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Special thanks to all the Workshop Session Co-leaders

Special thanks to all the Roundtable Facilitators and Scribes

Acknowledgements *continued*

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Acknowledgements *continued*

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Catherine Stewart, Director of Finance

Audio Visual:

Michael Johnstone, MJ Audio Visual Productions

General Information

Name Badges:
Please wear your name badge in order to gain admittance to the meetings, plenary sessions, exhibit hall and social functions. A name badge for a one-day registration does not include the cost of the Welcome Reception for the Washington National Cathedral. Guest tickets to the Welcome Reception may be purchased at the registration desk at a cost of $95.00.

Registration:
The Symposium Registration Office will be located off the Promenade Foyer in the Senate Room located on the first floor of the hotel throughout the program dates: Tuesday, January 29 through Thursday, January 31. Registration is open during the following hours:

Tuesday, January 29	7:00 to 17:00
Wednesday, January 30	8:00 to 17:00
Thursday, January 31	8:00 to 17:00

Roundtable Sessions:
This year at WCBP 2019, there are two roundtable sessions that will consist of a total 48 topics. The first session will be held on Tuesday, January 29 from 16:00 to 17:00 and the second session will be held on Wednesday, January 30 from 11:30 to 12:30.

The sessions will last 60 minutes each. There will be ten (10) seats to a table. **Seating will be on a first come, first serve basis.** Certain topics will be repeated on both days so if your first topic choice is full when you arrive, try choosing a different topic and, if possible, revisit your original selection on the second day. These roundtables will include a facilitator, whose role is to help assist the discussion and ensure a lively exchange, and a scribe, whose role is to make general anonymous notes about the discussion so others will have a chance to view the discussion even if they could not participate. The discussion notes will be posted to the CASSS Website within a three week period after WCBP ends for all CASSS members to access.

Roundtable MiniCases are a new format to this year's WCBP that were developed to address the needs of attendees looking to learn more about a subject but don't have an extensive background in that area. These sessions will feature a brief introduction to the topic that will include data, examples or a case study intended to stimulate both discussion and learning. The subsequent discussion will be facilitated by experienced professionals and will focus on knowledge sharing.

The roundtables will be held in the following rooms:

- Cabinet Room
- Chinese Room
- Palm Court Ballroom
- Pennsylvania Room (located on the second floor) – MiniCase Roundtable
- Rhode Island (located on the second floor) – MiniCase Roundtable
- South Carolina (located on the second floor) – MiniCase Roundtable
- Virginia Room (located on the second floor) – MiniCase Roundtable
- **NOTE:** Maximum capacity in each second floor room is 30 seats. No exceptions. Come early to get a seat!

General Information *continued*

CASSS staff will be available in each room to start the sessions on time and provide a five-minute warning when the session is about to end.

The roundtable topics are posted in the back of the final program agenda and in the mobile app.

Workshop Session Formats:
Different workshop topics need to be approached in different ways in order for their full potential to be reached. WCBP 2019 will feature two different workshop formats to enhance discussion of key topics of interest.

1. **The Standard Format**
   This is the workshop you usually think of as being associated with WCBP. Industry and Regulatory Agency co-chairs focus on generating discussion over the entire period of the session. As with all workshop formats, audience participation is critical to success.

2. **The Plen-shop Format**
   Sometimes, a presentation of background material before discussion begins is a good thing. The plen-shop format allows for that. In these sessions, one or more short presentations will be followed by intensive discussion. It's not a plenary session, it's not a workshop - it's a Plen-shop!

Additionally, we will have a workshop in the standard format which will have the topic chosen by WCBP 2019 attendees while at the meeting! We realized that sometimes we may miss an important breaking topic because of how far in advance we work to ensure a high-quality conference. The crowd sourced hot topic workshop allows attendees to suggest and vote for a topic of their choice and we will provide skilled facilitators - whatever the topic! **The vote for a hot topic will be through the CASSS mobile app. Please make sure to download the mobile app so that you can cast your vote!**

Technical Seminars:
Luncheon technical seminars will be held on Tuesday, January 29 from 12:45-13:45 and on Wednesday, January 30 from 13:00-14:00. Additionally, we are offering three 30-minute technical seminars during the extended break periods on Wednesday, January 30 from 15:45-16:15 and on Thursday, January 31 from 10:45–11:15.

Wi-Fi Access:
We will have Wi-Fi access available throughout all of our program meeting spaces.

Business Center:
The Business Center is located on the Mezzanine level as part of the UPS Store. The Business Center is staffed during these hours: Monday through Friday 8:00 to 18:00; Saturday 10:00 to 16:00 and closed on Sunday. However, the computers are still accessible 24 hours/seven days a week; they are self-automated by swiping a credit card.

