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# Bioassays – Performance and Statistical Interpretation

# Stability Testing of Biopharmaceuticals

## Düsseldorf/Neuss, Germany
## 19-20 November 2014

**SPEAKERS**

**PROF DR TUDOR ARVINTE**
University Basle, Switzerland

**DR THOAMS FLAD**
Protagen, Germany

**DR MARKUS FIDO**
Vela Laboratories, Vienna, Austria

**DR TINO GALGON**
IDT GmbH, Dessau-Roßlau, Germany

**DR KARINE GONZALES**
Vela Laboratories, Austria

**DR ULRIKE HERBRAND**
Charles River Biopharmaceutical Service

**DR JON S. KAUFFMAN**
Eurofins Lancaster Laboratories, Pennsylvania, USA

**DR MANUELA LEITNER**
AGES – Austrian Agency for Health and Food Safety

**CHRISTIAN LINDEMANN**
Eufets, Germany

**DR MARCUS MREYEN**
Protagen

**DI (FH) MARKUS ROUCKA**
Vela Laboratories, Austria

**DR PETRA SCHLICK**
AGES – Austrian Agency for Health and Food Safety

**VERA SIMIC**
Medicines and Medical Devices Agency of Serbia

**ASHLEIGH WAKE**
Intertek Lifesciences, UK

**MRS ZABIN YOUNES**
SGS M-Scan, United Kingdom

**HIGHLIGHTS:**

- Bioassays – Performance and Statistical Interpretation
  - Regulatory Requirements and Expectations
  - Pharmacokinetics
  - Biosimilars Characterization
  - Cell Potency Assays
  - Orthogenal Methods
  - HCP Assays

- Stability Testing of Biopharmaceuticals
  - Regulatory Requirements
  - Stability studies - shelf-life, activities and essential documents
  - Key Points of Consideration in Biotech Stability Testing
  - Optimising Packaging and Storage Conditions for Biotech Products

# Bioassays – Performance and Statistical Interpretation

## Objectives

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

Make yourself familiar with

- 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 that 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 Audience

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

## Moderator

Markus Roucka, *Vela Laboratories*

## Social Event

On the evening of the first congress day, on 19 November 2014, 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.

## Programme

**Regulatory Expectations and Experiences**

- Bioassays: Definition & requirements
- Relevant guidance documents
- A Regulator´s view on Bioassays for vaccines

**DR PETRA SCHLICK,** *AGES*

**Pharmacokinetics**

- Principle set-up and relevant guidelines
- Matrix evaluation and analytical design
- Comparison of two platform technologies
- Case Study for a monoclonal antibody

**DR KARINE GONZALES,** *Vela Laboratories*

**Influenza vaccine - SRD method in haemagglutinin antigen content determination**

- Influenza vaccine - strain selection, reagents preparation, production and vaccine types
- Regulatory requirements
- Assay parameters and assay performance evaluation and optimization
- Automated zone measurement vs optical zone measurement
- Results statistical interpretation by Combistats
- Trend analysis and lot to lot consistency monitoring

**VERA SIMIC,** *Medicines and Medical Devices Agency of Serbia*

**Design of cell lines for potency assays**

- Stable genetic modification and cell line selection
- Case studies: CDC, ADCC, binding assay
- Application in compliance with GMP

**CARSTEN LINDEMANN,** *Eufets*

**Characterization of Biosimilars with defined Bio-assays**

- Cytotoxicity assays (CDC, ADCC)
- Surrogate ('cell-free') approaches
- ICH Guidelines for Bioassays

**DI (FH) MARKUS ROUCKA,** *Vela Laboratories*

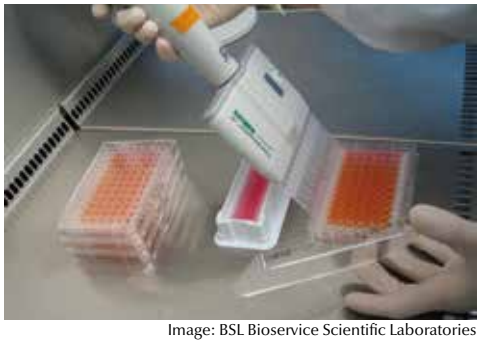

Image: BSL Bioservice Scientific Laboratories

**HCP Assay – New tools for an ongoing challenge**

- Stability Testing for QTPP Definition
- End of Shelf life
- Defining Stability programs linked to Reference Material
- Regulatory and practical Aspects
- Case Studies

