach.
- ICH Q2(R2) provides information and specifications for establishing, submitting, and maintaining evidence that an analytical method is fit for purpose (assuring drug product quality).

In summary, ICH Q14 and ICH Q2(R2) represent the harmonised scientific and technical principles for analytical methods throughout the lifecycle of analytical methods. ICH Q14, through the principles described, is intended to improve communication between industry and regulatory authorities and achieve more efficient, science-based and risk-based approval, as well as to facilitate post-approval change management of analytical methods. The revised form of ICH Q2(R2) continues to provide the general framework for validation of analytical methods, now expanded to include new technologies (e.g., for biological products or multivariate analytical methods).

Target Audience

The ECA Academy wish to actively involve analytical chemists, QC analysts, quality assurance associates & managers, R&D scientists, statisticians & managers as well as manufacturing 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

KEYNOTE Presentation at the Plenum Biological Manufacturing – Demanding Quality and Compliance Requirements

Dr Tilman Rock, SVP, Site Head Vienna (Austria), Boehringer Ingelheim Biopharma

ICH Q2(R2)/Q14: Mission accomplished?

- Needs for improvement in the current ICH Q2 Guideline
- Adjustments and additions in the Draft Guideline, revision 2
- Links to the new ICH Guideline Q14 "Analytical Procedure Development"
- How much lifecycle is in Q2(R2)?
- How illustrative are the examples in Annex 2?

Dr Joachim Ermer, Ermer Quality Consulting

Lifecycle Management of Analytical Procedures, Instruments and Systems in the USP

- USP General Chapter <1220> Analytical Procedure lifecycle
- Enhancement of USP General Chapter <1058> Analytical Instrument Qualification to a full lifecycle model
- Introduction of measurement uncertainty concepts for "fitness for purpose" and "fitness for use"
- Revision of acceptance criteria in spectroscopic instrument general chapters

Dr Chris Burgess, ECA Analytical Quality Control Interest Group

Next Steps of Practical Life Cycle Management in Laboratories

- Lifecycle management of analytical instruments and analytical procedures -one approach?
- Handling of analytical instruments seen from a life cycle perspective, new USP <1058>
- Next steps of implementing Stage 3 activities
- Inspection readiness of Ongoing Process Verification

Ulla Bondegaard, NovoNordisk

Insights into ICH Q14: Analytical Procedure Development

- Science and risk-based approaches for development and maintenance of analytical procedures regarding the intended use
- Minimal and elements of an enhanced approach for analytical procedure development
- Development of multivariate analytical procedures and for real time release testing (RTRT)
- Change management of analytical procedures based on risk management, comprehensive understanding and performance characteristics

Dr Mario Ramos, Valicare

Analytical Procedure Life Cycle Management – ICH Q14/ICH Q2(R2) | 22 November 2022

Impact of New ICH Q14 and Q2(R2) Draft Guidelines on Potency Assays – Focus on SPR
- Analytical procedure development – minimal versus enhanced approaches
- Changes to validation strategy compared to Q2(R1)
- SPR development and validation beyond potency assays – what must be considered for kinetic and affinity analysis?

Simon Gaderer, VelaLabs

Method Validation for Anti-Drug Antibodies (ADA) and Neutralizing Antibodies (NAbs)
- EU and FDA regulatory changes over the last 15 years
- "Moving" Quality System requirements from R&D to GCP to GCLP to GMP
- From BARQA to EMA reflection paper (GCLP)
- "Tailor-made" ligand-binding and neutralizing antibody assay
- Validation parameter

Dr Ralf Hess, Entourage

From Vision to Validation: The Method Live Cycle explained by the Example of a HPLC Method
- Method Development – ATP, QbD, and more
- Method Validation: - New ICH Q2 and possible impacts
- Lifecycle Approach from Feasibility up to Routine

