

IBC's 22nd International Intensive Symposium

Biological Assay Development, Validation & Maintenance

Critical Approaches for Critical Assays

April 30 – May 2, 2012 • Fairmont Copley Plaza • Boston, MA

Featured Presentations:

Ten-Year Review of Potency Assays from an FDA Reviewer's Perspective

Gerald Feldman, Ph.D., *Research Biologist, CDER, US FDA*

Update on the USP Chapters on Biological Assays

Timothy Schofield, M.A., *Managing Director, Arlenda USA*

Bioassay Design

David Lansky, Ph.D., *President, Precision BioAssay*

Industry White Paper on Implementing Surrogate Assays for ADCC Methods

Svetlana Bergelson, Ph.D., *Biogen Idec* and Xu-Rong Jiang, M.D., Ph.D., *MedImmune*

The Life-Cycle Approach to Bioassay Methods – Cradle to Commercialization

Developing Bioassays

- ◆ A dedicated workshop will specifically address bioassay development basics including the often overlooked problems you may face.

Validating Bioassays

- ◆ Hear how to validate methods using QbD as proposed by the new USP chapters and ICH approaches modified for biological methods.
- ◆ Case studies in this session include multiplexed assays, animal assays, cell-based assays for monoclonal antibodies, serological neutralizing assays, viral based methods and ELISAs.

Maintaining Bioassays

- ◆ Learn how to qualify rare reagents, re-qualify new reference material, utilize monitoring tools to identify emerging assay trends and establish systematic approaches to assure your method remains

Plus, Two New Practical Pre-Conference Workshops

- Advanced Tools for Assessing and Controlling Assay Variability and Spurious OOS Results
- Bioassay Development Basics 101

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Distinguished Faculty

Svetlana Bergelson, Ph.D.

Biogen Idec

Jamie Bird, M.Sc.

Emergent BioSolutions

Leonard Blackwell, Ph.D.

Pfizer

Bartek Bossak

Genentech, Inc

Kevin Brooks, Ph.D.

Emergent BioSolutions

Sonia Connaughton, Ph.D.

ImmunoGen

Gerald Feldman, Ph.D.

CDER, US FDA

Jaya Goyal, Ph.D.

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Bristol-Myers Squibb

Mike Sadick, Ph.D.

Aptuit

Sally Seaver, Ph.D.

Seaver Associates LLC

Timothy Schofield, M.A.

Arlenda USA

Hongran Stone, Ph.D.

Revance Therapeutics, Inc.

Tatyana Timiryasova, Ph.D.

Sanofi Pasteur Inc.

Thomas Waerner, Ph.D.,

Boehringer Ingelheim

RCV GmbH & Co KG, Germany

Rong-Rong Zhu

EMD Millipore

Return to your laboratory with new ideas and approaches to help you accelerate your bioassay projects.

Bioassay scientists are now reaching out and utilizing new technology at a dizzying rate. Quality-by-Design validations are becoming common, statistical tools are implemented during development and cells are being developed for single use applications. IBC's 22nd International Biological Assay conference is the must attend event for bioassay professionals who want to keep up with these changes. This informative, interactive conference is where scientists gather to discuss the real technical hurdles and how to overcome them.

If you are involved in the nitty-gritty of developing these critical assays, attend this meeting to find out new approaches and hear practical discussions centering around real world problems and solutions. You will learn how to get your assays approved and functioning with today's technologies. This conference focuses on the tools you need to quickly and efficiently develop critical biological assays needed for successful product development.

Knowing what is state of the art and expected by the regulators is a critical activity when developing bioassays for use in a QC laboratory. This is the place to find out about bioassays for various types of products including monoclonal antibodies, rDNA products, vaccine products and toxin products.

Plus, you will discover many practical approaches that can be applied immediately to your assays. Qualifying rare reagents, replacing and re-characterizing your reference material, new statistical approaches from detecting trends as part of your bioassay monitoring program, new innovative plate layouts, and approaches to determining lab-to-lab comparability are just some of the new and critical topics you will hear at this year's conference.

Register early for significant discounts. See the back cover for pricing details and deadlines.

