GMP Compliance, Outsourcing and Optimization QC Analytics

21/22 November, Düsseldorf, Germany

The conferences are part of PharmaLab
Analytics ▪ Bioanalytics ▪ Microbiology

Highlights

- Outsourcing in Pharmaceutical Laboratories
- Transfer to External Partners
- Technologies that make Lab of the Future
- Digitalisation
- Data Integrity and Cloud Computing
- Data Analysis and Trending for Contamination Control
- Update on USP <1220> and <1058>
- Analytical Procedure Life Cycle
- Opportunities and Challenges from ICH Q2 (R2) and Q14

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GMP Compliance Trends in Analytical Laboratories / Outsourcing in Pharmaceutical Laboratories | 21 November 2023

Background & Objectives

It is the aim of this course to address GMP compliance issues that are currently discussed as hot topics in analytical quality control laboratories and during GMP-/FDA-Inspections.

Furthermore, this conference will highlight the wide range of regulatory requirements and practical aspects that need to be considered when testing on a contract basis. The conference in particular addresses topics that are relevant from a GMP point of view.

Due to changing regulatory requirements, pharmaceutical quality control units are continuously facing new challenges. There are many regulatory requirements relevant for the pharmaceutical quality control, both in EU and in the US. Laboratory Managers and Analytical Scientists must be familiar with the different GMP-related topics and must be aware of the latest updates and the current interpretation.

Outsourcing is one of the critical process in the pharmaceutical industry. According to the EU GMP Guidelines (Chapter 7 – Outsourced Activities) "any activity covered by the GMP Guide that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party. The Quality Management System of the Contract Giver must clearly state the way that the Qualified Person certifying each batch of product for release exercises his full responsibility."

There are various reasons for outsourcing analytic testing. Tests are sometimes outsourced only for specific projects. However, the analyses are sometimes conducted externally for each batch of a product in routine quality control, for example if the manufacturer does not have the necessary know how or the required capacity.

This conference therefore deals with the following topics:

- Data Integrity
- Regulatory and legal requirements
- Business Continuity
- Selection and management of partners
- Practical aspects to consider when establishing contracts
- Auditing contract laboratories

Target Audience

This conference will be of significant value to

- Laboratory managers, supervisors and analysts
- Quality control managers
- Heads of quality control
- Qualified Persons (QPs)
- Analytical scientists
- Senior laboratory staff
- Responsible authorities

This conference is also intended for employees in Quality Assurance and from contract laboratories. Furthermore, it is useful for service providers, such as contract research organisations and contract manufacturers.

Moderation

Alexander Pfülb, *Labor LS*

Congress Key Note

Main Conferences on 21/22 November 2023

Key Note on 21 November: The Impact on the Revised Annex 1 for Rapid Microbiological Methods Implementation
Dr Michael Miller

Key Note on 22 November: Preparedness in Pandemic Vaccine Manufacturing and Deployment
Prof Dr Isabelle Bekeredjian-Ding

Programme

Data Integrity and Cloud Computing in GMP Compliant Laboratories – Presence, Future or a Contradiction? A Perspective from the Eyes of a GxP Auditor

- Data integrity in clouds for short
- The cloud service providers and their providers – "unknown beings"?
- Some points about supplier management
- Cloud risks for laboratory data
- How much "qualification and/or validation" is necessary?

Dr Timo Kretzschmar, Inosolve

Business Continuity in cGMP

- Audits, is there more important stuff than technical processes?
- Test reliability in times of shortage of trained personnel
- Processes top, framework conditions flop
- How does Generation Z think regarding working attitude compared to boomers, and how can the GMP industry adapt to it?