General Information *continued*

Photographic Equipment:
The use of cameras is not permitted during the lecture program, workshops or poster sessions. Cameras are permitted on the exhibit floor. However, permission from the vendors involved must be obtained before photographs can be taken.

Mobile App Training
Not sure how to sign-in or what you can do with the mobile app? Don't miss the Mobile App Trainng on Tuesday, January 29 at 10:15 in the Cabinet Room. Come join us as we show you how to get the most out of the CASSS mobile app.

Social Program
Tuesday, January 29, 2019
19:00 – 23:00 Welcome Reception Washington National Cathedral
NOTE: Transportation will be provided.

Wednesday, January 30, 2019
07:00 – 08:15 New Member Breakfast District Ballroom
Access to this event requires a "New Member" ribbon on the badge.

Wednesday, January 30, 2019
18:05 – 20:00 Exhibitor Reception East / State Rooms

New CASSS Members:
A breakfast will be held in the District Ballroom on Wednesday morning where you will be able to meet with some of our key program planning committee members. To gain access to this breakfast, you will be required to have a "New Member" ribbon on your badge. We hope you will join us at this "Meet and Greet."

Exhibitor Trivia Competition
Answer the exhibitor trivia questions in the mobile app to be eligible for a prize drawing. Visit the exhibits in the East / State Rooms to find the answers from each exhibiting company. Those with the highest point totals will be entered in the drawing which will take place Thursday, January 31 at 17:30 in the Grand Ballroom. You must be present to win.

CASSS Mobile App

We are pleased to once again offer the CASSS Mobile App for the CMC Strategy Forum January and WCBP 2019!

Top Ten Reasons You Need to Have the App:

- Connect and network with fellow attendees, speakers, and exhibitors
- View the schedule and create a personalized agenda
- Download speaker abstracts and handouts
- Take notes during the presentations and export later
- Play the Exhibitor Trivia game and Mobile App Challenge for chance to win great prizes
- Provide instant feedback on the speakers and sessions
- Receive all the latest information on schedule changes or updates
- View poster abstracts and connect with poster presenters
- Have all your questions answered during sessions through the activity feed
- Learn about everything Washington, DC has to offer!

The WCBP 2019 Mobile App is coming in January 2019. Log on and be a part of the CMC/WCBP Community!

STEP 1
OPTION 1: On your mobile phone, go to the App Store (Apple App Store, Google Play Store) and search "CASSS 365
OPTION 2: Use a QR code reader to scan the QR code on this page.
OPTION 3: To use the HTML version of the app, go to the internet browser on your mobile phone, tablet, or computer and go to the link www.tripbuildermedia.com/apps/casss365

STEP 2: Follow store instructions to download the CASSS 365 mobile app.

STEP 3: Open the app. It will ask for your username and password. THIS IS THE SAME INFORMATION YOU USE TO REGISTER FOR A CASSS MEETING.

STEP 4: Go to Events and select "CMC/WCBP" from the list. Enter your username and password again. This is the same username and password used in step three.

You now have access to the entire schedule, session abstracts, speaker handouts and bios – as well as the ability to connect with your fellow attendees.

Need Help?
Still not sure how to sign in and get the most out of the mobile app? Don't miss the Mobile App Training on Tuesday, January 29 at 10:15 in the Cabinet Room. You can also contact CASSS Meeting Coordinator Anna Lingel (alingel@casss.org) or stop by the registration office in the Senate Room.

WCBP 2019 Scientific Program Summary

TUESDAY, JANUARY 29, 2019

06:30 – 08:00 **Continental Breakfast** in East / State Rooms

07:00 – 17:00 **Registration** in the Senate Room

08:00 – 08:30 **CASSS Welcome and the 8th Annual William S. Hancock Award Announcement – Sponsored by CASSS** in the Grand Ballroom
Wassim Nashabeh, *F. Hoffmann-La Roche Ltd.*

08:30 – 08:45 **WCBP 2019 Introduction** in the Grand Ballroom
Stefanie Pluschkell, *Pfizer, Inc.*

08:45 – 10:15

ICH Countries: Regulators' Thoughts on Harmonization Successes and Challenges
Panel Discussion in the Grand Ballroom
Session Chairs: Carol Krantz, *Seattle Genetics, Inc.* and Helena Madden, *Biogen*

Panel Members:
Steffen Gross, *Paul-Ehrlich-Institut, Germany*
Celia Lourenco, *Health Canada, Canada*
Francesca Luciani, *Istituto Superiore di Sanità, Italy*
Nobumasa Nakashima, *PMDA-Pharmaceuticals and Medical Devices Agency, Japan*
Elkiane Macedo Rama, *ANVISA-Brazilian Health Regulatory Agency, Brazil*
Anthony Ridgway, *Health Canada, Canada*
Mats Welin, *Medical Products Agency (MPA), Sweden*

