26-28 September 2012  Lisbon, Portugal

Main Conference Topics
The BEBPA bioassay conference is designed by practicing bioassay scientists to tackle topics to help you develop, validate and maintain your bioassay.

This year topics include:

- Statistical Approaches to Understanding and Conquering Assay Variability
- Replacing Primary Cells in Your ADCC Potency Assay
- Developing Animal Based Potency Assay
- How to Replace an Animal Assay with a Cell-Based Method
- Developing a Battery of Assays to Characterize Antibody Fc Function
- Problems with BioAssay Monitoring and Pragmatic Solutions
- Validation of Multiplexed Assays

Plus! Two One Day Pre Conference Workshops to Choose from!

Workshop #1: Host Cell Protein Assay Development, Validation & Use in a QC Environment

Workshop #2: Process Capability: The Role of the Bioassayist

….and Case Studies!
- Nab assay for a nanobody product
- Developing cultured cell lines for ADCC effector cells
- Replacing animal FSH assay with a cell based method
- Developing a murine potency assay for a vaccine
- Testing biosimilar antibody products

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BEBPA’s 5th Annual Biological Assay Conference

Pre Conference Workshop #1 26 September 2012
Host Cell Protein Assay Development, Validation and Use in a QC Environment

A one-day workshop will be held on host cell protein impurity assays. Topics to be addressed include both technical and quality control issues. Technical topics include demonstrating antibody reagent coverage for HCP proteomes, the impact of assay format (particularly homogeneous vs. heterogeneous assays), and the use of multi-product assays vs. product-specific assays. Proteomic approaches to identifying specific HCP impurities in products will also be addressed. Quality aspects include varying specifications during product life cycle, the role of process validation of impurity clearance vs. lot release testing, and HCP profiles in second generation biologics. This workshop is the working session for starting an annual BEBPA conference on this topic to alternate between the US and EU. Please attend and become part of the future conference. Speakers below are confirmed but we are looking for more case studies.

### Schedule

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:30-8:45</td>
<td>Opening remarks</td>
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<tr>
<td></td>
<td>Chaired by Drs. Martin Vanderlaan and Laureen Little</td>
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<tr>
<td>8:45-9:15</td>
<td>Overview Talk</td>
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<td>Dr. Martin Vanderlaan, Director, Genentech</td>
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<td>9:15-10:30</td>
<td>Host Cell Development Case Studies</td>
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<td></td>
<td>• Biogen-Idec</td>
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<td>• BioMarin</td>
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<td>• Pfizer</td>
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<td>10:30-11:00</td>
<td>Morning Break</td>
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<tr>
<td>11:00-12:00</td>
<td>Clinical Significance of HCP exposure in patients</td>
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<td></td>
<td>• Invited**</td>
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<tr>
<td>12:00-1:30</td>
<td>Lunch</td>
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**We are currently looking for talks related to this topic. If you are interested in giving a talk, please send a title and abstract to bebpa@surewest.net.

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Pre Conference Workshop #2, 26 September 2012
Process Capability, The Role of the Bioassayist

Within the biotherapeutic industry there is an awakening of interest in process capability, the ability of a process to meet customer specifications. A process is considered capable if it can meet customer specifications at least 99.74% of the time. Process capability compares the voice of the process (represented by its mean and variation) with the voice of the customer (represented by specifications that express fitness for use). However, the true variation of a process (and its true capability) can never be known because the methods that are used to determine process variability superimpose their own measurement variability. Thus, it is important that the measurement variability be small compared to the expected process variability. This workshop develops the theoretical basis of process capability and its various indexes, and suggests ways of reducing bioassay measurement variability or making allowances for its presence.

