

IBC's 15th Annual

Well Characterized Biologicals

October 3-5, 2011 • Omni Shoreham • Washington DC

Learn from Practical Case Studies, Analytical Strategies and Regulatory Perspectives

Featured Regulatory Presentations

Characterization Strategies for Complex Biologics

Jee Chung, Ph.D., CDER, US FDA

Analytical Techniques for Protein Aggregates

Ewa Marszal, Ph.D., CBER, US FDA

Serological Assessment of Vaccine Effectiveness

Cara Fiore, Ph.D., CBER, US FDA

Modernizing Assays for Legacy Products

Ashutosh Rao, Ph.D., CDER, US FDA

Reference Standards/Life-Cycle Management

Carla Lankford, M.D., Ph.D., CDER US FDA

Characterization of Cell and Gene Therapy Products

Lilia Bi, Ph.D., CBER US FDA

Comparability of Biotechnology Products

Audrey Jia, M.D., Ph.D., CDER, US FDA

Characterization of Therapeutic Vaccines

Elena Gubina, Ph.D., CBER, US FDA

Regulatory Perspectives on Fc Effector Function

Marjorie A. Shapiro, Ph.D., CDER, US FDA

Visible and Subvisible Particulates

Testing methods, technologies and assays for measuring, analyzing and characterizing protein particles

Complex Antibodies, Biosimilars and Vaccines

Analytical strategies and regulatory perspectives for characterization and comparability of mAbs, biosimilars, vaccines and other biologicals

Functional Assays for Biologicals

Novel assay development and validation strategies and technologies

Novel Analytical Technology Implementation

Two dimensional techniques, emerging technologies and analytics of the future for protein characterization

Co-Located and Shared Exhibit Hall with:

Process 2 Product

October 4-5, 2011 • Omni Shoreham • Washington DC

Full agenda online at:

www.IBCLifeSciences.com/Process2Product

- Advanced Process Monitoring and Control
- Multivariate Analysis for Biologicals
- Biopharmaceutical Data Management
- Process Analytical Technologies (PAT): Applications and Case Studies

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Learn From Unpublished New Data and Multiple Case Studies

Now in its 15th year, IBC's **Well Characterized Biologicals** program continues to set the standard for conferences by providing a unique opportunity for industry scientists and FDA regulators to share best practices and regulatory expectations. Register today so you can find solutions for characterizing a wide spectrum of biological products, including the ever-growing number of complex protein products that are emerging.

By attending, you will have the opportunity to:

- Interact directly with **FDA reviewers** and hear their expectations and advice on characterization and comparability to improve your testing methods and CMC strategies
- Find practical strategies and **new methodologies** for characterizing biologicals that you can apply in your own lab to accelerate your product development efforts
- Hear **unpublished new data** on complex antibodies, vaccines, biosimilars and other biological products only available by attending this conference
- Learn from **15 case studies** which will discuss detailed analytical characterization efforts, challenges and solutions to help you navigate increasingly complex products and the changing regulatory environment
- Evaluate **new technologies and solutions** to your analytical R&D challenges through technology-focused conference sessions and the vendor exhibit hall
- Discover the latest in **two dimensional techniques** and **novel analytical technologies** being applied for subvisible/visible particulates, biosimilarity/comparability and functional biological assay development

Conference Advisory Board

Izydor Apostol, Ph.D., Scientific Director, Analytical and Formulation Sciences, Amgen, Inc.

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Nadine M. Ritter, Ph.D., Senior CMC Consultant, Biologics Consulting Group

John Stults, Ph.D., Director of Protein Analytical Chemistry-2, Genentech, Inc.

Take an Active Role in the Conference and Present a Poster

Any registered conference attendee may sign up to present a poster. Poster abstracts must be submitted online and conference and poster fees must be paid by **Friday, September 9, 2011** to be included in the conference materials and to ensure a poster board assignment. Posters should be PORTRAIT orientation, with maximum dimensions of 36" wide (3 feet) x 48" high (4 feet). 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 complete poster information, visit www.IBCLifeSciences.com/WCB.