**DR THOMAS FLAD,** *Protagen*

**Bioactivity Testing for Protein Therapeutics**

- Monoclonal Antibodies
- Biocomparability

**DR ULRIKE HERBRAND,** *Charles River Biopharmaceutial Service*

**Importance of Orthogonal Methods in the Analysis of Protein Aggregation: Case Studies**

- Complexity and diversity of protein aggregation
- Importance of analytical methods fo the success of biopharmaceuticals
- Presentation of new orthogonal methods
- Case studies

**PROF TUDOR ARVINTE,** *University Basle*

# Stability Testing of Biopharmaceuticals

## Objectives

During this course you will get to know the relevant aspects of stability testing for biological and biotechnological drug substances and drug products. You will learn about

- the basic requirements of stability testing and stability study design from the supervisory authority's view
- the peculiarities of stability indicating analytical methods
- optimising strategies regarding packaging and storage of biological/biotechnological material
- how to submit stability data for a marketing authorisation dossier according to the new Guideline on Quality Documentation

## Background

The active components in biotechnological/biological products are typically proteins and/or polypeptides. They have distinguishing characteristics to which consideration should be given in any well-defined testing program designed to confirm their stability during the intended storage period. The products are particularly sensitive to environmental factors such as temperature changes, oxidation, light, ionic content, and shear. In order to ensure maintenance of biological activity and to avoid degradation, stringent conditions for their storage are usually necessary.

The evaluation of stability may necessitate complex analytical methodologies. Appropriate physicochemical, biochemical and immunochemical methods for the analysis of the molecular entity and the quantitative detection of degradation products should also be part of the stability program.

In order to get the approval to conduct a clinical trial data have to be presented on the biological, chemical and pharmaceutical quality of Investigational Medicinal Product (IMP). In the new **Guideline on the Requirements for Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials** particular provisions are laid down on how to document stability and other quality related data within the CTD structure.

## Moderator

Dr Markus Fido, *Vela Laboratories*

## Target Audience

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

Image: Vela Laboratories

## Programme

**Stability studies - shelf-life, activities and essential documents**

- Product stability - a challenge for complex molecules
- Stability studies: Stability indicating methods not only for the FC
- Evaluation, specification and reporting

**DR MARKUS FIDO,** *Vela Laboratories*

**Regulatory Requirements**

- Guidance documents
- Authorities Expectation
- Classical Issues

**DR MANUELA LEITNER,** *AGES*

**Stability Studies: Key Points Of Consideration in Biotech Stability Testing**

- Overview of Stability and Associated Testing during the drug development lifecycle.
- How and when to do associated testing;
- Forced degradation studies, Shipment support studies and Compatibility Studies.

**MRS ZABIN YOUNES,** *SGS M-Scan*

**Critical Success Factors of a Biologics Stability Program**

- Method implementation
  - Method development or feasibility
  - Prevalidation/robustness testing
  - Protocol development
  - Validation or Transfer
- Stability study protocol
- Weekly Discussion
  - Agenda
  - Status
  - OOS/Investigations
  - Reference standard inventory

**DR JON S. KAUFFMAN,** *Eurofins Lancaster Laboratories*

**Stability Testing in Biosimilar Development – additional aspects to be considered**

- Stability Testing for QTPP Definition
- End of Shelf life
- Defining Stability programs linked to Reference Material
- Regulatory and practical Aspects
- Case Studies

**DR MARCUS MREYEN,** *Protagen*

**Stability Testing Experiences**

**ASHLEIGH WAKE,** *Intertek Lifesciences*

**Optimising Packaging and Storage Conditions for Biotech Products**

- Peculiarities of biotech products
- Transport/Storage conditions:
  - Planning of stability testing considering the supply chain
  - Cost-benefit considerations
  - Examples of stability studies
  - Presentation and documentation of data
- Packaging
  - Specific characteristics of packaging materials
  - Photostability studies
  - Transportation stress studies

**DR TINO GALGON,** *IDT Biologica*

# Speakers

**PROF TUDOR ARVINTE,** *Ph.D., Professor, Department of Biopharmaceutics, University of Geneva, Switzerland*
CEO, Therapeomic, Inc.