Alexander Pfülb, Labor LS

Shelf Life of Reagents in a Chemical-pharmaceutical Laboratory

- Shelf-life of inhouse produced reagents, buffers & critical materials
- Methods & parameters for shelf-life determination
- Microbiological methods & specifications for water as an example
- Practical examples & concepts for defining the shelf-life of reagents

Dr Jochen Kolb, BioChem

Understanding & preventing Human Errors

- What is human error?
- Definition, categories, and psychology of human error
- The right attitudes and behaviors for adequate error investigations
- The vicious cycle of „guilt"
- The right „error culture"

Dr Karl-Heinz Bauer, Boehringer

Microbiology Testing in Contract Labs

- Vaccine lot release - regulatory process
- Outsourcing analysis (test)
- Quality control labs requirements

Dr Radhakrishna Tirumalai, MSD, formerly at USP

Transfer to External Partners - Overcoming Pitfalls in Analytical Method Transfers

- Failure of analytical transfers as frequent issue with external partners
- What to consider when preparing analytical transfers
- How to reach the goal of right first time in transfers
- Tools and systematic approaches to coordinate analytical transfers
- Presentation of use cases

Dr Holger Bauer, Merck

Case Study: Technologies that make Lab of the Future and drive Collaborative Innovation

- Improvement of connection and collaboration between experts in life science, data science and digital technologies
- Digital backbone consisting of modular, scalable, flexible and easy to implement plug-n-play solutions
- How can data science, AI and IoT impact the lab of the future?

Lukasz Paciorkowski, A4BEE

Speakers

Dr Timo Kretzschmar, *Inosolve*. Sen. Consultant (extern)

Alexander Pfülb, *Labor LS*. Head of Customer Management

Dr Jochen Kolb, *BioChem*. General Manager

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

Dr Radhakrishna Tirumalai, *MSD, formerly at USP*.

Dr Holger Bauer, *Merck*. Global Analytical Technology Expert

Lukasz Paciorkowski, *A4BEE*. Chief Strategy Officer.

Laboratory Optimization, Automation and Digitalization
22 November 2023

Background & Objectives

The aim of this conference is to show possibilities to optimize the organization of an analytical laboratory. 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 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.

With this conference, participants will get to know tools for more effective and efficient control of laboratory activities.

You become informed about

- Optimization of laboratory processes - practical examples
- Cost-efficient design of a laboratory
- Case studies for laboratory automation/digitalization
- New analysis methods for the optimization of processes in the laboratory
- Tools to measure and monitor optimizations

Target Audience

This conference will be of significant value to

- Laboratory managers, supervisors and analysts
- Quality control managers
- Heads of quality control
- Qualified Persons (QPs)
- Analytical scientists
- Senior laboratory staff
- Responsible authorities

This conference is also intended for employees in Quality Assurance and from contract laboratories. Furthermore, it is useful for service providers, such as contract research organisations and contract manufacturers.

Moderation

Dr Karl-Heinz Bauer, *Boehringer*

Speakers

Dr Christina Müller, *Boehringer Ingelheim Pharma GmbH*. Senior Data Manager

Susan Cleary, *Novatek International*. Director of Product Development

Anke Hossfeld, *Merck*. Global PM Pharma Development

Mathias Fuchs, *Wega*. Scrum Master, Agile Coach, Enabler for Agilized Validation Setups.

Dr Laura Bailac, *bioMérieux*. Senior Scientist

Melissa Schülein, *Labor LS*. Microbiology/Central Service

Niels Visschers, *MSD*. Senior Specialist

Dr Bob McDowall, *R.D. McDowall Limited*. Director

Alexander Doppelreiter, *Reference Analytics GmbH*. CEO/Head of Quality Control

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

Programme

Annex 1: Data Analysis and Trending for Contamination Control

- Understand evolving regulations
- List the critical data for investigation and root cause analysis
- Ability to define a trend review frequency in an SOP
- Insight into which trend tools to apply to the data
- Learn what the trend is telling us about the process

Dr Christina Müller, Boehringer Ingelheim Pharma
Susan Cleary, Novatek International

Future QC Testing using Automation and Robotics – a Digitalized Foundation of Sterility Testing

- Overview on possibilities to full QC automation within the laboratory
- Benefits and challenges of automation
- First concepts of automated new QC workflows
- Case study for improved data integrity through digitalization within sterility testing