Sponsor and Exhibit Opportunities: Access Two Audiences with One Investment

IBC's Well Characterized Biologicals conference is co-located with IBC's Process2Product conference. The conferences will share all networking breaks in a joint exhibit and poster hall, giving sponsors and exhibitors access to attendees from both conferences. You will meet regulators, scientists, managers and directors from multiple bioprocess disciplines including Analytical R&D, Quality, Process Development, Manufacturing, Engineering and Automation. IBC's sponsorships ensure you the proper balance between attendees and exhibitors so you can spend more time developing your deals and less time searching for possible partners.

To learn more about sponsoring or exhibiting, please contact Jennifer Thebodo at (508) 614-1672 or jthebodo@ibcusa.com

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For up-to-date program information and to register, visit: www.IBCLifeSciences.com/WCB

7:45 *Registration and Coffee*

8:40 **Chairperson's Welcome and Opening Remarks**

Nadine M. Ritter, Ph.D., *Senior CMC Consultant, Biologics Consulting Group*

Evolving Paradigms in Biopharmaceutical Products: New and Legacy Products

8:45 **Common Mistakes Seen in Phase 1/2 CMC Studies**

Typically, the primary CMC focus for IND-enabling studies is to minimize product safety risks during first-in-human trials. But in order to best position the CMC package for the end of Phase 2, there are several additional elements that should be considered. Numerous CMC activities performed during Phase 1 and 2 can be strategically designed to efficiently support late phase studies. And, if performed in alignment with ICHQ10 'knowledge management' principles, they add considerable value to late-phase partnering or licensing/acquisitions. This presentation will highlight several common CMC mistakes made during early development, as observed from over two decades of experience with both small and large biotech organizations, and a wide variety of biopharm products.

Nadine M. Ritter, Ph.D., *Senior CMC Consultant, Biologics Consulting Group*

9:15 **CASE STUDY An Integrated Assessment for Early Product Development**

Early identification of the potential risks associated with the development of protein therapeutics can result in significant time and cost savings. This talk will show how an integrated assessment early in product development has identified key degradation pathways and the related risks. This early assessment is used to develop the most viable drug candidates and inform future development work.

David Spencer, *Scientist I, Analytical Biochemistry, MedImmune, Inc.*

9:45 **NEW UNPUBLISHED DATA Detecting and Quantifying Low Level Sequence Variants and Post-Translational Modifications**

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/WCB for updates.

Dingyi Wen, Ph.D., *Principal Scientist, Analytical Biochemistry, Biogen Idec, Inc.*

10:15 *Networking Refreshment Break*

10:45 **NEW UNPUBLISHED DATA CASE STUDY A Case Study: Characterization of a Legacy Protein Therapeutic to Meet 21st Century Requirements**

The challenges involved in characterizing a legacy protein therapeutic, with a manufacturing process originally developed 30 years ago, will be discussed. Fermentation of the native microorganism is followed by multiple purification steps. In order to obtain licensure in new territories, new state of the art analytical methodologies were required to clearly define the role of purification steps, and to confirm that the process, although utilizing older technologies, was able to generate highly consistent drug substance high purity.

John Brehm, Ph.D., *Scientific Program Manager, Centre for Emergency Preparedness, Health Protection Agency, United Kingdom*

11:15 **Modernizing Assays for Legacy Products**

The rapid evolution of analytical sciences and our understanding of the complexity of biological products have generated opportunities for industry and regulatory agencies to seek and implement newer analytical methods for legacy products. However, changing from an older, less sensitive method to a newer methods presents significant scientific and regulatory challenges. This talk will discuss the specific needs and challenges that arise from these new ventures with a view to generating ideas to implement modern analytical methods for legacy products.