Sarah Herzog, Reference Analytics

Development and Validation of a Customized Amplex UltraRed Assay for Sensitive Hydrogen Peroxide Detection in Pharmaceutical Water
- Decontamination with hydrogen peroxide (H2O2) and the connection with filling simulations with WFI
- H2O2 trace analysis in water – enabling safe and reliable use of H2O2 for decontamination of isolators or cleanrooms
- Assay development, optimisation and validation of a customised Amplex UltraRed assay
- Use in process development and qualification

Dr Alexandra Heussner, Vetter

A Full Spin on Analytical Lifecycle Management: Proof of Concept
- The proof of concept, combining the analytical lifecycle management approaches on drug product analysis using liquid chromatography

Dr Lúcia Volta e Sousa, Infosaúde - LEF

Moderation

Dr Joachim Ermer, Ermer Quality Consulting

Speakers

Ulla Bondegaard | *NovoNordisk, Denmark.*
Specialist.

Dr Chris Burgess | *Chairman of the ECA Analytical Quality Control Interest Group and Member of the USP Expert Panel on Validation and Verification.*

Dr Joachim Ermer | *Ermer Quality Consulting, Germany.*

Simon Gaderer | *VelaLabs, Austria.*
Head of Ligand Binding Assay Group.

Dr Ralf Hess | *Entourage, Germany.*
Principal Project Consultant.

Dr Alexandra Heussner | *Vetter, Germany.*
Head of Laboratory.

Dr Mario Ramos | *Valicare, Germany.*
GMP Consultant.

Lukas Renner | *Reference Analytics, Germany.*

Dr Lúcia Volta e Sousa | *Infosaúde - LEF, Portugal.*
Analytical Development & Validation Manager.

Laboratory Optimization, Automation and Digitalization
23 November 2022

Background & Objectives

The aim of this 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.

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 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 Audience

This 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

KEYNOTE Presentation at the Plenum
Impurities - USP Draft Chapter <477>
User-Determined Reporting Thresholds (UDRT), and Other Relevant Chapters

Dr Christian Zeine, Senior Manager Scientific Affairs EMEA, USP

Operation of PCs & Networks in GMP Labs

- GMP-networks: Structure & Access control
- Backup, Restore & Archiving of IT-Systems & Data
- System Safety & Security
- Change Management in GMP Networks
- Periodic System Review
- Requirements for GMP-PCs & GMP-Peripherals (e.g. printers, scanners)

Dr Karl-Heinz Bauer, Boehringer Ingelheim

Laboratory Control from the Cloud, SaaS and Data Integrity – an Excurse

- Auditor's view of cloud data management in the lab
- (Un)justified fears of cloud applications
- GxP relevant points for qualification/validation
- GxP relevant points on the integrity of laboratory data
- Availabilities of the Data
- Security/Safety and Data Security

Dr Timo Kretzschmar, Insolve

Qualification of Automated Laboratory Systems Including Required Computer System Validation

- Techniques and possible workflows for qualification including risk analysis, DQ, IQ, OQ and PQ of automated laboratory systems used in quality control
- Techniques for computer system validation of the required interfaces to LIMS and MES systems
- How supplier can support their customer for an efficient qualification and validation
- Practical examples

Dr Carsten Börger, Valicare

MACSQuant Analyzer - a Flow Cytometry Instrument for the GMP Use Case

- Requirements on Computerisation/21CFR Part 11 and Eudralex Annex 11
- Delivered on board Onboard Features
- Meeting global GMP compliance requirements by design

Dr Dmitry Fridman, Miltenyi

Laboratory Optimization, Automation and Digitalization
23 November 2022

Implementation of a LIMS integrated with the ERP
- Definition of sampling and testing based on vendor's quality record (reduced sampling, reduced testing, skip lot, certification of vendor)
- Laboratory workload plan based on ERP work orders
- Chemicals inventory control and planning Analytical Methods library workflow
- Data Integrity requirements – how to design, specify and test QR Code labels usage