Anke Hossfeld, Merck

Agile Validation

- Approach that enables GxP compliant validation as an agile, paperless process
- Agile, flexible development approaches in compliance with regulations and highest quality standards

Mathias Fuchs, Wega

Challenges and Solution for the Performance Validation of EM Automation

- Automatization technologies that improve environmental monitoring (EM) practices
- Automated method as part of environmental control of pharmaceutical production
- 3P®STATION, a colony counter system based on automatic timely plate reading incubation
- Risk analysis between the traditional method and the 3P®STATION

Dr Laura Bailac, bioMérieux

From Theory to Practice: Current Requirements for Microbiological Monitoring – Establishing Efficient Strategies for Microbiological Monitoring based on Integrated, Proprietary Software Tools

- From planning hygiene monitoring to implementation - what to look out for?
- And now? Interpret and present results
- LS-pedia - Competent. Up-to-date. Individual. A microbiological reference compendium

Melissa Schülein, Labor LS

Considerations when introducing Automated EM Systems in a Large Biopharmaceutical Company

Niels Visschers, MSD

Key to Digitalisation: Understanding and redesigning your Laboratory Processes

- Why automating the status quo is a bad idea
- Redesigning any process requires you to map and understand your current process first
- Fit the informatics solution to the new process or vice versa?
- Case study examples

Dr Bob McDowall, R.D. McDowall Limited

Is my Contract Laboratory big enough for becoming Paper-Less? A Case Study

- The cost of being a paper-based contract laboratory
- Roadmap for becoming paper-less
- Validation of a cloud-based solution for laboratory information management
- Real-life example – digitalization of a small laboratory

Alexander Doppelreiter, Reference Analytics

Key Performance Indicators (KPIs) in Pharmaceutical Quality Control Laboratories - Tools to measure and monitor Optimizations

- Definition of KPIs, Strategy, Balance Scorecard
- Goals for KPIs
- Examples for QC/Laboratory Performance Parameters & Balanced
- Scorecards

Dr Karl-Heinz Bauer, Boehringer

The Social Event

On the evening of the first congress day, on 21 November 2023, 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.

Analytical Procedure Life Cycle Management/Validation of Analytical Procedures – ICH Q14/ICH Q2(R2) | 21/22 November 2023

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.

In March 2022 the European Medicines Agency (EMA) published the ICH guidelines Q2(R2) on validation of analytical procedures and the ICH Q14 on analytical procedure development for public consultation (Step 2b).

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.

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).

Target Audience

This conference will be of significant value to

- Laboratory managers, supervisors and analysts
- Quality control managers
- Heads of quality control
- Qualified Persons (QPs)
- Analytical scientists
- Senior laboratory staff
- Responsible authorities

PharmaLab Exhibition

Parallel to the conferences, participants will have the opportunity to visit the accompanying trade exhibition. It offers comprehensive information about available products, services and the latest developments around the laboratory.

All details at:

www.pharmalab-congress.com/exhibitors-plan.html

Programme Day 1

Update on USP <1220> and <1058>

- USP General Chapter <1220> Analytical Procedure lifecycle
- Enhancement of USP General Chapter <1058> Analytical Instrument Qualification to a full lifecycle model
- Eurachem Draft guideline
- ECA AQCG Guide on Analytical System and Instrument Qualification

Dr Christopher Burgess

Introduction to the new ECA Analytical Quality Control Group (AQCG) Guide on Analytical Instrument Qualification and Software Validation (AIQ&SV)

- Rationale and purpose of the guide
- Content overview
- Selected contents in detail

Dr Christopher Burgess, Burgess Analytical Consultancy
Dr Bob McDowall, R.D. McDowall Limited

Product Life Cycle Concept from the Perspective of the Authorities - Enhanced Approach in Process Validation & Production Routine

- Validation Lifecycle
- Quality by Design
- Process Analytical Technology
- Statistical Process Control

Dr Rainer Gnibl, Government of Upper Bavaria

Iterative Validation Approach for Precision: Stage 1 or Stage 2?