Ashutosh Rao, Ph.D., *Product Quality Reviewer, Division of Therapeutic Proteins, CDER, US FDA*

11:45 **Q&A Panel Discussion with Morning Speakers**

12:15 *Networking Luncheon*

Strategic Discussion Sponsorship Opportunity

Does your company have an exciting technology or approach for protein product characterization? Would you be interested helping to shape a discussion session or workshop at this conference on a topic of your choosing related to characterization strategies for biologicals? Please contact Jennifer Thebodo at jthebodo@ibcusa.com for more information on sponsoring a strategic discussion or workshop during this lunch break and other times during the conference.

Characterizing Complex Antibody Products – Brave New Worlds

1:30 **NEW UNPUBLISHED DATA Analytical Challenges Characterizing Size Variants of an Auristatin Based Antibody-Drug Conjugate**

Auristatin-based antibody-drug conjugates (ADCs) are a growing class of targeted therapeutics generated by selective site-specific conjugation of a cytotoxic agent to cysteine residues typically involved in inter-chain disulfide bond formation. Developing an understanding of ADC size variants, including their distribution and identity, is an important component of developing a control strategy for these molecules and directly contributes to process characterization and validation efforts. Strategies for characterizing the size distribution of these ADCs, as well as analytical challenges associated with these efforts, will be described.

Adam Fung, Ph.D., *Scientist, Analytical Biochemistry and Formulations, Seattle Genetics*

2:00 **NEW UNPUBLISHED DATA Characterization Strategies for Antibody-Maytansinoid Conjugates**

Antibody-Maytansinoid Conjugates (AMCs) are immunoconjugates that consist of antibodies with multiple molecules of a maytansinoid cytotoxic agent attached. By using well-designed processes, AMCs can be manufactured very consistently. However, these manufacturing processes inherently introduce additional heterogeneity into the immunoconjugate, beyond that already present in the antibody. Process, analytical and regulatory strategies for addressing this heterogeneity will be discussed.

Godfrey Amphlett, Ph.D., *Vice President, Process and Analytical Development, ImmunoGen, Inc.*

2:30 **NEW UNPUBLISHED DATA CASE STUDY Characterization of Sym004: a Combination of Two Monoclonal Antibodies Targeting the Egf Receptor**

Combinations of antibodies and antibody mixtures are presently being evaluated as drug candidates to treat serious indications especially within the oncology field. We have developed an antibody mixture, Sym004, a product consisting of two monoclonal antibodies targeting EGFR, which is currently being evaluated in clinical trials. This presentation will outline the characterization strategy that has been established to address analytical challenges of antibody mixtures relative to monoclonal products.

Frank Nygaard, Ph.D., *Senior Scientist, Symphogen A/S, Denmark*

3:00 *Networking Refreshment Break*

3:30 **NEW UNPUBLISHED DATA CASE STUDY Ang2-VEGF CrossMab: Development and Characterization of a Novel Bispecific Human IgG1 Antibody to Treat Solid Tumors**

The talk describes the successful expression of a new format for a 1+1-bispecific antibody called CrossMab. The combination of the knob-into-hole technology and the crossover of the CH1 and CL domain on one side of the bispecific antibody allows the generation of cell lines producing the CrossMab with high titer and excellent quality. Development of the production process and analytical characterization of the CrossMab will be presented.

Kay Stubenrauch, Ph.D., *Senior Scientist, Biologics Research, Roche, Germany*

4:00 **Characterization Strategies for Complex Biologics**

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/WCB for updates.

Jeong Chung, Ph.D., *Biologist, Division of Therapeutic Proteins, CDER, US FDA*

4:30 **Characterization of Cell and Gene Therapy Products**

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/WCB for updates.

