2nd Annual NAb Conference

BIOPHARMACEUTICAL EMERGING BEBPA BEST PRACTICES ASSOCIATION

Presenters from:

BioAgilytix

Bristol-Myers Squibb

Covance

EuroDiagnostica Biomonitor

FDA

Genentech

ImmunoGen Inc

LGC

MedImmune

Promega

Public Health England

Quality Services

Statistical Designs

Conference Topics

- **Development of Rare Reagents Including**:
  - ✓ Use of Frozen Ready-to-Use Cells
  - ✓ Good Tissue Culture Practices
  - ✓ Bridging Lots of Rare Reagents for Consistency
- **Understanding How to Set Cut Points**
  - ✓ Assessing Dynamic Cut Points
- **NAb Case Studies**
  - ✓Anti-Drug Conjugates NAb Assays
  - ✓Comparison of Ligand Binding NAb Assay with Cell Based ADCC Assay
  - ✓Development of Anti-Antibody NAb Assay
- AND Much More

Keynote Talk

FDA Regulator provides insight into regulatory and scientific requirements for NAb Assays

For more information: www.BEBPA.org NAb Conference, February 11-12, 2016

NAb Conference, Day 1, February 11, 2016

To view abstracts, click on the titles of the talks

Regulatory Update

Session Chaired by: Dr. Laureen Little

9:00: Key Note Speaker: NAb Me Well–FDA Regulatory Perspectives on Neutralizing Antibody Assays
Dr. Joao Pedras-Vasconcelos, FDA

Assay Component Development

9:45: Growing Cell Stocks for Cell-based Nab Assays
Dr. C. Jane Robinson, Consultant

10:30-11:00: Morning Break

11:00: Achieving high quality cell-based bioassay through controlled preparation of bioassay-ready cells
Dr. Mei Cong, Promega

11:30-1:00: Lunch

1:00: Managing Critical Reagents in Cell-based Neutralization Assays: From Preparation to Bridging New Batches
Dr. Bassam Hallis, Public Health England

Case Studies

Session Chaired by: Dr. Jane Robinson

1:30: Development of a Functional Neutralizing Antibody Assay Using Engineered Immortal Reporter Cells and Sciences-Biologics Bristol-Comparison to a Primary Cell Antibody Dependent Cellular Cytotoxicity Assay.
Marina Juhel, Bristol-Myers Squibb

2:00: Strategies for Development of a Suitable Platform for Detection of Anti-Therapeutic Neutralizing Antibody
Mark O'Dell, Covance

2:30-3:00: Afternoon Break

3:00: Biochemical Characterization of Neutralizing Anti-Idiotype Antibodies Directed Against Mirvetuximab Soravtansine (IMGN853)
Sven Loebrich, ImmunoGen Inc

3:30: Selection of Ligand Binding Nab Assay to Support Benralizumab Clinical Development: Comparison with an ADCC MoA Cell-based Assay
Dr. Yuling Wu, MedImmune

Vaccines & Neutralizing Antibodies

4:00: Vaccine Characterization and Evaluation: Assays for Real Correlates
Dr. Bassam Hallis, Public Health England

4:30: Conference Adjourns

NAb Conference, Day 2, February 12, 2016

Emerging Practices for NAb Assays

Session Chaired by: Laureen Little

9:00: Immunogenicity Assessment of Next-generation Therapeutic Protiens
Dr. Michael Tovey, EuroDiagnostica Biomonitor

9:30: Recommendations for the Successful Transfer Between Laboratories of Cell-based Neutralizing Antibody Assays
Richard Hughes, LGC

10:00: Developing a Cell-based Neutralizing Antibody Assay. How Hard Could it Be?
Dr. Paul Caldwell, Covance

10:30-11:00: Morning Break

NAb Conference, Day 2, February 12, 2016

To view abstracts, click on the titles of the talks

Statistical Approaches

11:00: **Is it a Classical Calibration Line? Or is it a Four-parameter Logistic Model? Or is it Both?**

Dr. Stan Deming, Statistical Designs

11:30: **Assessment of a Dynamic Cut Point in a 384-well Cell-based Neutralizing Antibody Assay**

David Rusnak, BioAgilytix

12:00-1:30: Lunch

Interactive Survey and Mini-Course

1:30-4:00: Use of Design of Experiments (DOE) to Jump Start Method Development.

This is a survey/mini-course on the use of Design of Experiments. Basic Principles of DOE will be presented in a friendly and user friendly fashion. A case study, using cell culture optimization will be presented to provide a concrete example. Throughout the course, attendees will provide feed-back on their current use of these approaches using anonymous clickers.

Drs. Laureen Little, Quality Services & Stan Deming, Statistical Designs

4:00 Conference Adjourns

Comments About Last Year's Conference:

"Excellent conference with good discussion and challenging issues that is facing the field "

"Well-organized, interesting topics."

"Great to speak with others having similar Clinical issues"

"Very useful to hear real life experiences and challenges rather than just reading guidance documents."

"Intimate conference that promotes discussion among attendees"

"Certainly worthwhile. Great scientific atmosphere which promotes a lot of discussion and sharing of issues about a relatively young assay type in drug development. "

"This is the best focused conference I've attended in recent years. The conference was well run, speakers adhered to allocated time. More importantly, the quality and depth of presentations were great. There was also a fair amount of time for networking with attendees during the breaks/lunch. I would definitely attend another BEBPA conference and recommend it!"

Thank you to our 2016 Sponsor:

Reserve Your Space Today

Name: Dr./Mr./Ms. _____

Email: _____

Job Title: _____

Phone Number: _____

Department: _____

Company: _____

Address: _____

Country/Postal Code: _____

Please Indicate Payment Method:

☐ **Enclosed Check (Payable to: BEBPA)**

☐ **Credit Card**

☐ **Visa** ☐ **Mastercard** ☐ **Amex**

Card Holder _____

Card Number _____

Exp Date _____

CVN _____

Signature _____

Hotel Information:

Hyatt Palm Springs
285 North Palm Canyon Drive
Palm Springs, CA 92262

Tel: 1-800-233-1234

Hyatt Reservation Link

4 Easy Ways to Register:

Fill out this sheet and mail it to:
BEBPA
PO Box 7087
Citrus Heights, Ca 95621

Call: 916.729.0109

Register Online:
Www.BEBPA.org

Fax: 916.729.0134

Enjoy a Quality Meeting at Not-for-Profit Prices

☐ **2 Day Conference- $1077.00**

☐ **Certificate of Attendance- $30.00**

☐ **Please Sign Me Up for a Poster Presentation- $60.00**

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.