- Use of data from development for validation (ICHQ2(R2), Q14)
- Reportable value and (quality-by-design) replication strategy
- How to establish the replication strategy?
  - Reliable determination of the variance components in Stage 1 and confirmatory precision study in Stage 2
  - From exploratory precision study in Stage 2

Dr Joachim Ermer, Ermer Quality Consulting

The impact of the new ICH Q14 on the Practical Approach to Transfer of Analytical Procedures

- Practical interpretation of the new text about method transfer of analytical procedures in ICH Q14
- Examples of risk assessments in relation to transfer of analytical procedures
- The role of the acceptance criteria in ICH Q14
- Example of efficient comparative study design
- How to conclude on a comparative study

Ulla Bondegaard, Novo Nordisk

Case study: Standard and Extended Use of a Validated, Customized Amplex UltraRed Assay for Sensitive Hydrogen Peroxide Detection in Pharmaceutical Water

- Validation of a customized Amplex UltraRed assay, which is capable of quantifying hydrogen peroxide (H2O2) in water for injection (WfI) selectively, sensitively, accurately, precisely and robustly
- Extended of the use to developmental studies within process development by applying a platform design for multiple matrices including biological drug products

Dr Alexandra Heussner, Vetter Pharma

Moderation

Dr Christopher Burgess

Programme Day 2

Opportunities and Challenges from ICH Q2 (R2) and Q14 for the Analytical Lifecycle

- What's new?
- What's ready now, ready soon or may be for later?
- Where may it lead us?

Jean-Francois Dierick, GSK

Analytical Target Profile (ATP) for Large Molecules

- ATP as a corner stone of the analytical procedure development strategy
- Role of ATP in lifecycle management of analytical procedure
- Case studies for biotherapeutic proteins

Annick Gervais, UCB

Validation for MAA/NDA

- Overview of relevant guidelines, pharmacopeial monographs
- ICH Q2 R1 vs. R2
- Practical aspects of method validation (incl. examples)

Dr Xaver Schratt, GBA Pharma

Implementation of Quality by Design Principles for Analytical Assay Development and Validation

- Regulatory requirements for QbD in drug testing
- The potential obstacles and advantages associated with adoption of QbD methodology in the context of QC product testing
- Case study on implementing QbD for mRNA cancer vaccine testing

Dr Mohamad Toutounji, Molgenium

HPLC Stability-indicating Procedure Design using Analytical Procedure Lifecycle Approach and AQbD Principles

- Analytical Quality by Design fundamentals and evolution of QbD in the pharmaceutical environment
- Introduction to USP General Chapter <1220> Analytical Procedure Life Cycle
- Case study – USP <1220> Stage 1: HPLC stability-indicating procedure design using AQbD principle
- Understanding the expectations of USP <1220> and implications of ICH Q14 and Q2(R2)

Dr Amanda Guiraldelli, USP

The Use of Design of Experiment to ensure appropriate Understanding throughout a Method's Lifecycle

- Method development strategy
- Method optimisation by response surface resign
- Method risk assessment
- Method robustness testing by fractional factorial design
- Method ruggedness assessment by measurement systems analysis
- Method equivalence testing by TOST (Two one-sided test)

Patrick Jackson, GSK

Strategies of Overcoming Risks of changing Analytical Methods

- Risks associated with analytical procedure changes
- Reviews strategies to mitigate the risks

Dr Stephan Kirsch, Novartis

Validation of Specific Methods for Inhalation Drug Products

- Key aspects of inhalation drug products (MDIs, DPIs and Nebulizers)
- Main regulatory requirements (guidelines and pharmacopoeia general chapters)
- Specific test methods and general specifications for MDIs and DPIs
- Impact of regulatory requirements on the validation of key performance methods
- Examples for Validation of DDU and APSD methods
- Optimization of methods
- Example of semi-automated method for DDU testing of MDI