Lilia Bi, Ph.D., *Biologist/Reviewer, Division of Cellular and Gene Therapies, CDER US FDA*

5:00 *Q&A Panel Discussion with Afternoon Speakers*

5:30 *Close of Day One*

8:10 **Chairperson's Remarks**
Carl Co, Ph.D., *Scientist, Genentech, Inc.*

New Approaches with Functional Assays for Biologicals

8:15 **NEW UNPUBLISHED DATA CASE STUDY Design of Experiments (DOE) for Potency Assay Optimization**
Abhishek Mathur, Ph.D., *Senior Scientist, Biological Characterization, Amgen, Inc.*

8:45 **NEW UNPUBLISHED DATA CASE STUDY A Strategy for Assessing Fc Effector Functionality and Novel Bioassays for Monitoring of Antibody Effector Functions**

Kendall D. Carey, Ph.D., *Scientist II, Analytical Biochemistry, MedImmune, Inc.*

9:15 **CASE STUDY Assessment of Functional Activity of Monoclonal Antibodies**

The presentation will describe the development of functional assays for characterization of monoclonal antibody therapeutics with complex biological function involving both antigen and Fc receptor binding regions. Development of multiple biological assays to characterize complex protein therapeutics is faced with many challenges, including which aspects are measured and how control limits are established. Unique challenges in developing these assays such as complement dependent cytotoxicity (CDC), antibody dependent cellular cytotoxicity (ADCC), complement activation will be discussed using examples and case studies.

Tatjana Matejic, Ph.D., *Associate Research Fellow, Analytical Research and Development, Pfizer, Inc.*

9:45 *Networking Refreshment Break and Exhibit/Poster Viewing*

10:30 **NEW UNPUBLISHED DATA CASE STUDY Use of AlphaScreen and OCTET Red to Assess FcγR(s) and FcRn Binding**

Several case studies will be presented which highlight the relative merits and use of FcγRs and FcRn binding assays based on AlphaScreen and OCTET Red technologies. A correlation between FcγRs binding and ADCC activity will also be presented.

Carl Co, Ph.D., *Scientist, Genentech, Inc.*

11:00 **Regulatory Perspectives on Fc Effector Function**

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/WCB for updates.

Marjorie A. Shapiro, Ph.D., *Chief, Laboratory of Molecular and Developmental Immunology, Division of Monoclonal Antibodies, CDER, US FDA*

Vaccine and Protein Characterization and Comparability

11:30 **Serological Assessment of Vaccine Effectiveness**

Cara Fiore, Ph.D., *Microbiologist, Regulatory Scientist, Division of Vaccines and Related Products Applications, Office of Vaccines Research & Review, CBER, US FDA*

12:00 *Networking Luncheon and Exhibit/Poster Viewing*

1:10 **Chairperson's Remarks**

Steven L. Giardina, Ph.D., *Director, Process Analytics/Quality Control, Biopharmaceutical Development Program, SAIC-Frederick, Inc.*

1:15 **Characterization of Therapeutic Vaccines**

Elena Gubina, Ph.D., *Reviewer and Expert Biologist, Division of Cellular and Gene Therapies, CBER, US FDA*

1:45 **NEW UNPUBLISHED DATA CASE STUDY Biophysical Characterization of Vaccines: In Reference to Chikungunya Virus VLP Vaccine**

We develop vaccines against different diseases caused by pathogens such as HIV, Influenza, Chikungunya, Ebola and Marburg using a variety of state-of-the-art analytical tools for vaccine characterization and assay development. Some of these assays can also be used for accelerated stability testing, stress studies, and forced degradation studies of the vaccines. These assays can help in performing in-depth biophysical characterization and may be used for screening optimal formulation conditions for a given vaccine. We will present data on the characterization of CHIKV VLP vaccine using some of these techniques.

