



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

# Bioanalytic Bioassays QC Testing

Bioanalytics and Bioassays:  
Challenges for Biological Drug Substances  
and Products

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Testing and Analytics of Cells, Tissues  
and ATMPs

12-13 November 2019 | Düsseldorf/Neuss, Germany

# Bioanalytics and Bioassays - Challenges for Biological Drug Substances and Products - 12 November 2019, Düsseldorf/Neuss -

## Objectives

This Conference will inform you about GMP, GLP and GCLP principles and how they apply to potency Bioassay, limits tests, pharmacokinetics. You become informed about

- International regulatory requirements
- Current developments of methodology
- Pharmacokinetics
- Biosimilar characterization

## Background

The number of biopharmaceutical products is increasing in the clinic and in the market. Their excellent targeting ability is the result of a high complexity. Therefore suitable analytical tests are necessary to ensure the structure and purity of biopharmaceutical drug substances and drug products. But the complexity cannot be measured by analytical tests alone. Therefore, the development process of all biopharmaceutical products requires non-analytical tests to fully evaluate their functionality and safety. Biopharmaceutical development is a multi-disciplinary effort that involves many professionals with diverse backgrounds. This course will help team members without the appropriate technical background by clarifying the timelines, requirements and significance of Bioassays based testing. The types of methods that will be addressed are cell-based assays, immunoassays and molecular assays.

## Target Group

- Manufacturing process professionals
- QA/QC staff and regulatory personnel
- Clinical staff, pharmacologists and toxicologists
- Project Managers & outsourcing personnel
- Analytical chemists and biochemists

## 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

*Markus Roucka, VelaLabs – A Tentamus Company*

## Speakers

*Thomas Fechner, Agilent Technologies, Germany*  
Principal Scientist.

*Dr Marcus Gutmann, Microcoat Biotechnologie, Germany*  
Project Leader Endotoxin Services.

*Dr Norbert Handler, RD&C Research, Development & Consulting*  
Managing Director.

*Patrick Jackson, GSK, UK*  
Investigator in CMC-Analytical.

*Thomas Ludwig, VelaLabs A Tentamus Company, Austria*  
Group Leader for cell-based assays.

*Markus Roucka, VelaLabs – A Tentamus Company, Austria*  
Lab Head and Business Development.

*Prof. Dr. Hartwig Schulz, Consulting and Project Management for Medicinal and Aroma Plants, Germany*  
Prof. Dr. Schulz used to work for the Julius Kühn-Institut (JKI).

## Programme

**Key Note Presentation at the Plenum**  
**New ICH Q14 and ICH Q2 Revision – an industry view**  
*Dr Joachim Ermer, Sanofi-Aventis Deutschland*  
*Head of QC Lifecycle Management Frankfurt Chemistry*



**Regulatory Requirements of analytical procedure & validation**  
*Dr Norbert Handler, RD&C Research, Development & Consulting*

- Description of analytical procedure
- Information on validation
- Changes and re-validation?
- Practical Experiences

**How to overcome some of the challenges when analysing Biological Drug Substances and Products**

*Thomas Fechner, Agilent Technologies*

- Comparing traditional Assays with more innovative Analytical Techniques
- Sample preparation, Separation, Detection
- Data processing for multitude of Bioanalytics and Assays
- Different technologies (HPLC, UHPLC, LC-MS, LC-HRMS and others)

**Analytical Quality by Design Through the Lifecycle**

*Patrick Jackson, GSK*

- Analytical Target Profiles, how to write them, how they help technique selection, procedure development and validation
- Procedure Development Strategies
- Procedure Robustness and Ruggedness confirmation
- Procedure Knowledge and Lifecycle Management

**State-of-the-Art evaluation of potency & cell-based bioassays**

- Potency evaluation using a bioassay
- Cell based potency assays and their challenges
- Combination of assay results
- Equivalence margin development

*Thomas Ludwig, VelaLabs – A Tentamus Company*

**Process for automatization of a Bioassay**

*Dr Marcus Gutmann, Microcoat Biotechnologie*

- Why is automatization of a process needed?
- Market analysis of available instruments
- Implementation of automatized assay in a regulated environment

**Application of fast and non-destructive analysis techniques in quality and in-process control**

*Prof. Dr. Hartwig Schulz, formerly Julius Kühn-Institut (JKI)*

- Analytical screening of wild plants
- Analytics to improve breeding of medicinal plants: Selection of suitable individual plants with desired ingredient profiles
- Analytics to optimize the cultivation of medicinal plants (fertilization, location, climate, harvest time, post-harvest influences...)
- Analytics to improve the manufacturing process (drying, distillation, extraction, compounding...)
- Rapid analysis for the final inspection of pharmaceutical products

**Lectin Array – a novel technology for investigation of pharmaceutical products**

*Max Roucka, VelaLabs – A Tentamus Company*

- Testing of intact proteins with low material consumption
- Glycan profiling to perform extensive high-throughput analysis
- Enables rapid and high-sensitivity profiling of complex glycan features
- Case studies: (i) glyco-engineered mAb and (ii) Biosimilarity story

# Testing and Analytics of Cells, Tissues and ATMPs - 13 November 2019, Düsseldorf/Neuss -

## Objectives

This session 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.