Dr Manfred Fischer, Fischer Consulting

Moderation

Dr Joachim Ermer, *Ermer Quality Consulting*

Speakers

Dr Christopher Burgess, *Burgess Analytical Consultancy*. Managing Director

Dr Gerd Jilge, *Formerly Boehringer Ingelheim Pharma*. Retired Head of a Method Development Laboratory

Dr Rainer Gnibl, *Government of Upper Bavaria*

Dr Joachim Ermer, *Ermer Quality Consulting*

Ulla Bondegaard, *Novo Nordisk*. Specialist

Dr Alexandra Heussner, *Vetter Pharma*, Lab Manager

Jean-Francois Dierick, *GSK*. Strategic Analytical Validation and Lifecycle Lead - Analytical R&D

Annick Gervais, *UCB*. Head of Analytical Development Sciences

Dr Xaver Schratt, *GBA Pharma*. Team Leader Global Quality Management. Member of Management Team Site Neuried

Dr Mohamad Toutounji, *Molgenium*. CEO

Dr Amanda Guiraldelli, *USP*. Scientific Affairs Manage

Patrick Jackson, *GSK*. Investigator

Dr Stephan Kirsch, *Novartis*, Director Scientific Office Analytical Development

Dr Manfred Fischer, *Fischer Consulting*. General Manager

Organisational Details

The Fees

A one-day ticket/two-day ticket will enable you to visit the congress (21 November/22 November 2023) either only on day 1 or only on day 2 or on both days. The charges for the one day tickets are € 690,- plus VAT, for the two days ticket € 1.380,- plus VAT. They include lunch and beverages during the conferences and in breaks as well as the social event on the evening of the first congress day (Due to the special fees for the congress, ECA membership discounts are not applicable). The visit of the pre-conference on 20 November 2023 for € 590,- can be combined with the congress (see registrations options on the last page). Charges are payable after receipt of invoice.

Location

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Cell and Gene Therapies/ATMPs - Quality and Safety
21/22 November 2023

Background & Objectives

This meeting is aimed at manufacturers and developers of cells, tissues, cell- and tissue-based products or ATMPs and deals with microbiological and analytical quality requirements, suitable methods and test systems and their implementation and validation. Representatives from authorities and colleagues from small-scale and industrial manufacturing and academic institutions will explain the current regulatory requirements and report on their experiences during inspections and implementation in the company.

Modern regenerative medicine systems such as cells and tissues or ATMPs (gene therapeutics, somatic cell-based products and tissue-based products) represent an innovative group of medicinal products that is becoming increasingly important. With the entry into force of several regulatory directives, e.g. the European Directive EC 1394/2007 for ATMPs, such products have been classified as medicinal products and as such must comply with EU requirements for medicinal products. Although the biopharmaceutical industry has significantly intensified its activities in this area, 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 meeting compliance requirements for quality, safety and GMP aspects and approval. The frequently given manufacturing conditions also contribute to this, e.g. the open manipulation of cells and tissues necessary for obtaining such products on a medical-surgical level, or the short shelf life of the obtained end product. And potentially there are always conflicts when it comes to the relevance of different guidelines, e.g. when an Annex 1, or an Annex 2 or a WHO Guideline does not harmonise with the ATMP Guideline.

But also rapid tests and analyses are a challenge for such products with a short shelf life in terms of

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

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

Speakers

Alicja Fiedorowicz, *Dark Horse Consulting.* Senior Consultant.

Matthias Heemskerk, *CellPoint, a Galapagos company.*
Head of Analytical Development.

Dr Sascha Karassek, *Charles River Laboratories.*
Scientist R&D Bioassay.

Dr Sabine Hauck, *Leukocare.*
EVP Corporate Development.

Dr Ferran Sanchez, *Sciex.*
Market Development, Manager, Pharma/CRO EMEA.

Dr Sebastian Ulbert, *Fraunhofer-Institut für Zelltherapie und Immunologie.* Deputy Head of Institute Head of Department Vaccines and Infection Models.

Dr Markus Fido, *MFI Consulting.*
CEO.

Dr Stefanie Bayer, *Labor LS.*
Director Molecular Development.