Indresh K. Srivastava, Ph.D., *Director, Purification and Analytical Development, Vaccine Production Program Laboratory, Vaccine Research Center, NIAID, National Institutes of Health*

2:15 **NEW UNPUBLISHED DATA CASE STUDY Comparability Assessment of a MAb after Clone and Process Changes**

To improve cell culture consistency and cell productivity, the clone and cell culture processes of a recombinant MAb product were changed between Phase I/II and Phase III manufacturing. These changes introduced marked differences in product size and charge variant distribution. A new size variant was observed in both SEC and non-reduced CE-SDS methods. The characterization results suggested that the new size variant was an antibody fragment. This talk will present the characterization of the differences between products produced from different processes and the assessment of product comparability.

Connie Lu, Ph.D., *Scientist, Protein Analytical Chemistry, Genentech, Inc.*

2:45 *Networking Refreshment Break and Exhibit/Poster Viewing*

3:15 **NEW UNPUBLISHED DATA CASE STUDY Assessment of Process Residuals using Commercial Assays**

The National Cancer Institute has been developing a chimeric monoclonal antibody, ch14.18, for over a decade for the treatment of pediatric neuroblastoma. Multiple lots of product using hollow-fiber technology have been manufactured to keep pace with demand, making lot-to-lot comparability a continuing product quality issue. This case study focuses on the challenges associated with using commercially available kits for tracking the removal of product-related impurities, in particular host cell proteins and bovine serum albumin.

Steven L. Giardina, Ph.D., *Director, Process Analytics/Quality Control, Biopharmaceutical Development Program, SAIC-Frederick, Inc.*

3:45 **Regulatory Perspectives on Comparability of Biotechnology Products**

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/WCB for updates.

Audrey Jia, M.D., Ph.D., *Drug Quality Reviewer, Division of Monoclonal Antibodies, CDER, US FDA*

Biosimilars and Similarity

4:15 **Challenges in Establishment of Biosimilarity: An Approach with Rational Scientific Justification**

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/WCB for updates.

Kimberly May, Ph.D., *Associate Director, Merck & Co.*

4:45 **NEW UNPUBLISHED DATA CASE STUDY Assessment of Protein Structure Similarity by Nuclear Magnetic Resonance Spectroscopy: Applications to Biosimilars and Manufacturing**

Demonstration of structural comparability for biologics and biosimilars is a requirement for product submissions to regulatory agencies. Analytical techniques that examine the overall fold and chemical integrity of biomolecules are commonly used. Additional high order structural information with atomic resolution can be obtained through NMR spectroscopy. The use of NMR methods to compare protein structures to support development of biosimilars and to determine the impact of manufacturing process changes will be discussed.

Carlos Amezcua, Ph.D., *Research Scientist, Technology Resources, Baxter Healthcare Corporation*

5:15 *Close of Day Two*

Venue and Accommodations

Omni Shoreham

2500 Calvert Street NW, Washington, DC 20008

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Hotel Reservation Phone: 1-800-THE-OMNI (reference IBC or Well Characterized Biologicals)

Room Reservation Website:

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Please call the hotel directly at the number above before **September 9, 2011** to be included in IBC's dedicated room block for this conference. Please identify yourself as a participant in IBC's Well Characterized Biologicals conference to receive the reduced room rate. Be sure to make your reservations as soon as possible as rooms tend to fill up very quickly and all reservations are subject to availability.

Additional Registration Information

For onsite registrations, please add \$100.

Program content and speakers subject to change. Conference badges are non-transferable and lost badges will not be replaced without payment of the full conference registration fee.

Please note that payment is required in advance of the conference. Please make check(s) (in U.S. funds drawn on a U.S. bank) payable to IBC Life Sciences. Confirmation of your booking will be sent. MasterCard, Visa and American Express are accepted.

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SPECIAL NEEDS: If you have a disability or special dietary needs, please let us know in order that we may address your special needs for your attendance at this show. Please send your special needs via email to custserv@ibcusa.com.