2012 Conference Highlights Include:

- The Rules for Validation Bioassays are changing, don't be left behind. Hear the newest QbD approaches in the New Validation USP Chapter Review.
- To keep your assays working every day in every lab you need practical and easy to implement tools. Learn these techniques in our case studies from those who have done it by assessing comparability and monitoring system suitability.
- Struggling with ADCC assays for your monoclonal antibody product? Hear when and how industry scientists have proposed surrogate potency assays.
- Learn hints about making your assay robust from our case studies discussing reference material, cells, control samples and everything else your assay needs
- Case studies about validating multiplex assays, functional antibody assays, complex animal assays and serological assays help you understand what it really takes to have your bioassay accepted by regulators.
- Consistency: Avoid unexpected testing failures, inability to release clinical and/or commercial product or a sudden need to redevelop your potency assay. Our consistency session discusses statistical monitoring tools designed to identify emerging trends and a case study demonstrating how to perform lab-to-lab comparability studies.
- Assay Components: The Devil is in the Details Session tackles approaches on how to re-characterize new reference material and qualify rare reagents plus a case study from Genentech about how to systematically determine that your current method is functioning as it did during the validation phase.
- Sessions on Neutralizing Assays and Host Cell Proteins methods discuss specialized issues of optimizing for sensitivity and broad specificity.

Who Should Attend?

This highly practical and technical conference is specially designed for scientists, analysts, assay statisticians, and managers who work with biological assays during biotech and biopharmaceutical development or routine product release. Regulatory and Quality Assurance professionals who deal with submitting or overseeing complex assays will also gain much needed insight to successfully deal with biological assays.

Marketing Opportunities at Biological Assay Development & Validation

Interested in participating as an exhibitor or sponsor at the 22nd International Biological Assay Development, Validation & Maintenance? Many exciting opportunities are available to extend your sales and marketing efforts.

To learn more, please contact **Jennifer Thebodo, Sales Manager, Sponsorship & Exhibits**, at 508-614-1672 or jthebodo@ibcusa.com

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Take an Active Role in the Conference and Present a Poster

Any registered conference attendee may register to present a poster. The deadline to submit an abstract online is April 2, 2012 to have the abstract be included in the conference materials. Poster abstracts and registrations received after April 2, 2012 are subject to availability of an onsite poster board and will not be included in the conference materials.

Full payment of conference registration and poster fees must also be received by this date for the abstract to be included in the conference materials and a poster board assignment to be made (see the registration page for details on the poster fee). Posters should be PORTRAIT orientation, with maximum dimensions of 36 inches wide (3 feet) x 48 inches high (4 feet). Please verify poster dimensions before printing your poster. Oversize posters may not fit. Please note: Poster presentations may not be used as exhibit displays or for marketing purposes, and all posters are subject to approval by conference organizers. Only one poster presentation is allowed per registered attendee/author.

For up-to-date program information, visit: www.IBCLifeSciences.com/Bioassays

Workshop #1:**Advanced Tools for Assessing and Controlling Assay Variability and Spurious OOS Results***Workshop Leader:***Laureen E. Little, Ph.D., Principal Consultant, Quality Services***Workshop Instructors:***Timothy Schofield, M.A., Managing Director, Arlenda****David Lansky, Ph.D., President, Precision Bioassay Inc.****Part 1: Managing Variability in the Bioassay**

This workshop will highlight the association between bioassay measurement variability and decision risks associated with their use, and will illustrate designs and data analysis strategies for managing those risks. Topics covered by this session include:

- The relationship between systematic and random variability, and decision risks during product development and monitoring
- Experimental strategies for exploring sources of variability
- Bioassay designs using blocking and randomization to mitigate the risk of systematic variability
- Effective use of replication in release measurement, stability assessment, and bioassay maintenance

This workshop will combine concepts with hands-on exercises to reinforce the implementation of the design and analysis tools.

Timothy Schofield has recently joined Arlenda, a statistical consulting and software company providing support to the pharmaceutical, devices, and analytical testing industries. Prior to joining Arlenda Tim was Director in the U.S. Regulatory Affairs department of GlaxoSmithKline where he provided regulatory support to vaccines, as well as head of the Nonclinical Statistics department in Merck Research Labs, supporting development and manufacture of Merck pharmaceuticals, biologics, and vaccines. In addition to his service to GSK and Merck, Tim is co-chair of the USP Statistics Expert Committee and a member of the USP Bioassay Validation ad hoc panel where he led efforts to write Chapter <1033> Bioassay Validation.

