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Biological Assays Conference

Official Brochure

28-30 September 2011, Nice, France

Hear from the following Organizations:

- Ablynx NV
- Aeras Global TB Vaccine
- Aptuit
- Boehringer Ingelheim
- Codexis, Inc
- Covance
- EDQM
- Ferring Pharmaceuticals
- GlaxoSmithKline
- Genentech
- Grey Rigge Associates
- HPA
- Lonza
- MedImmune
- NIBSC
- Novartis Pharma
- PharmaNet Consulting
- Promega Corporation
- Quality Services
- Sandoz
- Seattle Genetics
- Statistical Designs

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:

- Practical tips on qualifying rare reagents including cells and references
- Walking the statistical tightrope-practical approaches to bioassays
- Generic DOE strategies for optimization of bioassays: a two-step approach
- Automating bioassays to improve throughput and precision
- Replacing in-vivo assays with in-vitro methods
- Developing a toolkit approach to characterize Ab effector function
- USP bioassay chapter update
- Developing sensitive neutralization and other supporting assays

Plus! One Day Workshop QC– Proofing Your Bioassay

This year we will tackle the tough issues surrounding how to prepare your assay to support a commercial product. Don't struggle with the last minute activities and imposed last minute changes which can cause a delay in product commercialization. Topics include:

- Validation: ICH or Statistical Approaches
- Preparing your assay to support any potency specification
- Establishing bioassay monitoring practices
- Designing a practical and robust OOS procedure

Case Studies

.....and Cases Studies!

- Bioassays for Biosimilars
- Developing bioassays for high affinity nanobodies
- PCR analysis for supporting serological assays
- Development of a neutralizing anti-drug assay
- FC effector platform Assays
- Reporter gene bioassay development

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BEBPA's 4th Annual Biological Assay Conference

Pre-Conference Workshop: QC– Proofing Your Bioassay

9:00-9:15 Open of Workshop: Organizers' Comments
Dr. Jane Robinson, NIBSC, UK

9:15-10:00 The Validation Trap: ICH versus USP Stype Validations
Dr. Laureen Little, Principal Consultant, **Quality Services**

10:00-10:30 Repeatability - Pooling Variances
Dr. Stanley Deming, President, **Statistical Designs**, USA

10:30—11:00 Morning Break

11:00-12:00 Specifications and Capability Calculations
Dr. Stanley Deming and Dr. Laureen Little

12:00—1:30 Luncheon

1:30-2:15 QC Strategy for Confirming Out-Of-Specification Bioassay Results
Due to the inherent variability of biological assays and the variety of methods used for determining reportable result, distinguishing a true OOS bioassay result from an invalid result is complicated. FDA guidance on dealing with OOS results explicitly excludes biological assays while USP chapter <111> is silent on the topic. This talk will present one strategy implemented in a GMP QC lab to determine whether a bioassay result will be reported as a true OOS result.
Dr. Susan Robinson, QC Manager**, Seattle Genetics,** USA

2:15-3:00 Monitoring the Performance of Biological Assays: How Do You Make Sure Your Potency Assay is Telling You the Truth?
The precision and accuracy around potency measurements can vary, depending on overarching assay strategy (e.g., in vivo bioassays versus in vitro bioassays) and exact assay technology (e.g., 4-day proliferation assay versus 1- or 2-day reporter gene assay). Thus potency assays must be constantly monitored as objectively as possible to confirm proper assay execution and ensure valid data generation/analyses. This session will describe the strategies/approaches that have been used to provide sufficient assay monitoring, as well as potential pitfalls of incorrectly assigned or constrained parameters.
Dr. Michael Sadick, Sr. Manager, **Aptuit**

3:00-3:30 Exhibit/Poster and Refreshment Break

***3:30-3:45* ELISA Methods in Quality Control: Development, Monitoring and Validation**
Enzyme-linked immunosorbent assays (ELISAs) are commonly used in the Quality Control of biopharmaceuticals. Their application includes the control of the depletion of process related impurities as well as the identification, quantitation or potency determination of biological test substances. This talk provides assistance for defining key parameters in assay development, evaluation of assay performance and method validation by considering specifically the intended use of the assay to fulfill scientific and regulatory requirements.
Dr. Thomas Waerner, Head Cell & Molecular Biology, **Boehringer Ingelheim RCV GmbH & Co KG**