Dr Mahdieh Rahmatollahi, *Thermo Fisher Scientific.*
Field Application Scientist - Genetic Sciences (qPCR-dPCR).

Dr Nicole Paland, *Minerva Biolabs.*
Head Product Development.

Dr Cornelia Rosner, *Minaris.*
Team Lead Tech Transfer/Clinical Quality Control.

Olga Müller, *Tetec.*
Head QC.

Dr Ruth Röder, *Microcoat.*
Director Endotoxin Services.

Dr Christian Faderl, *bioMérieux.*
Project Leader.

Programme Day 1

Analytical Challenges in Development of Cell and Gene Therapies

- Regulatory expectation for analytical testing of ATMP
- Creation of analytical testing strategy, analytical target profile and working operational ranges
- Challenges in development, optimization and validation of assays for ATMP testing
- Example of delays to approval due to analytical testing hurdles

Alicja Fiedorowicz, Dark Horse Consulting

Challenges of a Point-of-Care Model for Cell Therapy from an Analytical Perspective

Matthias Heemskerk, CellPoint, a Galapagos company

Potency Testing for ATMPs

- Guideline requirements for potency testing of advanced therapy medicinal products (ATMPs)
- Challenges
- Reflection of MoA
- Matrix Approach
- Validation Considerations
- Brief case studies for plasmid and LNP products

Dr Sascha Karassek, Charles River Laboratories

Analytical Methods to Support mRNA-LNP Formulation Development

- Method selection based on USP guidelines and literature
- Aligning CQA with suitable analytical methods
- Analytical data for the selected toolbox

Dr Sabine Hauck, Leukocare

Achieve Lower LLOQs for siRNA Quantification in Plasma Using Microflow LC

- Overcome the difficulties of analyzing oligonucleotides using microLC
- Easy transfer of high flow LC to microLC
- Get extra level of sensitivity thanks to the combination of a high end triplequadrupole with microLC

Dr Ferran Sanchez, Sciex

Analysis of Radiation-Inactivated Pathogens for Vaccine Development (LEEI)

- Low energy irradiation (LEEI) is a novel method for the production of inactivated vaccines, with several advantages over chemical inactivation
- Pathogens treated with LEEI largely maintain their surface antigens
- Downstream analysis includes verification of inactivation and antigenicity testing

Dr Sebastian Ulbert, Fraunhofer-Institut für Zelltherapie und Immunologie

Different Analytical Tools to characterize ATMPs - from Assay Development to Release Testing

- Different therapeutics – different analytical methods
- Differences during product development – which level is necessary at which stage?
- Regulatory needs versus internal needs for characterization – mandatory or nice to have?
- Product release & stability studies – and their specification
- Examples of dedicated methods – high end discussion & alternatives

Dr Markus Fido, MFI Consulting

Selection of Appropriate Methods for Detection of Microbiological Contaminations in ATMPs

- Shelf life of many ATMPs is usually short (one to five days); in addition, many ATMPs are derived from cells and tissues
- For ATMPs with a shelf life of three to five days, several methods are available
- For ATMPs with an even shorter shelf life of approximately one day, just a few are available for cell based products
- In the presentation data is shown achieved by using rapid ATP bioluminescence for standard rapid tests and qPCR for ultra rapid testing

Dr Stefanie Bayer, Labor LS

Programme Day 2

Innovations in Quality Control for Cell and Gene Therapy using Digital PCR

- Feasibility of determining AAV genometiter,
- Evaluating AAV Genome Integrity on dPCR using linkage analysis
- Calculating full/empty capsid ratio using multiplex data on dPCR
- Choosing the right technology for product safety and quality (e.g. resDNA)
- Update on regulatory guidelines for dPCR

Dr Mahdieh Rahmatollahi, Thermo Fisher Scientific

Development of a Digital PCR-Based System for the Detection of Residual DNA in Pharmaceutical Pproducts