Part 2: Approaches to Determining and Minimizing OOS from Bioassays

For processes with low variation, high precision measurement systems, and wide customer specifications it is relatively easy to avoid out of specification results. Unfortunately, for many biotechnology products, the (required) bioassay often has large variation; this alone raises several challenges for management. Product specifications should be driven by customer (medical) needs (i.e., the width of the therapeutic window). To separate process variation in potency from measurement variation requires some assay replication; in some cases stability data can provide an estimate of assay variation. In this workshop we will develop:

- A conceptual understanding of how medical needs (or clinical experience) can drive a set of relevant product specifications.
- An understanding of how product specifications, combined with process capability, and process variation determine total error limits on reportable values.
- Several practical methods for each of the following: establishing approximate product specifications, estimating process variation, and estimating assay errors.
- An understanding of the tradeoffs among product specifications, assay bias, assay variability, product degradation rates, numbers of replicate assays, and the risk of OOS.
- Finally, based on this background, understand how to use the validation approach in draft USP <1033> to set assay validation performance criteria that will simultaneously control the risk of OOS while keeping the number of assay replicates required under a practical limit.

David Lansky's educational background includes a year at the University of Michigan in Electrical and Computer Engineering, a B.S. in Botany from San Francisco State University, followed by three graduate degrees from Cornell: an M.S. in Entomology then an M.S. and Ph.D. in Biometry. David has worked on bioassay development, analysis and validation for over 20 years. Most of his experience is in industry, including 10 years at Searle/Monsanto/Pharmacia and nine years as the owner and lead consultant at Precision Bioassay, Inc., a consulting firm focused on statistical methods and software for bioassay.

Workshop #2:**Bioassay Development Basics 101***Workshop Leaders:***Michael Merges, Director, Biopharmaceutical Support Services, Catalent Pharma Solutions****Michael Sadick, Ph.D., Senior Manager, Large Molecule Analysis and Characterization, Aptuit**

Biological assays can be precise and easy to perform. This bioassay development workshop will begin with an overview of the basic tools required for success: analyst training, critical reagent maintenance, laboratory/equipment set-up and regulatory expectations for Phase I/III clinical trials. Practical approaches to designing assay formats, system suitability, and preparation for bioassay transfer will be discussed and case studies will be presented.

- **Analyst training**
- **Critical reagent care**
- **Assay formats**
- **Cells**
- **Team with a CRO?**
- **Regulatory expectations**

Michael Merges is Director of Catalent's Biopharmaceutical Support Services (BPS). BPS's focus is the transfer, development, validation, and performance of bioassays. Michael has experience with many techniques including cell-based (primary cells and cell lines) bioassays, immunological/neutralization assays, ELISA, and Flow Cytometry. He joined Catalent from Lonza where he was Associate Director of Bioservices. Prior to that, he was at the University of Maryland's Institute of Human Virology where he served as the Institute's Research Supervisor. He has also conducted viral immunology research at the National Cancer Institute and Johns Hopkins University. He obtained his Bachelor's Degree in Microbiology from The Pennsylvania State University and his Master's Degree in Microbiology/Virology from Hood College.

Michael Sadick received his B.A. in biology from Johns Hopkins, in Baltimore, and his MS and Ph.D. in immunology from University of Washington in Seattle. He worked as research faculty at UCSF Medical Center for five years. Following his work at UCSF Medical Center, Michael then worked for 10 years (1991 – 2001) at Genentech in South San Francisco as a Senior Scientist in the Bioassay Group supporting Pharmaceutical Science efforts (Phases I – III). Michael was recruited to Eli Lilly and Co. as a Research Advisor in 2001 to help lead biotechnology efforts, leading the Bioassay Groups, Molecular Biology and Virology in support of Phase I-III projects, as well as providing guidance for commercial bioassay testing, all on a global level, working with FDA and EMEA regulatory agencies. In 2007, Michael joined Aptuit, a CRO in Kansas City, MO, as a Senior Manager in the Large Molecule Analysis and Characterization (LMAC) division.

Schedule for Both Workshops

8:00	Registration and Coffee
9:00	Workshops Begin
10:30-11:00	Networking Refreshment Break with Poster and Exhibit Viewing
12:30-1:30	Luncheon in Poster and Exhibit Hall
1:30	Workshops Resume
3:30-4:00	Networking Refreshment Break with Poster and Exhibit Viewing
5:00	Close of Workshop

7:00 *Registration and Coffee*

8:00 **Welcome and Chairperson's Opening Remarks**

Lauren E. Little, Ph.D., *Principal Consultant, Quality Services; Editor and Publisher, BioQuality*

Featured Presentation

8:15 **Update on the USP Chapters on Biological Assays**

The USP chapters on biological assay development, validation, and analysis have undergone final review prior to publication in USP NE. 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, M.A., *Managing Director, Arlenda USA*

Dealing with Animal Potency Assays

8:55 **Lessons Learned: How to Develop a Well-Controlled Animal Potency Assay for QC Release and Stability**

The animal potency assay was designed and refined to balance the dynamic range, product specification, and number of animals used. In addition, the assay variability was identified and controlled.