3:45-4:30 Validation of antibody assays based on historical data and system suitability
Dr. Mary Matheson, Senior Scientist**, HPA UK**

4:30-5:15 Applied Bayesian Statistical Analysis of Lab Data
Despite their success, frequency based statistical approaches suffer from difficulties such as the inability to formulate models in many cases of practical utility as well as issues with interpretation even when such models exist. In the last few decades computational advances have unlocked widely applicable Bayesian approaches that do not suffer such limitations. We briefly review the nature of these two paradigms and use practical examples to motivate the needs for Bayesian methods. Applied analysis drawn from common use cases of laboratory data (such as means testing, ANOVA, and ratio analysis) will be presented.
Dr. Richard Fox, Research Fellows, **Codexis Inc**

5:15 End of Workshop

Main Conference, Day 1: 29 September 2011

8:00-8:15 Open of Conference: Welcome and BEBPA Update
Dr. Laureen Little, Principal Consultant, **Quality Services**

***8:15-8:55* Developing Bioanalytical Methods - Balancing the Statistical Tightrope**
Often the inherent variability experienced with bioanalytical assays and in particular, bioassays, are commonly poorly understood and often developed in an empirical and sometimes haphazard manner. Tools do exist to help the developer but often a requirement to grasp statistics deters individuals. Furthermore the prospect of an under pressure scientist taking time out to learn a complex statistical tool of unknown benefit is easily deferred with other operational demands. This talk discusses development of assays from the development scientist's perspective with examples on how to get the balance right when developing complex assays by applying practical experience, emerging statistical tools and just plain common sense.
Dr. Lee Smith, Managing Director, **Grey Rigge Associates**

Rare Reagents for Bioassays

8:55-9:35 Effect of Critical Reagents on Bioassay Performance
Reducing assay variability is a key objective to develop high quality bioassays in quality controlled environment. Assay reagents and 96-well microtiter plates are critical components of a bioas-

say. Their effects on assay performance is often observed but yet less understood. We will describe a study aimed to systematically examine the effects of plates from various suppliers on several bioassays. The results will shed light on the causes of variability and approaches for improvement.
Dr. Frank Fan, Director of Research, **Promega Corporation**

9:30-10:15 Cells: Practical Considerations for Bioassays
Cell-based assays can be precise and easy to perform. However, well characterized cells and cell culture methods are critical to assay success. This presentation will describe the options and steps required for obtaining reproducible cell-based assay results. Case studies will address documentation, training, equipment, supplies, and reagent issues.
Michael Merges, Associate Director, **Lonza**

10:15-10:45 Morning Break

10:45-11:25 Reference Standards for Bioassays
Bioassays are comparative and use a reference standard to measure a relative potency. Development of an in-house reference standard is required early in the product development. For some products, an external reference standard (such as a pharmacopeial or WHO International Standard) may be available and suitable for calibration of the in-house standard. Issues that need to be considered in the development and use of reference standards include demonstration of functional similarity of reference standard and test material, stability of the reference standard, continuity on replacement of a reference standard and potential problems on changing the bioassay system.
Dr. Jane Robinson, NIBSC, UK

11:25-12:05 Update: USP Chapters on Biological Assays
The USP chapters on biological assay development, validation, and analysis have undergone final review prior to publication in USP NF. Comments received from industry and FDA have been addressed in the final chapters. This talk will give an overview of the chapters, highlighting both the practical and statistical recommendations. The chapters will be contrasted to other regulatory guidances on analytical methods.
Timothy Schofield, Director, Reg. Affairs, **GlaxoSmithKline**

12:05-1:30 Luncheon

Development and Validation

1:30-1:35 Session Chairs: Dr. Nicola Crawford, MedImmune, LLC and Dr. Laureen Little, Quality Services