- Residual DNA - the presence of DNA fragments from a host organism in the final product from recombinant biological processes
- Safety concern due to their associated increased oncogenicity, infectivity, and immunogenicity
- Regulatory Limits
- Digital PCR (dPCR)as a higher sensitive system in comparison to the golden standard qPCR
- Three dPCR-based detection kits for the detection of residual DNA impurities in pharmaceutical products manufactured in Escherichia coli, Chinese hamster ovary cells (CHO) or HEK293 human cells

Dr Nicole Paland, Minerva Biolabs

Transfer of Complex Analytical Methods for ATMPs

- Technology transfer framework
- Concept and modes of tech transfer
- Applications and implications for complex analytical methods
- Case studies

Dr Cornelia Rosner, Minaris

Mycoplasma Testing & Evaluation for ATMPs – Lessons Learned!

- Comparison of SYBR-Green based and probe-based assay
- Challenges in method development & analysis
- Troubleshooting
- Method validation of a probe-based assay

Olga Müller, Tetec

Challenges of Endotoxin Detection During Development of a Novel product

- Presentation of a case study for identification of an analytical method for the quantification of endotoxin associated with a novel immunotherapeutic virus-like particle (VLP), where intrinsic endotoxin contamination is expected
- Demonstration how development of novel drug products can raise new challenges for endotoxin testing
- Comparison of BET and MAT testing for this new product
- Overcoming BET limitations for this product with MAT

Dr Ruth Röder, Microcoat

Automating the Future of Cell and Gene Therapy: Streamlining Endotoxin Detection, Data Integrity and Compliance Solutions with recombinant Factor C

- he interest of a highly specific endotoxin detection assay based on ELISA-technology and recombinant Factor C (rFC) to overpower the C&GT product interferences
- he advantages of semi- and full automation of endotoxin testing for the streamlining of the cell and gene therapy quality control program
- High throuput full automated endotoxin testing with data integrity
- How to achieve compliance (EP and USP chapters for endotoxin testing update, Annex 1 overview for data integrity)

Dr Christian Faderl, bioMerieux

Easy Registration

Registration Form:
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+49 (0) 6221 84 44 34

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www.pharmalab-congress.com

Registration Options PharmaLab 2023

I want to take part in:

- ☐ PharmaLab Pre-Conference Workshop "4th International Mycoplasma qPCR Testing User Day" (20 Nov 2023) - € 590,- plus VAT
- ☐ PharmaLab Conferences on 21 Nov 2023 – € 690,- plus VAT
- ☐ PharmaLab Conferences on 22 Nov 2023 – € 690,- plus VAT
- ☐ PharmaLab Conferences on 21 and 22 Nov 2023 – € 1,380,- plus VAT

With a one-day ticket/two-day ticket for the PharmaLab Conferences (21 Nov/22 Nov 2023) you can attend any conference offered that day/both days. It includes 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.

☐ Yes, I would also like to take part in the Social Event on the evening of 21 November. ☐ No

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 (21 November 2023)** and I'm primarily interested in the conference:

- ☐ ECA – GMP Compliance Trends in Analytical Laboratories/Outsourcing in Pharmaceutical Laboratories
- ☐ ECA – Analytical Method Validation and Life Cycle Management - ICH Q14/Q2 (R2) (Day 1)
- ☐ ECA – Endotoxin and Pyrogen Testing (Day 1)
- ☐ ECA – Alternative and Rapid Microbiological Methods (Day 1)
- ☐ ECA – Cell and Gene Therapies/ATMPs - Quality and Safety (Day 1)

☐ I would like to attend on **day 2 (22 November 2023)** and I'm primarily interested in the conference:

- ☐ ECA – Laboratory Optimization, Automation and Digitalization
- ☐ ECA – Analytical Method Validation and Life Cycle Management - ICH Q14/Q2 (R2) (Day 2)
- ☐ ECA – Endotoxin and Pyrogen Testing (Day 2)
- ☐ ECA – Alternative and Rapid Microbiological Methods (Day 2)
- ☐ ECA – Cell and Gene Therapies/ATMPs - Quality and Safety (Day 2)

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.

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

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Reservation Form (Please complete in full)

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