**DR THOMAS FLAD,** *Protagen Protein Services, Heilbronn, Germany*
Global Director Business Development.

**DR MARKUS FIDO,** *Vela Laboratories, Vienna, Austria*
Founder and Chief Executive Officer.

**DR TINO GALGON,** *IDT Biologica GmbH, Dessau-Roßlau*
Director Pharmaceutical Development, responsible for development of formulations, development and validation of analytical methods as well as process development.

**DR KARINE GONZALES,** *Vela Laboratories, Vienna, Austria*
Senior Scientist at Dept. Assay Development.

**DR ULRIKE HERBRAND,** *Charles River Biopharmaceutical Service GmbH, Erkrath, Germany*
Scientific Officer Biosafety & Bioassay Services, Biologics Testing Solutions.

**DR JON S. KAUFFMAN,** *Eurofins Lancaster Laboratories, Pennsylvania, USA*
Senior Director, Biopharmaceutical Services.

**DR MANUELA LEITNER,** *AGES – Austrian Agency for Health and Food Safety*
Quality Assessor for plasma derived Medicinal Products and Plasma Master File.

**CARSTEN LINDEMANN,** *Eufets, Idar Oberstein, Germany*
Project Management RNA manufacturing projects for external customers.

**DR MARCUS MREYEN,** *Protagen Protein Services, Heilbronn*
Director Business development.

**DI MARKUS ROUCKA,** *Vela Laboratories, Vienna, Austria*
Head of Laboratory, Dept. Assay Development.

**DR PETRA SCHLICK,** *AGES – Austrian Agency for Health and Food Safety*
Quality Assessor Biologics, Dept. BPSV.

**VERA SIMIC,** *Medicines and Medical Devices Agency of Serbia*
Scientist at National Control Laboratory- Biological Laboratory.