Flavio Kawakami, Doctorbit/ISPE

How do I find the best LIMS for my lab?
- Preparation of the selection
- Where do I stand right now? (as is)
- Where do I want to go? (to be)
- What exactly do I want to realize? (URS)
- How do I choose the right provider? (RFP)
- What can which system do? (Demo)

Joachim Post, wega Informatik

Optimization and Real-Time Documentation during the Test for Sterility in Cleanrooms
- The problem with paper-based yet timely documentation especially in cleanrooms
- A strategy to use existing computerized systems and further develop their properties
- Overview of the typical documentation steps in sterility testing
- Development history, starting from a very paper-intensive process to a paperless laboratory

Olivia Halamoda, Labor LS

How to Transfer your Innovation from Lab Scale to Manufacturing?
- Critical steps from lab towards GMP manufacturing
- Insights and challenges during transfer from lab scale to manufacturing
- Points to take into consideration to ensure a successful transfer

Dr Dana Quaden, Medace

Annex 1 in The Age of Digitization: Reimagining Contamination Control Takeaway Tools
- Digitization in quality management and contamination control
- Remote and hybrid work
- Integrated Metrics
- Process flow metrics and KBIs

Parsa Famili, Novatek
Dr Anne-Grit Klees, Merck

The Lab of the Future – Today
- What are the important components to consider - digitalization, automation, integration, robotics, AR, VR
- What are the different technologies that will facilitate achieving this and how and where to start
- Key considerations when evaluating new technologies
- How to build a business case to show the return on investment and communicate the impact to the business

Sinead Cowman, Lonza

Moderation

Dr Karl-Heinz Bauer, Boehringer Ingelheim

Speakers

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

Dr Carsten Börger | *Valicare, Germany.*
Senior Project Manager.

Sinead Cowman | *Lonza, Ireland.*
Associate Director Strategy & Marketing - Informatics.

Parsa Famili | *Novatek International, Canada.*
President & CEO.

Dr Dmitry Fridman | *Miltenyi, Germany.*
Global Product Manager.

Olivia Halamoda | *Labor LS, Germany.*

Dr Anne-Grit Klees | *Merck, Germany.*
Lead Expert, Product & Portfolio Manager BioMonitoring / Environmental Monitoring Franchise.

Flavio Kawakami | *Doctorbit/ISPE, Portugal.*
GAMP CoP Chair (vol.).

Dr Timo Kretzschmar | *Insolve, Austria.*
Senior Consultant / Projektmanagement.

Joachim Post | *wega Informatik, Germany.*
Senior LIMS Consultant.

Dr Dana Quaden | *Medace, The Netherlands.*
Quality Associate GMP.

Cells, Tissues and ATMPs – Quality Control
22/23 November 2022

Background & Objectives

This conference is for cells, tissues, cell- and tissue-based products and ATMPs and deals with microbiological and analytical quality requirements, appropriate methods and test systems and their implementation. Representatives of authorities and colleagues from the small-scale and industrial manufacturing sectors will explain the current requirements and report on their experiences during inspections and implementation in the company.

Modern systems of regenerative medicines, such as cells and tissues or ATMPs (gene therapeutics, somatic cell-based products and tissue-based products) represent an innovative group of drugs that is becoming increasingly important. With the entry into force several regulatory guidelines e.g. of the European Directive EC 1394/2007 for ATMPs, such products were classified as medicinal products and must therefore comply as such with the EU requirements for medicinal products. Although the biopharmaceutical industry has considerably intensified its activities in this field, many of these products are developed and manufactured at universities, hospitals and in small and medium-sized enterprises. These university or medical roots lead to special challenges for the respective institutions as well as for the regulatory authorities in fulfilling the compliance requirements for quality, safety and GMP aspects and approval. This is also forced by frequently given manufacturing conditions, e.g. the open manipulation of cells and tissues, which are necessary for obtaining such products on a medical/surgical level or by the short shelf life of the obtained final product.
Rapid testing and analysis are a challenge for such short shelf life products in terms of:

- Comparability with Compendial Methods
- Sensitivity and Robustness
- Suitability Testing and Validation
- Variability

Target Audience

This conference is aimed at all persons who

- are involved in the extraction and manufacture of Cells, Tissues and ATMPs
- Responsible persons from quality assurance and control of Cells, Tissues and ATMPs
- are responsible for microbiological or analytical testing
- perform inspections or audits of ATMPs facilities
- deal with the authorisation

Programme Day 1

KEYNOTE Presentation at the Plenum
Biological Manufacturing – Demanding Quality and Compliance Requirements
Dr Tilman Rock, SVP, Site Head Vienna (Austria), Boehringer Ingelheim Biopharma

Welcome /Analytical Toolbox AAV Virus
Dr Sabine Hauck, Leucocare

Analysis Strategies for Cell and Gene Therapy Products

- Understanding the advantages and challenges of quantitative and qualitative based methods
- Providing rich information about advances in real time bioanalytics for ATMPs
- Exploring best practice to perform assay qualification and transfer from lab to manufacturing
- Addressing the regulatory requirements for analytical development

Dr Mohamad Toutounji, Sanofi

Personal Experience of Biological Raw Material Sourcing for an Early Stage ATMP and Considerations for Later Clinical Stage Development

- Raw materials of human origin: quality requirements and sourcing
- Biological raw materials in early clinical phases (and the importance of choosing correctly early during process development)
- Comparability of biological raw materials and second source suppliers

Sidonie Karlsson, Amniotics

Cells of Quality: ICH in the Lab - ICH S6, Q5A-D in the Context of Cell Banking Cell Substrates for the Production of ATMPs

- ICH S6, Q5A-D in the context of cell banking
- Cell substrates for the production of ATMPs
- Identity, Purity and Stability of cell lines (Q5D), from pre-master cell banks to and of production cells

Assoc. Prof Dr Simon Schulz, Entourage

Cells, Tissues and ATMPs – Quality Control
22/23 November 2022

Batch Release and Stability Studies, especially for ATMPs – a Challenge?
- Batch definition, appropriate analytics and batch release – method choice & time
- Release specification and stability specification – maybe different
- Safety, potency - what else?
- Risks, responsibility & decisions – especially for autologous product

Dr Markus Fido, MFI Bio-Consulting

Bioactivity Testing for Cell and Gene Therapy Products
- AAV
- Lenti virus
- CAR-T
- Matrix approach

Dr Ulrike Herbrand, Charles River Laboratories

Analytical Quality by Design Approach: a Challenge for Viral Vector Testing in Gene Therapies
- Needs and challenges to apply Analytical Quality by Design to Biotherapies
- Use of AQbD to improve and control two biological methods for lentiviral vector testing: ELISA & PCR
- Critical method variables identification and risk level evaluation
- MODR establishment by use of Design of Experiments and Analytical Control Strategy definition
- Comparison of AQbD approach between both methods

Isabelle Moineau, AKTEHOM
Dr Anne Sophie Cottard, Yposke

Automation of Hematopoietic Progenitor Cell (HPC) Processing: a Platform for ATMP Manufacturing
- Standardisation of closed-system volume reduction for starting material and thawed HPC products by automation: Sepax-2 - Cytiva data on reproducibility
- Automation of liquid nitrogen (LN2)-free GMP-compliant controlled-rate cryopreservation of 100ml cryobags: Via Freeze Quad - Cytiva data on reproducibility and comparability to gold standard for LN2 cryopreservation system
- Standardisation of water-free GMP-compliant cryobag thawing: ViaThaw - Cytiva: data on traceability and comparability to gold standard
- Opportunities and challenges for introducing automation into critical steps of ATMP manufacturing

Dr Bechara Mfarrej, Institut Paoli-Calmettes

Development of a Cell-based Potency Bioassay for mRNA Medicine
- Feasibility testing of different detection methods
- Optimization of the procedure using DOE
- Evaluation of assay performance and implementation of a control chart for the assay live cycle management

Sabrina Rottal, VelaLabs

Moderation

Dr Sabine Hauck, Leucocare

Programme Day 2: Please note that the second day (23 November) will be held together with the conference on *Alternative and Rapid Microbiological Methods*.