Hongran Stone, Ph.D., *Senior Director, Revance Therapeutics, Inc.*

9:35 *Networking Refreshment Break with Poster and Exhibit Viewing*

9:55 **Challenges in Establishing Vaccine Potency**

An assessment of vaccine potency is necessary to predict clinical effectiveness from lot to lot and insure safety and efficacy. Assays designed to access vaccine potency are by necessity indirect and often rely on in vivo animal models or in vitro bioassays. The challenge is establishing a correlate between the in vitro and in vivo models that effectively addresses the mechanism of action and is acceptable to the regulatory agencies. This is compounded by the complexity of the vaccine that may contain multiple antigens in addition to an excipient or adjuvant. Animal models that respond to the vaccine are ideal; however in vitro assessment is necessary to routinely evaluate manufacturing consistency, stability, and strength. An approach to an in vitro potency assay is discussed in relation to the challenges of establishing an in vivo correlate, stability indicating properties, and vaccine complexity.

Leonard Blackwell, Ph.D., *Principal Scientist, BioTherapeutics Pharmaceutical Sciences, Pfizer*

10:35 **Development of a Mouse Relative Potency Test**

Abstract unavailable at press date. Please visit www.IBCLifeSciences.com/bioassays for program updates.

Jamie Bird, M.Sc., *Supervisor, Emergent BioSolutions*

11:15 **Validation of a Multiplexed Serology Assay for the Measurement of Specific IgG Antibodies to DTaP Antigens for Concomitant Vaccine Trials**

Hear a case study of validation of a multiplex serology assay (DTP-6 IgG) designed to simultaneously measure IgG antibody levels to six DTaP vaccine antigens serum samples. The DTaP antigens included in the assay are PTx, FHA, PRN, and FIM 2/3 of Bordetella pertussis, DTd of Corynebacterium diphtheriae, and TTd of Clostridium tetani. Validation parameters that were assessed included sensitivity, limits of quantitation, ruggedness, precision, dilutability, specificity, selectivity and accuracy.

Greg Kulnis, *Associate Research Scientist, PPD Vaccines and Biologics Lab*

11:55 *Luncheon in Poster and Exhibit Room*

The Evolving Art of Measuring Antibodies in Serum

1:00 **Implementing Electrochemiluminescence and Flow Cytometry Based Blocking Antibody Assays for the Clinical Development of Biotherapeutics**

Bioassay or blocking assays are commonly used to determine the ability of Anti-Drug Antibody (ADA) to neutralize biological effect of the drug. To determine whether ADA blocked binding of drug to the receptor or ligand expressed on cell surface, Flow cytometry and ECL based methods were employed during clinical development of two biotherapeutics. This presentation will cover the challenges during implementation of such bioassays in routine clinical testing.

Jaya Goyal, Ph.D., *Principal Investigator, Biogen Idec*

1:40 **Challenges that are Unique to the Development of Cell-Based Neutralizing Antibody Assays**

Immunogenicity concerns for biologics necessitate the need for functional assays to detect neutralizing antibodies in patient matrix that can impact safety and efficacy. While cell-based assays are the preferred format for neutralizing antibody (NAb) assays, they present unique technical challenges due to the effect of matrix components. A case study that highlights some of the challenges faced in the development of a NAb assay will be presented.

Renuka C. Pillutla, Ph.D., *Associate Director, Bristol-Myers Squibb*

Potency Assays for Multi-Functional Antibody Products

2:20 **Chairperson's Remarks**

Xu-Rong Jiang, M.D., Ph.D., *Associate Director, MedImmune*

2:30 **Assessment and Control of the Effector Functions of Therapeutic Antibodies: Position Paper Co-Authored by Members of Working Group Representing MedImmune, Genentech, Biogen Idec, Merck, Eli Lilly, and Amgen**

The presentation will provide an overview of the white paper on Fc effector function of therapeutic antibodies published in February 2011 (Nature Reviews Drug Discovery 10, 101-111). A summary of the current knowledge of antibody Fc functionality, a strategy for assessing the effector functions of different classes of therapeutic antibodies (including Fc fusion proteins) and a proposed path for routine testing and controls for manufacturers of antibody products will be covered.