1:35-2:05 Generic DOE for Potency Assay Optimisation
The goal of the design-of-experiment (DOE) strategy is to develop a robust potency assay with a minimal number of experiments. Once the preferred assay set-up and appropriate tools have been selected, all assay variables are to be tested in a multi-factorial DOE strategy. This approach optimises the assay conditions and identifies the important interactions between 10 predefined assay variables. A generic two-step DOE approach is proposed. First, a screening DOE is performed to screen for the most significant variables Based on the outcome of the screening DOE, a second DOE is designed comprising only the relevant variables identified in step 1. We present the application of the generic DOE strategy to develop an inhibition potency assay for a Nanobody® that inhibits its binding of a natural ligand to a cancer target.
Dr. Heidi Wouters, Biostatistician, **Ablynx NV**

2:05-2:45 Optimizing Cell-based Assay Throughput of Automated Liquid Handling Systems - Successes and Challenges
Liquid handling robotics are an underused resource in many assay applications, the technology is often dismissed in favour of the bench Analyst. Data will be presented to demonstrate that robotics can aid not only in terms of assay throughput but also delivering consistent reproduction of complex plate designs and providing gains in the observed repeatability and precision.
Dr. Louise Pritchett, Study Director, **Covance**

2:45-3:25 ***Exhibit/Poster and Refreshment Break***

3:25-4:05 Cascade Reaction Type Bioassays – Setup, Assay Performance, and Assessment of Similarity
We recently set up a QC-purpose bioassay for a complement inhibitor. The inhibitor titration curve showed a very steep slope, reflecting the switch-like behavior of the cascade. The steep slope of the curve complicated the assessment of similarity of Standard and Test sample. In conventional hypothesis testing of similarity, ~70% of samples failed when assessed by parallel line analysis, and ~60% failed when the 4P logistic fit option was used. Therefore, *ad hoc* sample acceptance criteria were defined empirically based on assay development data. Approaches for a more rational and sound implementation of equivalence testing according to USP chapter <1032> are put up for discussion.
Dr. Oliver Anderka, Bioanalytics, **Novartis Pharma**

4:05-4:45 Bioassays: A Tool for Biosimilar Development
The development of biosimilars requires a directed Quality by Design approach to match the reference product. Bioassays are key tools to functionally characterize biopharmaceuticals, and play an essential role during biosimilar development. Examples will be presented reflecting the bioassay strategy during the directed development of a biosimilar product.
Dr. Adelheid Rohde, Bioanalytics, **Sandoz GmbH**

4:45-5:25 Selection, Development, Validation and Justification of a Cell-based Potency Assay for an Anti-CXCR4 Nanobody®
Nanobodies have a high degree of sequence and structural homology to human immunoglobulin VH domains but with distinct features that favor high affinity binding and enables functionality towards difficult targets such as chemokine receptors. This high affinity is a challenge in the development of batch-release potency assays, especially for multivalent Nanobodies with avid target binding. The selection, development, validation and justification of a cell-based potency assay for ALX-0651, a biparatopic high-affinity Nanobody targeting the C-X-C Chemokine Receptor type 4 (CXCR4), will be presented.
Dr. Benedikte Serruys, Associate Scientist, **Ablynx NV**

5:25 ***No Host Networking Reception in Bar***

BEBPA's 4th Annual Biological Assay Conference

Main Conference, Day 2: 30 September 2011

Animal Assays

8:00-8:05 Chairperson's Opening Remarks
Dr. Stanley Deming, President, **Statistical Designs**, USA

8:05-8:45:Collaborative study to establish a 3R alternative to the vaccination challenge assay of rabies vaccine. A serological potency assay for rabies vaccine (inactivated) for animal use, developed and validated at the Paul Ehrlich Institut, Germany, has been assessed in a collaborative study in the EDQM Biological Standardisation Programme. The study demonstrated the transferability of the proposed assay and confirmed its general suitability as a batch potency test. The new assay provides a significant 3R improvement, reducing the number of animals used and the amount of suffering entailed.
Dr. Catherine Milne, Scientific Officer, **EDQM**

Poster Session
8:45– 9:25 Poster Talks
Back by popular demand! Two posters will be selected for 15 minute presentations in the main conference. This is great opportunity for students and junior analysts to present.
Presenters to be selected day 1 of the conference.