Speakers

Dr Anne Sophie Cottard | *Yposkesi, France.*
Responsible of method validation and Analytical Life Cycle Management.

Dr Markus Fido | *MFI Bio-Consulting, Austria.*
CEO.

Dr Sabine Hauck | *Leucocare, Germany.*
Vice President Research & Development.

Dr Ulrike Herbrand | *Charles River Laboratories, Germany.*
Scientific Director Global in-vitro Bioassays.

Sidonie Karlsson | *Amniotics, Sweden.*
Production Manager.

Dr Bechara Mfarrej | *Institut Paoli-Calmettes, France.*
Research and Development engineer, Responsible Person in interim.

Dr Isabelle Moineau | *AKTEHOM, France.*
Analytical Leader.

Sabrina Rottal | *VelaLabs, Austria.*
Application Specialist - R&D and Analytical Development.

Assoc. Prof Dr Simon Schulz | *Entourage, Germany.*
Senior Management Consultant.

Dr Mohamad Toutounji | *Sanofi, The Netherlands.*
Molgenium as principal scientist for ATMP.

Programme Day 2

KEYNOTE Presentation at the Plenum
Impurities - USP Draft Chapter <477> User-Determined Reporting Thresholds (UDRT), and Other Relevant Chapters
Dr Christian Zeine, Senior Manager Scientific Affairs EMEA, USP

Microbiological Control of ATMPs
- Aseptic Technique
- Environmental monitoring (EM)
- EM excursion investigation
- Formulating effective CAPA from EM excursion investion

t. b. a.

Implementation of a Comprehensive Rapid Microbial Contamination Control Platform for Testing of Sterile Pharmaceuticals and Cell-Based Therapies using ATP Bioluminescence
- Various applications and possible uses of this ATP bioluminescence technology
- Practical experience with
  - Implementation
  - Validation
  - Verification

Stefan Gärtner, Labor LS
Dr Lucia Ceresa, Charles River Laboratories

Ultra-Rapid Microbial Detection in Cell & Gene Therapy Products: the closest you can be to Real-Time Release
- Development of a specific C&GT ultra-rapid sterility test application
- Comparison to methods currently in use
- Matrix compatibility / method suitability
- Future validation approaches

Corinne de la Foata, bioMerieux

Viral Safety – Evaluation of Eukaryotic Cell Bank Purity with a Special Focus on Adventitious Agents and Replication Competent Viruses
- Evaluation eukaryotic cell banks:
  - Determination of adventitious agents *in vitro* by sophisticated cell culture technologies (Ph. Eur. 2.6.16 / 5.2.3)
  - Evaluation of defined virus induced effects such as cytopathic effect (CPE), Hemadsorption, Hemagglutination
  - Alternative methods for testing of Adventitious Agents
- Short view on Prokaryotic cell banks à purity and bacteriophage contamination

Larissa Nkenmei-Pietsch, Tentamus

Short Shelf Life and Sterility Testing - Challenges of Cell-Based ATMP Market Supply
- Sterility: Quality by Design tools applied
- Technical challenges: solutions and questions

Debora D`Amico, Tetec

Rapid Sterility by qPCR for ATMPs
- The compendial methods for sterility testing of cell and gene therapy products (ATMPs) USP <71>, Ph. Eur. 2.6.1 and Ph. Eur. 2.6.27
- USP <1223>, Ph. Eur. 5.1.6. and TR#33 - the Possibility of using alternative test methods
- Current alternative methods their incubation time incubation time and matrix interference
- Important distinction between background contamination (DNA) and viable microorganisms
- Method combining bacterial growth and enrichment with qPCR