Svetlana Bergelson, Ph.D., *Associate Director, Biogen-Idec*

3:10 **Challenges Associated with the Functional Testing of Therapeutic Antibodies**

Case studies for the set up and optimization of functional assays such as Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) as well as a Complement-Dependent Cytotoxicity (CDC) for therapeutic antibodies will be presented. In addition to these MOA assays, the set up and validation of a flow cytometric binding assay according to ICH Q2(R1) guidelines will be presented using Rituximab as an example.

Ulrike Herbrand, Ph.D., *Scientific Officer, Bioassays, Charles River Biopharmaceutical Services GmbH, Germany*

3:50 *Networking Refreshment Break with Poster and Exhibit Viewing*

4:20 **Fast and Quantitative Bioassays for Monitoring Fab & Fc Functionalities of Therapeutic Antibody**

Abstract unavailable at press date. Please visit www.IBCLifeSciences.com/bioassays for program updates.

Xu-Rong Jiang, M.D., Ph.D., *Associate Director, MedImmune*

5:00 **Challenges in Potency Assay Development for Antibody Maytansinoid Conjugates**

Abstract unavailable at press date. Please visit www.IBCLifeSciences.com/bioassays for program updates.

Sonia Connaughton, Ph.D., *Senior Scientist, ImmunoGen*

5:40 **Identification and Biological Characterization of a Recombinant Fusion Protein Product-Variant**

Abstract unavailable at press date. Please visit www.IBCLifeSciences.com/bioassays for program updates.

Jun Kim, *Associate Scientist, MedImmune*

6:20 *Close of Tuesday Sessions*

Group Discounts Provide Significant Savings

Companies can benefit from significant savings on standard registration fees when registering 3 or more people from the same company for the event at the same time. For group discount information, please call 646-895-7445.

7:00 *Morning Coffee*8:00 **Welcome and Chairperson's Opening Remarks**Sally Seaver, Ph.D., *President, Seaver Associates LLC***Featured Presentations**8:10 **Ten-Year Review of Potency Assays from an FDA Reviewer's Perspective**

A bioassay (or an in vitro potency assay) is a critical component of the control systems that monitor consistency and stability of a manufactured biological product. Potency assays used at early stages of product development may not be the same as those used during late stage product development or for licensure - often there is a need to modify or change the assay to meet additional FDA requirements. This presentation is aimed at providing an overview of some of the Agency observations, experiences and expectations regarding bioassay development over the last decade.

Gerald Feldman, Ph.D., *Research Biologist, CDER, US FDA*8:50 **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, Ph.D., *President, Precision BioAssay*9:30 *Networking Refreshment Break with Poster and Exhibit Viewing***How Consistent is your Assay?**9:55 **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.

Thomas Waerner, Ph.D., *Head Cell & Molecular Biology, Boehringer Ingelheim RCV GmbH & Co KG, Germany*10:35 **Bioassays: When Less Is More**

Abstract unavailable at press date. Please visit www.IBCLifeSciences.com/bioassays for program updates.

Kevin Brooks, Ph.D., *Biostatistician, Emergent BioSolutions*11:15 **Measuring Comparability of Potency Assay Results Between Development (Non-GMP) and Manufacturing (GMP) Laboratories**

During the life of a product the potency assay goes through progressive phases from development to the validation of its use for a release assay. These phases usually occur in different laboratories, with a transfer of the assay from the development laboratory to the manufacturing laboratory. To ensure a successful transfer, it is important that both laboratories obtain comparable assay results. We used a blinded panel of specimens and common critical reagents to perform assay testing in three laboratories involved in assay transfer. Concordance, Altman-Bland Agreement and Precision analyses were performed on quantifiable assay results.

Janet L. Lathey, Ph.D., *Director, Emergent BioSolutions*11:55 *Lunch on your own***Assay Components: The Devil is in the Details**1:30 **Reference Recharacterization for Potency Assays Using Replicate Testing in Four-Parameter Logistic Model**

Clinical laboratories utilize various reference standards during testing for potency assays. Two types of references are used: International reference standards or in-house standards. The international reference standards are bought from WHO, CBER, NIBSC, etc. Very often clinical laboratories prepare new reference lots to be used for testing because the lot is depleted or has reached the expiration date. In order to be used, the new reference needs to be re-characterized, i.e., the potency of the new lot shall be within specifications when compared to the old lot, the reference standard, to determine whether it is appropriate to switch the bioassay standard lot to the new lot. This paper describes reference recharacterization study design for potency assay using four-parameter logistic model.