9:25-9:55 Morning Break

9:55-10:35 Comparison of Two Direct Neutralizing Assay Formats Using a Recombinant Drug as Agonist
A comparison of the development and qualification of a full curve assay- and a limit assay format for detection of neutralizing antibodies against an agonistic drug. The assays utilize a stably transfected cell line with cAMP as read-out. Critical parameters such as sensitivity, drug tolerance and precision will be compared. Performance, pros and cons and lessons learned will be discussed.
Dr. Janka Ryding, Research Scientist, **Ferring Pharmaceuticals**

Antibody Assays

10:35-10:40 Chairperson's Opening Remarks
Dr. Hans-Joachim Wallny, Novartis

10:40-11:20 Nicola Crawford Invited to Speak
Dr. Nicola Crawford, Associate Director, **MedImmune, UK**

11:20– 12:00 Use of an Effector Function Toolkit to Characterize Antibody Fc Function
The *in vivo* activity of a number of antibody therapeutics is believed to be mediated by their ability to engage effector function. These biological activities result from initial interactions between antibody Fc and C1q, or Fcγ receptors on effector cells. Given the diversity of activities that comprise effector function, it is important to have a well-diversified 'toolkit' of assays to enable a detailed mechanistic understanding of antibody Fc function. A case study will be presented highlighting the impact of this 'toolkit' on the development strategy of an antibody therapeutic.
Dr. Max Tejada, Senior Scientist, **Genentech**

12:00-1:30 Luncheon

1:30– 2:10 Influence of Glycosylation on Receptor Binding on a Therapeutic Protein
The glycosylation profile of a therapeutic protein from different expression systems will be presented. Data will be presented that evaluates the impact of the different glycosylation profiles on the ability of the protein to bind to key target receptors. These receptors are associated with its mode of action to effect immunomodulation. The binding profiles are evaluated utilising Biacore and glycosylation profiles by fluorescently labelled uPLC.
Dr. Sian Estdale, Senior Manager, **Covance**

Bioassays Requiring Sensitivity

2:10-2:15 Chairperson's Opening Remarks
Dr. Bassam Hallis, **HPA**, UK

2:15-2:55 Determination of the Limit of Detection and the limit of Quantitation during Assay Development
The determination of LOD and LOD is increasingly becoming a regulatory concern for calculation of sero-conversion, sero-protection or geometric mean when licensing a vaccine product. *The* usefulness and optimal throughput of an assay may depend on the appropriate determination of the LOD and the LOQ. This presentation describes the design, testing and statistical procedures required to determine the LOD and LOQ during assay development. The procedures to be used to confirm the LOD and the LOQ during assay validation are discussed.
Dr. Eloi Kpamegan, Assistant Director, **Aeras Global TB Vaccine Foundation**

2:55-3:25 *Exhibit/Poster and Refreshment Break*

3:25-4:05 Determination of LLoD and LLoQ for a real time PCR assay in support of the Animal Rule
During this talk the processes and studies used to determine the Lower Limit of Quantification (LLOQ) (the lowest standard in the calibration curve) and the Lower Limit of Detection (LLOD) (the lowest quantity of DNA, copy number, at which 95% of results are predicted to be positive)in the real time PCR assay for *Bacillus anthracis* will be described; specifically focusing on the generation of a standard curve and evaluation by the R^2 coefficient, reproducibility of the standards and subsequent Probit analysis and assay efficiency.
Dr. Jennifer Kane, Project Manager, **HPA**

4:05– 4:45 Develaopment and Validation of a Neutralizing Antibody Assay for Antibody-drug Conjugates
In support of clinical development of an antibody-drug conjugate, a neutralizing antibody (Nab) assay was developed and validated based on the primary mechanism of action of the antibody-drug conjugate and a relevant cell-based cytotoxicity assay. To reduce product interference in the Nab assay, an effective sample extraction preparation was introduced. Efforts in developing a robust and reliable Nab assay as well as the results from the assay validation will be presented.
Dr. Mary Hu, Director, **Seattle Genetics**

4:45 Conference Adjourns

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