8:10 **Chairperson's Remarks**

Dirk Chelius, Ph.D., Head of Mass Spectrometry, Process Sciences & Production, Novartis Pharma AG, Switzerland

Novel Analytical Technology Implementation

8:15 **NEW UNPUBLISHED DATA CASE STUDY Quantification of Posttranslational Modifications in Recombinant Proteins Using Stable Isotope Labeled Internal Standard and Mass Spectrometry**

With the implementation of Quality by Design concept to biopharmaceutical drug development, there is a demand for accurate quantification of Critical Quality Attributes during the product lifecycle. We have developed a method to quantify the posttranslational modifications in recombinant proteins using Stable Isotope Labeled Internal Standards (SILIS) and MS. Several examples using microbial and mammalian expressed recombinant proteins will be shown to demonstrate the advantages of this approach, which include superior accuracy and precision.

Gang Huang, Ph.D., Principal Scientist, Process and Product Development, Amgen, Inc.

8:45 **Fully Automated N-glycosylation Analysis of Monoclonal Antibodies**

The standard method for the analysis of glycosylation of monoclonal antibodies at Novartis includes enzymatic cleavage by PNGase F of 2AB labeled glycans followed by liquid chromatography and fluorescence detection. This time consuming method was compared to a high-speed fully automated analysis of N-glycans on a microfluidic LC-MS chip device. Validation parameters of this new technology will be presented and compared to the standard method.

Dirk Chelius, Ph.D., Head of Mass Spectrometry, Process Sciences & Production, Novartis Pharma AG, Switzerland

9:15 **Technology Workshop**

New Proteins, New Problems: Analytical Clues to the Stability of Proteins during Manufacture and Storage



Early prediction of how a candidate therapeutic protein will behave during manufacture and storage over extended periods has always been highly desirable to help identify optimum candidates and reduce development risks. As the biopharmaceutical industry begins to move beyond relatively well understood protein formats like mAbs this is becoming increasingly critical as many of the exciting new formats are proving 'troublesome' or at the very least less predictable. This presentation will review some of the analytical 'clues' to a protein's suitability for subsequent manufacture and long term storage. This will include some commonly used stability indicators and some more speculative ideas with a particular focus on measurements which can be made rapidly and early in development.

Simon Webster, Ph.D., Chief Scientific Officer, Avacta Limited, United Kingdom

9:45 **Networking Refreshment Break and Exhibit/Poster Viewing**

10:15 **Technology Workshop**

Enabling Technologies for Characterization of Biologicals: Label-Free Analysis of Active Concentration and Stability



Biacore™ and MicroCal™ systems enable label-free protein interaction analysis, generating unique data on the interactions between proteins and other biomolecules. Biacore™ systems enable elucidation of the speed (kinetics) and strength (affinity) of protein interactions, as well as active concentration with or without a reference standard. MicroCal™ DSC systems enable measurement of the stability of biotherapeutics. Together these systems provide comprehensive characterization of biotherapeutics enabling critical decisions needed for confident lot release.

Michael B. Murphy, Ph.D., Senior Application Scientist, GE Healthcare Life Sciences

10:45 **NEW UNPUBLISHED DATA An Examination of LC/MS-Based Approaches for Host Cell Protein Characterization**

While traditional HCP ELISA allows relative quantification of bulk HCPs, the technique offers no information on quantities or identities of individual HCPs. This presentation details efforts to apply methods including online 2-D LC/MSn, as well as offline HCP enrichment to better inform the impurity profiles of biological products.

Matthew R. Schenauer, Ph.D., Postdoctoral Fellow, Analytical and Formulation Sciences, Amgen, Inc.

11:15 **A Regulatory Perspective on Reference Standard Establishment and Life-Cycle Management**

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/WCB for updates.

Carla SR Lankford, M.D., Ph.D., Product Quality Reviewer, Division of Monoclonal Antibodies, CDER US FDA

11:45 **Lunch on your own**

1:10 **Chairperson's Remarks**

Joseph Kutza, Ph.D., Director, CMC Regulatory Affairs, MedImmune, Inc.