Elói Kpamegan, Ph.D., *MSF, Director, Novavax, Inc.*2:10 **Maintaining Bioanalytical Methods in a Regulated Environment**

Our BioAnalytical Assays department is currently evaluating various assay maintenance methods, activities and practices in an effort to better harmonize initial assay validation with long-term assay maintenance, and to better characterize assay performance over time. It is therefore important that analytical methods function both accurately and consistently. The following is a test case which demonstrates an alternative approach to experimental set-up, data analysis, and result interpretation when performing the following assay maintenance activities: 1) Reagent incorporation. 2) Long term reagent stability determination. 3) Monitoring long term assay performance. 4) Anticipating possible future performance issues based upon past data.

Bartek Bossak, *Research Associate, Genentech, Inc.*2:50 **Qualification of Reagents for Use in Viral Serological Neutralization Assays**

The quality of reagents dictates the performance of cell-based assays and control of these reagents is important to ensure the reproducibility and consistency of the assay. The qualification of reagents used in serological neutralization assays, including viruses, cells, fetal bovine serum, cell culture medium, primary antibodies, secondary antibodies, and assay quality controls are described. The methods discussed here have been successfully applied to a variety of serological neutralization assays using viruses such as paramyxoviruses, orthomyxoviruses and flaviviruses.

Tatyana Timiryasova, Ph.D., *Scientist, Sanofi Pasteur, Inc.*3:30 *Networking Refreshment Break with Poster and Exhibit Viewing***Developing MultiProduct Host Cell Protein Assays**4:00 **Host Cell Protein Characterization for Bioprocess and Product Quality Improvement**

Host cell proteins (HCPs) are among the major biomanufacturing process-related impurities and are considered as CQA (critical quality attributes) by regulatory agencies. HCPs must be closely monitored for downstream purification steps and final drug product to ensure process consistency and product safety. Although ELISA has been the most common method for HCP quantification, one of the major drawbacks of HCP ELISA is assay accuracy since no single available ELISA assay kit has demonstrated to contain antibodies capable of detecting all the HCPs in CHO based biologics production process. In this presentation, orthogonal methods such as 2D-silver/western, 2D-DIGE and LCMSMS were used to achieve comparative study of identity of HCP standard used in Cygnus HPC ELISA (Cygnus 3G) with HCPs from three in-house null CHO cell lines.

Rong-Rong Zhu, *Senior Scientist, EMD Millipore*4:40 **Quantitation of Host Cell Proteins in Biopharmaceutical Processes: Successes and Challenges**

At Biogen Idec, Host Cell Proteins (HCPs) are measured with in-house multi-product HCP assays using the ECL MSD platform. Presented here is our assay development strategy and a case study of an issue encountered during qualification of several products produced in Chinese Hamster Ovary (CHO) cells using the in-house assay.

Catherine Ramsey, Ph.D., *Scientist, Biogen Idec*5:20 *Close of Conference*

Plan now to attend this highly technical conference which provides you with just the right mixture of practical technical tools, overview of regulatory trends, today's latest emerging technologies and multiple product case studies to help you develop, validate and maintain your bioassay.

Don't take our word for it...see what your colleagues have to say:



IBC's 22nd International Intensive Symposium

Biological Assay Development, Validation & Maintenance

Critical Approaches for Critical Assays

April 30 – May 2, 2012 • Fairmont Copley Plaza • Boston, MA

- Hear it first hand: An FDA reviewer's perspective on the past 10 years of potency assays
- Don't be left behind. Hear the most recent validation case studies: QbD and ICH approaches.
- Keeping your assay up and running: tips about comparability, monitoring and qualifying rare reagents

www.IBCLifeSciences.com/Bioassays

"The combination of statistical method and workshops with case studies give the participants a true grasp of how to apply modeling technologies to assay development and validity – great job!"

– Duane Brumm, Baxter

"Very timely topics and expert speakers that make the topics understandable."

– George Kamplaus, Biogen Idec Syntonix

"This is a really practical, useful and enjoyable conference to anyone, including me, the beginner in the bioassay world. It was sort of a challenge to myself."

– Soyoung Yong, Celtrion Inc

"The conference tackles the key issues concerning all industry bioassay personnel and manages to touch on very familiar problems."

– Srinderi Khambhampity, Dr Reddy's Labs