Dr Anja Fritsch, Confarma

ScanRDI System - Validation and Implementation of an Alternative Sterility Test (Solid Phase Cytometry) for a Cell and Gene Therapy Product
- Overview of the ScanRDI system - detection principle and work-flow
- Why the ScanRDI for cell-based products? - Results of the Scan-RDI evaluation study
- Overview of ScanRDI - validation results for cell-based products
- Current status of ScanRDI - evaluation for in-process control (media/buffer)
- Risks and challenges of the ScanRDI method

Mahsa Mohammadi, Novartis

Implementation of a Real Time PCR-based Method for Release Testing the Sterility of ATMPs, a Practical Approach
- Real Time PCR method as sterility test for cellular products and the detection limit according to Pharm. Eur. 2.6.27
- Special requirements of a molecular biological method (multi-room concept)
- Practical implementation taking into account possible risk factors

Yasmin Heynen, Labor LS

Moderation

Dr Michael Miller, Microbiology Consultants

Speakers

Debora D`Amico | *Tetec, Germany.*
Team Leader Quality Control Microbiology & Hygiene Monitoring.

Dr Lucia Ceresa | *Charles River Laboratories, Italy.*
Senior Technology and Market Development Manager.

Corinne de la Foata | *bioMerieux, France.*
R&D Senior Manager.

Dr Anja Fritsch | *Confarma, France.* Scientific Officer.

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

Yasmin Heynen | *Labor LS, Germany.*
Biological Laboratory Technician.

Dr Michael Miller | *Microbiology Consultants, USA.* President.

Mahsa Mohammadi | *Novartis, Switzerland.*
Senior AS&T Specialist/ Analytics, Launch and Transfer-Large Molecules.

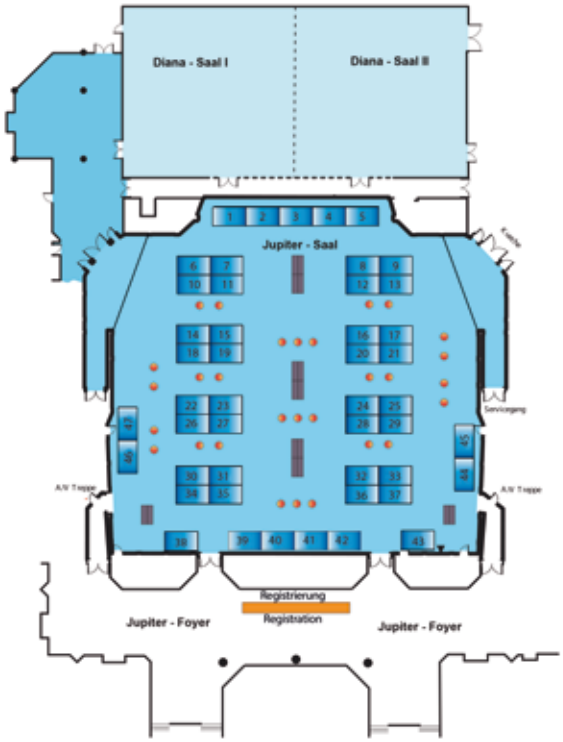
Larissa Nkenmei-Pietsch | *Tentamus, Germany.*
Head of Cell and Immune Analytics.

Exhibitors Information

The Exhibition

Is your company specialised in products and services for pharma laboratories?

As an exhibitor in the PharmaLab exhibition you can take advantage of the unique opportunity to directly address users and decision makers in the areas analytics, bioanalytics, from microbiological laboratories, Quality Assurance and Quality Control. In addition to high-level discussions during the Congress you can also get in touch with Congress delegates and with speakers during the Social Event.



