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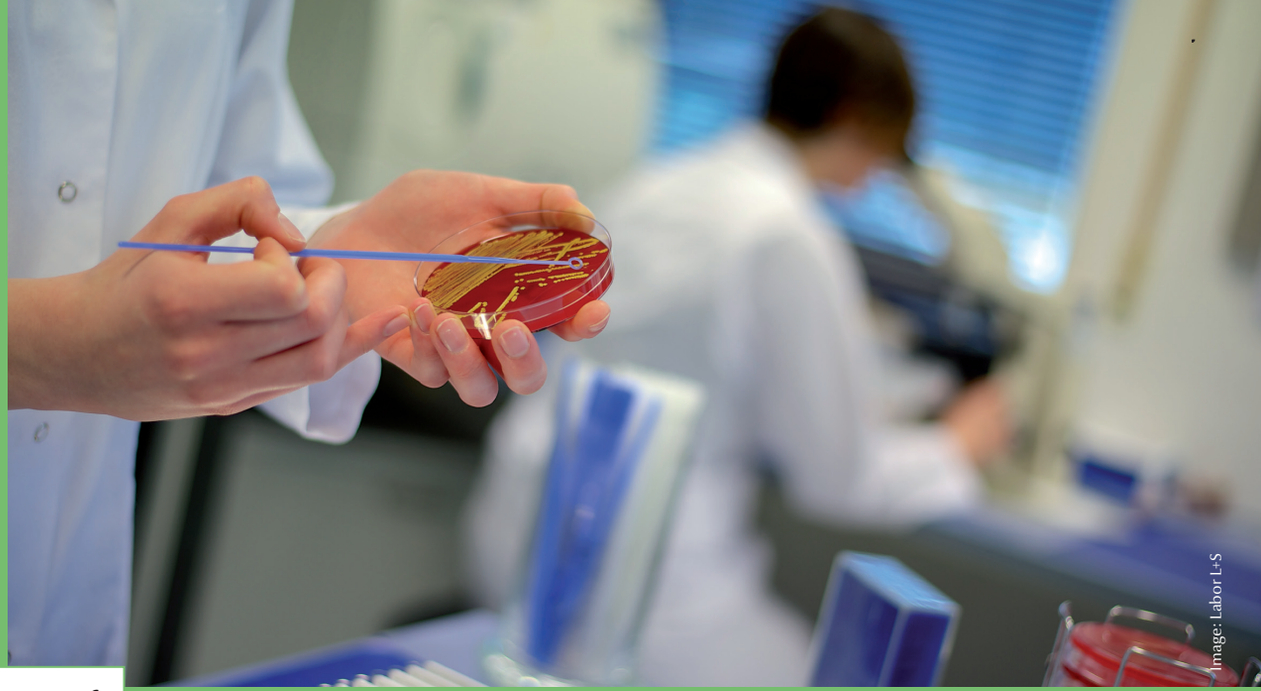

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Validation Approach of Bioassays Using Statistical Methods

SPEAKERS

PROF DR EDWIN VAN DEN HEUVEL
University of Technology, Eindhooven

DR PIETA IJZERMAN-BOON
MSD, The Netherlands

Düsseldorf/Neuss, Germany
11 November 2015

HIGHLIGHTS:

- Guidelines
- Type of Bioassays
- Basic Statistics
- Calculation
- Combination
- Test Set-up
- Accuracy and Precision
- Sensitivity and Specificity
- Linearity and Range
- Limit of Detection & Quantitation and Robustness

Validation Approach of Bioassays Using Statistical Methods

Objectives

The number of biopharmaceutical products is increasing in the clinic and in the market. This requires the development of biological tests to fully evaluate the biological functionality and safety. For the validation of such bioassays several experiments must be performed to demonstrate that the method is capable of measuring the biological activity of test samples. To quantify the performance statistical methods form an indispensable tool.

Background

This workshop will provide information on the types of experiments and the statistical analyses that may be performed to calculate the bioactivity and estimate the validation parameters of bioassays. The workshop will discuss the guidelines on analysis and validation and the methods will be illustrated with real cases on bioassays.

Moderator

Prof. Edwin van den Heuvel, *University of Technology, Eindhoven*

Target Audience

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

Speakers

PROF. EDWIN VAN DEN HEUVEL, *University of Technology, Eindhoven, The Netherlands*
Edwin van den Heuvel started his professional career in Statistics after obtaining his PhD in 1996. He started as a consultant in industrial statistics with the Institute of Business and Industrial Statistics and afterwards became head of the statistics department at the pharmaceutical company MSD. Since 2010 he is fulltime professor Medical Statistics at the UMCG (University Medical Center Groningen). Since October 2014 he is Professor at the TU/e department of Mathematics and Computer Science will be closely involved with the development of the Data Science Center Eindhoven (DSC/e).

DR PIETA IJZERMAN-BOON, *MSD, Oss, The Netherlands, Associate Director Quantitative Sciences/Center for Mathematical Sciences-Europe*
Pieta C. IJzerman-Boon received her education at the University of Twente, the Netherlands. In 1995 she obtained her M.Sc. degree in Applied Mathematics, followed by a Ph.D. in Statistics in 1999. She joined MSD after her PhD. In 2011 she moved to the non-clinical statistics group in the company, where she currently works as a senior statistician at the Center for Mathematical Sciences.

Programme

Introduction
- Guidelines
- Type of bioassays
- Basic Statistics

Bioactivity (USP <111>, EP5.3)
- Calculation
- Combination
- Test set-up

Statistics for validation (USP<1032>, <1033>, <1034>)
- Accuracy
- Precision
- Sensitivity & Specificity
- Linearity & Range
- Limit of detection & quantitation
- Robustness

Agenda

Time	Validation Approach of Bioassays Using Statistical Methods Wednesday, 11 November 2015
9.00 h	Welcome and Introduction
9:15 h	**Module I:** Guidelines
9:45 h	Type of Bioassays
10.30 h	Basic Statistics
11.00 h	Break *(Take advantage of the break to visit the exhibition)*
11.30 h	**Module II – Bioactivity (USP <111>, EP5.3):** Calculation
12.00 h	Combination
12.30 h	Test Set-Up
13.00 h	Lunch Break *(Take advantage of the break to visit the exhibition)*
14.30 h	**Module III – Statistics for Validation (USP <1032>, <1033>, <1034>):** Accuracy and Precision
15:15 h	Sensitivity and Specificity
16.00 h	Break *(Take advantage of the break to visit the exhibition)*
16:45 h	Linearity And Range
17.30 h 18:00 h	Limit of Detection & Quantitation and Robustness

Easy Registration

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69007 Heidelberg
Germany

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Dates
Wednesday, 11 November 2015, 09.00 – 18.00 h
(Registration Wednesday, 11 November 08.00 – 09.00 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
€ 690,- (€ 345,- for EU GMP Inspectors) for one day ticket plus VAT
€ 1.380,- (€ 690,- for EU GMP Inspectors) for two days ticket plus VAT

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**.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.pharmalab-congress.com

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