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<tr>
<td>9:00-9:15</td>
<td>Open of Workshop: Organizer’s Comments</td>
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<td>Dr. Stanley Deming, PhD, Statistical Designs</td>
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<td></td>
<td>Dr. Stanley Deming, President, Statistical Designs, USA</td>
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<tr>
<td>10:30-11:00</td>
<td>Morning Break</td>
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<tr>
<td>11:00-12:00</td>
<td>“Process Capability Concepts, Part II”</td>
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<td>Dr. Stanley Deming, President, Statistical Designs, USA</td>
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<td>12:00-1:30</td>
<td>Lunch</td>
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<tr>
<td>1:30-2:15</td>
<td>The Dreaded OOS: Real or Phantom?</td>
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<td></td>
<td>David Lansky, President, Precision Bioassay</td>
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<td>2:15-3:00</td>
<td>Reducing Sources of Bioassay Variability</td>
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<td>Timothy Schofield, Managing Director, Arlenda, Inc</td>
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<tr>
<td>3:00-3:30</td>
<td>Afternoon Break</td>
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<tr>
<td>3:30-4:15</td>
<td>Reducing Sources of Bioassay Variability</td>
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3 Ways to Register:

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Session 1: Bioassays for Antibody Products

Session Chaired by: Hans Joachim Wallyn, PhD, Novartis

9:50-10:30: Biological Methods for Assessment of Fc Effector Function of Antibodies and Fc-containing Molecules.

Dr. Svetlana Bergelson, Associate Director Biogen-Idec
10:30-11:00: Morning Break

11:00-11:40: Case study of a monoclonal antibody analyzed with three different bioassays.

Mette Willer Oldenborg, Sr. Research Scientist, Novo Nordisk

11:40-12:20: Troubleshooting on Performance When Developing Bioassays for mAb’s.

Dr. Ulrike Herbrand, Scientific Officer, Charles River Biopharmaceutical Services

12:20-1:30: Lunch

1:30-2:00: Mode of Action Testing of Therapeutic Antibodies.

Dr. Laureen Little, Principal Consultant, Quality Services

2:00-2:30: ADCC Potency Assays for Biosimilar Monoclonal Antibody Analysis.

Dr. Laureen Little, Principal Consultant, Quality Services

2:30-3:00: Development of a Bioluminescent Cell-based Bioassay to Measure Fc Effector Functionality in Antibody-dependent Cellular Cytotoxicity.

Dr. Ulrike Herbrand, Scientific Officer, Charles River Biopharmaceutical Services

3:00-3:30: Afternoon Break

3:30-4:00: Regulatory-Compliant Validation of a Standardized ADCC Potency Assay.

Dr. Teresa Surowy, R&D, Promega Corporation, USA


Dr. Alexis Rossignol, Project Manager, Clean Cells.

5:20-6:00: Problems with monitoring Assays:

Drs. Stanley Deming, Bassam Hallis with Pamela Proud.
9:00-9:10: Welcome

Bioassay Development Case Studies

9:10-9:50: Accounting for variability in relative potency estimates
Bioassays are inherently variable. It is not sufficient to report only estimates of relative potency. The variability of relative potency must also be calculated and reported. The variability of a relative potency estimate is increased by the noisiness of the assay data and the lack of fit to the model, including lack of fit due to non-parallelism. In this presentation we explore how variability can be used to assess the suitability of assays. We also demonstrate how, as an alternative to suitability testing, variability can be incorporated into downstream analyses. Specifically we use lot release testing and the estimation of shelf life as examples. We show that by incorporating variability into these analyses, rather than excluding assays through suitability testing, it is possible to make the best use of available data.

Kelly Fleetwood, Statistician, Quantics Consulting Ltd

9:50-10:30: Bioassay Design
Bioassay designs are constrained by practical considerations, statistical principles, and variation in biological materials. Good design, lab technique, and analyses combine to yield high performance bioassays. Recent simulations illustrate the impact of design and analysis on bioassay performance over useful ranges of potency and variation (both within and between assays).