The **charges per stand are 3.980,- Euro** plus VAT. The following services are included:

- Booth including exhibition wall with the size of 3,32 x 1,91 m, 1 table, 2 chairs and power
- Participation for the person mentioned on the registration form is free of charge
- Lunch and refreshments during the conferences
- Participation in the Social Event
- 2 free tickets for your clients
- On-site support

Materials for your Marketing

As an exhibitor you can take advantage of various marketing materials for promoting your presence. These include

- online exhibition banner – for your website and as signature in your e-mails.
- an ad in the GMP Journal (subject to extra charges) – get directly in touch with your target group

You will find more detailed information on these materials on the Congress website at www.pharmalab-congress.com.

Sponsoring

Moreover, take advantage of the sponsoring opportunities to make Congress delegates aware of your company. In addition to sponsoring coffee breaks or lunches on the 1st and 2nd Congress day there are plenty of other sponsor possibilities. You will find the details on the website.

Do you have any questions with regard to the exhibition? Then please contact:
Ronny Strohwald, (Organisation), Tel. +49 (0) 6221/84 44-51,
E-Mail: strohwald@concept-heidelberg.de.

Easy Registration

Registration Form:
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www.pharmalab-congress.com
www.pharmalab-kongress.de

Dates
Tuesday, 22 November 2022, 09.00 – 18.00 h
Wednesday, 23 November 2022, 09.00 – 18.00 h
(Registration Tuesday, 22 November/Wednesday, 23 November, 08.00 – 09.00 h)

Venue
Crowne Plaza Hotel Düsseldorf / Neuss
Rheinallee 1
41460 Neuss, Germany
Tel.: +49 (0) 2131 77 - 00
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Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.pharmalab-congress.com

PLEASE NOTE
- There will be no reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.
- There will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as downloads.

Organisation & Contact
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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

Social Event
On 22 November 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.

Registration Options
I want to take part in:
- ☐ PharmaLab Pre-Conference Workshop "3rd International Mycoplasma qPCR Testing User Day" (21 Nov 2022) - € 590,- plus VAT
- ☐ PharmaLab Conferences on 22 Nov 2022 – € 690,- plus VAT
- ☐ PharmaLab Conferences on 23 Nov 2022 – € 690,- plus VAT

With a one day ticket/two days ticket for the PharmaLab Conferences (22 Nov/23 Nov 2022) you can attend any conference offered that day/both days. It includes participation in any conference on that day/on both days and the visit of the exhibition. In addition, it comprises lunch and beverages during the conferences and in breaks (on one or both days) as well as the social event on the evening of the first congress day.
Please mark if you would like to attend the Social Event.To be able to prepare the conference rooms, 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 conference per day.

- ☐ I would like to attend on **day 1 (22 November 2022)** and I'm primarily interested in the conference:
  - ☐ ECA – Analytical Procedure Life Cycle Management - ICH Q14/ICH Q2(R2)
  - ☐ ECA – Endotoxin and Pyrogen Testing (Day 1)
  - ☐ ECA – Alternative and Rapid Microbiological Methods (Day 1)
  - ☐ ECA – Cells, Tissues and ATMPs – Quality Control (Day 1)
  - ☐ I would also like to take part in the Social Event on the evening of 22 November.
- ☐ I would like to attend on **day 2 (23 November 2022)** and I'm primarily interested in the conference:
  - ☐ ECA – Laboratory Optimization, Automation and Digitalization
  - ☐ ECA – Endotoxin and Pyrogen Testing (Day 2)
  - ☐ ECA – Cells, Tissues and ATMPs and Alternative Microbiological Methods (Day 2)

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Mr ☐ Ms ☐ Dr

First name, Surname

Company

Department

Important: Please indicate your company's VAT ID Number P.O. Number (if applicable)

Street/P.O. Box

City Zip Code

Country

Phone/Fax

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
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks 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 dedutions- 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)! German law shall apply. Court of jurisdiction is Heidelberg.

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.

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