**ASHLEIGH WAKE,** *Intetek Lifesciences, United Kingdom*
Biotechnology Programm Manager.

**ZABIN YOUNES,** *SGS M-Scan Ltd, United Kingdom*
Stability Services Manager.

# Agenda

| Time | Bioassays – Performance and Statistical Interpretation<br>Wednesday, 19 November 2014 | Stability Testing of Biopharmaceuticals<br>Thursday, 20 November 2014 | Time |
|---|---|---|---|
| 9.00 h | Welcome and Introduction | Welcome and Introduction | 9.00 h |
| 9:15 h | Regulatory Expectations and Experiences<br>*Dr Petra Schlick, AGES* | Stability Testing of Biopharmaceuticals<br>*Dr Markus Fido, Vela Laboratories* | 9:15 h |
| 9.30 h | | | 9.30 h |
| 9:45 h | Pharmacokinetics<br>*Dr Karine Gonzales, Vela Laboratories* | | 9:45 h |
| 10.00 h | | Regulatory Requirements<br>*Dr Manuela Leitner, AGES* | 10.00 h |
| 10:15 h | | | 10:15 h |
| 10.30 h | Influenza Vaccine – SRD Method in Haemagglutinin antigen content determination<br>*Vera Simic, Medicines and Medical Devices Agency of Serbia* | | 10.30 h |
| 10:45 h | | | 10:45 h |
| 11.00 h | Break<br>*(Take advantage of the break to visit the exhibition)* | Break<br>*(Take advantage of the break to visit the exhibition)* | 11.00 h |
| 11:15 h | | | 11:15 h |
| 11.30 h | Design of cell lines for potency assays<br>*Carsten Lindemann, Eufets* | Stability Studies: Key Points Of Consideration in Biotech Stability Testing<br>*Mrs. Zabin Younes, SGS M-Scan* | 11.30 h |
| 11:45 h | | | 11:45 h |
| 12.00 h | | | 12.00 h |
| 12:15 h | Characterization of Biosimilars with defined Bioassays<br>*DI (FH) Markus Roucka, Vela Laboratories* | Critical Success Factors of a Biologics Stability Program<br>*Dr Jon S. Kauffmann, Eurofins Lancaster Laboratories* | 12:15 h |
| 12.30 h | | | 12.30 h |
| 12:45 h | | | 12:45 h |
| 13.00 h | Lunch Break<br>*(Take advantage of the break to visit the exhibition)* | Lunch Break<br>*(Take advantage of the break to visit the exhibition)* | 13.00 h |
| 13:15 h | | | 13:15 h |
| 13.30 h | | | 13.30 h |
| 13:45 h | | | 13:45 h |
| 14.00 h | | | 14.00 h |
| 14:15 h | | | 14:15 h |
| 14.30 h | HCP Assay – New tools for an ongoing challenge<br>*Dr Thomas Flad, Protagen* | Stability Testing in Biosimilar Development – additional aspects to be considered<br>*Dr Marcus Mreyen, Protagen* | 14.30 h |
| 14:45 h | | | 14:45 h |
| 15.00 h | | | 15.00 h |
| 15:15 h | Bioactivity Testing for Protein Therapeutics<br>*Dr Ulrike Herbrand, Charles River Biopharmaceutical Service* | Stability testing Experiences<br>*Ashleigh Wake, Intertek Lifesciences* | 15:15 h |
| 15.30 h | | | 15.30 h |
| 15:45 h | | | 15:45 h |
| 16.00 h | Break<br>*(Take advantage of the break to visit the exhibition)* | Break<br>*(Take advantage of the break to visit the exhibition)* | 16.00 h |
| 16:15 h | | | 16:15 h |
| 16.30 h | | | 16.30 h |
| 16:45 h | Importance of Orthogonal Methods in the Analysis of Protein Aggregation: Case Studies<br>*Prof Dr Tudor Arvinte, University Basle* | Optimising Packaging and Storage Conditions for Biotech Products<br>*Dr Tino Galgon, IDT Biologica* | 16:45 h |
| 17.00 h | | | 17.00 h |
| 17:15 h | | | 17:15 h |
| 17.30 h | Final Discussion | Final Discussion | 17.30 h |
| 17:45 h | | | 17:45 h |
| 18:00 h | | | 18:00 h |
| 18.30 h | Social Event for Congress Delegates, Speakers and Exhibitors | | 18.30 h |

## 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
Wednesday, 19 November 2014, 9.00 – 18.00 h
Thursday, 20 November 2014, 9.00 – 18.00 h
(Registration Tuesday, 18 November, 19.00 – 20.30 h and
Wednesday, 19 November/ Thursday, 20 November, 8.00 – 9.00 h)

### Venue
Swissôtel Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss
Germany
Tel.: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
Emailus@swissotel-duesseldorf.de

### Fees
EUR 690,- for one day ticket plus VAT
EUR 1.380,- for two days plus VAT

The conference fee is payable in advance after receipt of invoice and includes lunch on that day as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day (19 November 2014) 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 further information please visit 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

### 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! Charges are payable after receipt of the invoice.

### Organisation & Contact
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**For questions regarding content:**
Axel H Schroeder (Operations Director) at +49-6221/84 44 10, or per e-mail at schroeder@concept-heidelberg.de.
**For questions regarding reservation, hotel, organisation etc.:**
Mr Detlef Benesch (Organisation Manager) at +49-6221/84 44 45, or per e-mail at benesch@concept-heidelberg.de.

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I would like to attend the following conference:
☐ **Bioassays – Performance and Statistical Interpretation** (19 November 2014)
☐ **Stability Testing of Biopharmaceuticals** (20 November 2014)
Part of PharmaLab 2014, Düsseldorf/Neuss, Germany, 19-20 November 2014
☐ 2-Days Ticket for entire PharmaLab Congress (19-20 November 2014)

☐ Yes, I would like to participate in the Social Event on 19 November.
☐ Mr ☐ Ms

Title, first name, surname

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If you cannot attend the conference you have two options:
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