## Background

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 framework 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 is a challenge for such short shelf life products. Examples for the challenges are:

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

## Target Group

This seminar 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

## Moderation

*Dr Markus Fido, VelaLabs – A Tentamus Company*

## Speakers

*Dr Jörg Degen, Eurofins BioPharma Product Testing, Germany*  
Head of Microbiology.

*Dr Ilona Kalaszczynska, Medical University of Warsaw, Poland*  
Scientist at University Warsaw and QC Manager BMCT.

*Dr Claude Lemarié, Center for Cell Therapy Marseille, France*  
QC Management.

*Dr Michael J. Miller, Microbiology Consultants, USA.* Global expert in rapid methods, validation and pharmaceutical microbiology.

*Dr Claudia Papewalis, Valicare, Germany.* Senior GMP Consultant.

*Dr Antonio Rodríguez Acosta, Andalusian Initiative for Advanced Therapies -Biomedicines Institute (IBIMA), Spain.*  
Quality Manager and Deputy Qualified Person at Cell Manufacturing Unit (Regional University Hospital, Málaga. Spain).

*Dr Sigrid Roosendaal, Quality RA, The Netherlands.*  
Senior Consultant.

## Programme

**Key Note Presentation at the Plenum  
Laboratory Services - from Outsourcing to a  
strategic partnership**

*Dr Jürgen Balles, Dr Thomas Meindl and Ingo Grimm, Labor LS*



**Suitability of the test method for the test 'Microbiological Examination of cell-based Preparations' according to EP 2.6.27**

*Dr Jörg Degen, Eurofins Product Testing*

- EP 2.6.27
- Method description
- Comparison to 2.6.1
- Challenges
- Outlook to rapid methods

**RMM for sterility testing of an oncology cell therapy product using ATP bioluminescence**

*Dr Michael J. Miller, Microbiology Consultants*

- Method selection and validation
- Qualify a rapid sterility test and justify a novel sampling plan
- Pitfalls and regulatory discussions

**Validation of a flow cytometry based quantitative lymphocyte immunophenotyping method to qualify cellular products for immune effector cells processing**

*Dr Claude Lemarié, Center for Cell Therapy Marseille*

- Testing required
- Methodology
- Expected values and interpretation



Image: Charles River Laboratories

**Microbiological testing of Cell Based Medicinal Products using automated growth based methods**

*Dr Antonio Rodríguez Acosta, Andalusian Initiative for Advanced Therapies-Biomedicines Institute (IBIMA)*

- Saving efforts: method suitability results in cell based medicines
- Automated growth based methods: Alternative or Rapid Microbiological Methods?
- How to improve the method? Wishes of users.

**Challenges for cell-based medicinal products**

*Dr Ilona Kalaszczynska, Medical University of Warsaw*

- How to increase stability of cell-based medicinal products
- Can growth medium influence properties of cell-based medicinal product
- Variability between donors – how it can affect production process?

**Filling the gap – from bench to bedside**

*Dr Claudia Papewalis, Valicare*

- Safety, Identity and Functionality
- Regulatory Requirements
- ICH Q2(R)
- Strategies, Scheduling and Reporting
- Approval, market authorization and life cycle management

**Cell Based Potency Assays: Analytical Considerations from a Regulatory Perspective**


*Dr Sigrid Roosendaal, Quality RA*

- Development of a meaningful cell-based potency assay
- Approaches to limit analytical variation
- Validation and life cycle management of the potency assay

## Easy Registration

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

 **Reservation Form:**  
+ 49 6221 84 44 34

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

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

### Dates

Tuesday, 12 November 2019, 09.00 – 18.00 h  
Wednesday, 13 November 2019, 09.00 – 18.00 h  
(Registration 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 „2nd International Mycoplasma qPCR Testing User Day" € 490,-  
12 November 2019 € 690,-  
13 November 2019 € 690,-

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  
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D-69007 Heidelberg  
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### 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 Strohwalde (Organisation Manager) at +49-6221/84 44 51, or per e-mail at [strohwalde@concept-heidelberg.de](mailto:strohwalde@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)  
 Conferences on 12.11.2019  
 Conferences on 13.11.2019

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

- Bioanalytics and Bioassays - Challenges for Biological Drug Substances and Products** (12 November 2019)  
 **Testing and Analytics of Cells, Tissues and ATMPs** (13 November 2019)

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

Title, first name, surname

Company

Department

**Important:** Please indicate your company's VAT ID Number

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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 %.

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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)! (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

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