David Lansky, President, Precision Bioassay

10:30-11:00 Morning Break

11:00-11:40: Development and validation of a neutralizing antibody assay for anti-von Willebrand factor Nanobody® ALX-0081
Nanobodies® represent a novel class of therapeutic proteins based on the smallest functional fragment of heavy chain antibodies naturally occurring in the Camelidae family. The anti-von Willebrand factor (vWF) Nanobody ALX-0081 is in clinical development for treatment of patients with acquired thrombotic thrombocytopenic purpura (TTP), a rare thrombotic condition. To support assessment of immunogenicity, a functional neutralizing antibody (Nab) assay was developed and validated. Optimized assay conditions will be discussed, in which vWF interference was minimized and sensitivity maximized by means of sample purification. Validation results and the use of the Nab assay in clinical trials will be shown.

Dr. Tinneke Denayer, Head Pharmacology, Ablynx, NV

Developing and Replacing Animal Assays

Session Chair: Dr. Bassam Hallis, Head of Preclinical Development, HPA

11:40-12:20: Early Preclinical Development of a Murine Potency Assay for a Vaccine Product
Development of an in vivo potency assay presents many challenges. Information gathered during the earliest stages in development process is vital to determine essential parameters for further assay qualification. Each experiment adds to the knowledge base and eventually yields an assay that meets criteria for linearity, robustness, and repeatability. This presentation will summarize the development process of a murine potency assay for a vaccine product that can be analyzed using standard parallel line analysis.

Sheri D. Klas, Ph.D., Senior Preclinical Scientist, LigoCyte Pharmaceuticals, Inc.

12:20-1:30: Lunch

1:30-2:10: Challenges with validating animal component of potency assays
Potency assays are essential for the release and stability of vaccines. Most of these assays use an in vivo component involving the vaccination of animals followed by evaluation of immune responses of the generated sera. This case study will describe challenges encountered with optimisation and validation of the in-vivo component of a potency assay.

Dr. Emily Keeble, Senior Scientist, HPA

2:10-2:50: Development of multiplexed serological method for the potency testing of multicomponent vaccines
A serological potency assay on Guinea pigs is now referenced in the European Pharmacopoeia for DTacP vaccine. This alternative assay will reduce the number of animals due to the ability to use the same animals for multiple antigens. We developed a common immunogenicity assay on guinea pigs with a multiplex antibody detection method. The current potency assay was compared to the new potency assay. Data supporting the replacement of the current potency by the new alternative assay will be presented.

Martine Chabaud-Riou, R&D, Sanofi Pasteur

2:50-3:20: Afternoon Break

3:20-4:00: A New Cell Based Assay for the Replacement of the Steelman-Pohley in vivo Assay
We will present a new cell based assay (CBA) for replacement of the animal Steelman-Pohley in vivo assay for testing follicle stimulating hormone (FSH). For a single batch release test 35 animals are required in total. The new cell based assay (CBA) is based on the FSH-sensitive human granulosa cell line KGN. In KGN cells the progesterone production and secretion is induced specifically by FSH. The progesterone concentration in culture supernatants is quantified by diagnostic grade ELISA. The CBA is designed in the 96 well format for screening and full-dose-response analyses. The assay is validated for pharmaceutical batch release testing according to the USP (Chapter <1033>; Biological assay validation).

Dr. Christoph Giese, Director of QC, ProBioGen AG

4:00-4:40: Introduction to the Qualification and Validation of Titer Based Assay
The use of titer-based assays within pharmaceutical and biotechnology companies is driven in large part by the need to evaluate vaccine and drug targets derived from genomics and proteomics. Despite intensive use in drug and vaccine development, titer based assays have not been standardized and the methods of qualification and validation are not uniform. This presentation will introduce qualification and validation of titer based assays with specific examples for each ICH parameter to be assessed.

Eloi P. Kpamegan, Ph.D., MSF, Director Clinical & Nonclinical Biostatistics, Novavax, Inc

4:40-5:30: Poster Presentations

5:30: Conference Adjourns

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BEBPA: Who are we? What do we aim to accomplish?

The Biopharmaceutical Emerging Best Practices Association (BEBPA) is a not-for-profit association, founded in 2008, managed by and for the benefit of the biopharmaceutical scientific community. BEBPA provides an open forum for the presentation and discussion of scientific issues and problems encountered in the biopharmaceutical community.
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