Visible/Subvisible Particulates and Aggregates

1:15 **NEW UNPUBLISHED DATA Understanding and Correcting Biases in Optical Detection of Subvisible Particles**

The optical measurement of protein particulates is challenging because of their low optical contrast and unusual morphology. I will discuss measurement biases that occur for dynamic microscopy and light obscuration methods, as well as the development of new standards and methods to measure and correct for these biases.

Dean C. Ripple, Ph.D., Leader, Bioprocess Measurements Group, National Institute of Standards and Technology

1:45 **Protein Particulates – Recent Advances and a Case Study**

This talk will discuss recent advances in detection of protein particulates, and characterization techniques in efforts to understand mechanism of particulate formation. A case study will also be presented.

Tapan K. Das, Ph.D., Senior Principal Scientist, Biotherapeutics Pharmaceutical Sciences, Pfizer, Inc.

2:15 **NEW UNPUBLISHED DATA CASE STUDY Sorting Subvisible Protein Particles from Silicone Oil in the 500 nm to 5 µm Range**

Characterizing subvisible particles in the entire size range remains a challenge. Here, a novel method that relies on differences in particle buoyant mass is used to count and size particles in the 500 nm – 5 µm range demonstrating its ability to distinguish between silicone oil droplets and protein particles in a size range that is especially challenging. In addition, light obscuration and flow microscopy are used as complementary methods to evaluate high concentration mAb in prefilled syringes on accelerated stability.

Ankit R. Patel, Ph.D., Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.

2:45 **Networking Refreshment Break and Last Chance for Exhibit/Poster Viewing**

3:15 **NEW UNPUBLISHED DATA The Use of Flow Cytometry for the Detection of Subvisible Particles in Therapeutic Protein Formulations**

The amount, identity and size distribution of particles in parenteral therapeutic protein formulations is of immense interest due to potential safety and efficacy-related implications. Application of a flow cytometer, equipped with forward- and side-scattering as well as fluorescence detectors, to determine the number of subvisible particles in monoclonal antibody formulations will be described. This approach is characterized by protein aggregate selectivity, sub-micron detection limit, small sample amounts and high throughput. The use of the method to minimize purity and immunogenicity concerns will be discussed, and challenges of further analytical advancements outlined.

Henryk Mach, Ph.D., Senior Investigator, Vaccine Formulation and New Technology Development, Merck Research Laboratories

3:45 **NEW UNPUBLISHED DATA CASE STUDY Characterizing Stability Changes in a Human Monoclonal IgG Antibody That Result in an Increase in Opalescence**

A significant increase in opalescence was observed for a human monoclonal IgG2 antibody manufactured at Pilot scale. Stability results showed an acidic shift in the charge profile from time zero and a significant decrease in potency after 6 months. Peptide mapping revealed the acidic variants contain a higher level of a deamidated light chain peptide. In this study, the physical and chemical changes occurring in the antibody on stability that could result in an increase in opalescence are investigated.

Esohe Idusogie, Ph.D., Associate Director, Process Development Analytical, OncoMed Pharmaceuticals

4:15 **NEW UNPUBLISHED DATA CASE STUDY Approaches for Evaluating the Impact of Mechanical Stress on Therapeutic Proteins**

This talk will present a case study on the identification, optimization, and characterization of an appropriate mechanical stress methodology for comparability studies. A wide range of analytics, with a focus on sub-visible particles and solution turbidity, were employed to evaluate the stability impact and determine the variability of the mechanical stress methodology.

Nicholas Guzewicz, Staff Scientist, BioFormulations Development, Genzyme Corporation

4:45 **Analytical Techniques for Detection, Quantification and Characterization of Protein Aggregates in Biological Products**

Abstract not available at time of print. Please visit www.IBCLifeSciences.com/WCB for updates.

Ewa Marszal, Ph.D., Chemist, Laboratory of Plasma Derivatives, Division of Hematology, CBER, US FDA

5:15 **Close of Conference**