10:15 – 10:40 **Networking Break** – Visit the Exhibits in the East / State Rooms

10:15 – 10:40 **Mobile App Training**
Mobile App training in the Cabinet Room

Successes and Challenges of Drug Development when Speed is Critical for the Patient
Plenary Session in the Grand Ballroom
Session Chairs: Anthony Lubiniecki, *University of Maryland, Baltimore County* and Jennifer Mercer, *BioMarin Pharmaceutical Inc.*

10:40 – 10:45 **Introduction**

TUESDAY, JANUARY 29 *continued*

10:45 – 11:10 **CMC Strategy During the Accelerated Development of Brineura® (cerliponase alfa)**
David Jacoby and Linda Wilbur, *BioMarin Pharmaceutical Inc., Novato, CA USA*

11:10 – 11:35 **Navigating the CMC and Regulatory Challenges of a Breakthrough Therapy Product for Multiple Myeloma**
Gene Schaefer, *Janssen R&D, LLC, Malvern, PA USA*

11:35 – 12:00 **YESCARTA®'s Journey through Development, Approval and Beyond**
Mehrshid Alai-Safar, *Kite, a Gilead company, Santa Monica, CA USA*

12:00 – 12:15 **Panel Discussion - Questions and Answers**

12:15 – 14:00 **Lunch Break** – Participants on their own

12:45 – 13:45 **Technical Seminars**

Innovations in Biopharmaceutical R&D: A CRO's First-hand Experience with mAb Quantitation by nSMOL-LCMSMS, HRMS mAb Characterization via the new 9030 Q-ToF, a Dive into Cell Culture Exploration, and Much More
Sponsored by Shimadzu Scientific Instruments, Inc. **Cabinet Room**
NOTE: Lunch is provided for first 100 attendees

Two Birds with One Stone: Evaluating the Maurice for Platform mAb Charge and Size Variants
Sponsored by ProteinSimple, a Bio-Techne brand **Chinese Room**
NOTE: Lunch is provided for first 100 attendees

Increasing Throughput and Productivity for Host Cell Protein (HCP) Analysis
Sponsored by Agilent Technologies **District Ballroom**
NOTE: Lunch is provided for first 100 attendees

Automated Solutions for Relative Potency Assays, (GMP and Non-GMP), Now and Future State
Sponsored by Catalent Pharma Solutions **Grand Ballroom**
NOTE: Lunch is provided for first 100 attendees

High Performance LCMS Analysis in Biopharma: From Molecular Characterization to Routine Monitoring
Characterizing and Monitoring Quality Attributes in Monoclonal Antibodies using a High Resolution, Small Footprint LC-MS System
Sponsored by Waters Corporation **Palm Court Ballroom**
NOTE: Lunch is provided for first 100 attendees

TUESDAY, JANUARY 29 *continued*

Clinically Relevant Specifications and Quality Standards
Parallel Session in the Grand Ballroom
Session Chairs: Nina Cauchon, *Amgen Inc.* and Reed Harris, *Genentech, a Member of the Roche Group*

14:00 – 14:05	**Introduction**
14:05 – 14:30	**Developing Clinically Relevant Specifications: Summary of CMC Strategy Forum** Anthony Mire-Sluis, *AstraZeneca, Gaithersburg, MD USA*
14:30 – 14:55	**Patient-Centric Specifications: Product Quality Through a Focus on Product Understanding** Aparna Deora, *Pfizer, Inc., Chesterfield, MO USA*
14:55 – 15:20	**Strategy to Establish Clinically Relevant Specifications at Launch** John Stults, *Genentech, a Member of the Roche Group, South San Francisco, CA USA*
15:20 – 15:35	**Panel Discussion - Questions and Answers**

New Rapid Analytics and the Path to RTRT
Parallel Session in the District Ballroom
Session Chairs: Catherine Eakin, *Seattle Genetics, Inc.* and Kenneth Miller, *AstraZeneca*

14:00 – 14:05	**Introduction**
14:05 – 14:30	**Mapping Future Technology Needs and Prioritization of Critical Quality Attributes for Enabling In-line Monitoring and Real Time Release Testing** Vakhtang (Vaho) Loladze, *GlaxoSmithKline, King of Prussia, PA USA*
14:30 – 14:55	**Advances with In-line PAT: Multi-angle Light Scattering for Real-time Downstream Process Monitoring and Control** Douglas Richardson, *Merck & Co., Inc., Kenilworth, NJ USA*
14:55 – 15:20	**Faster Test, Faster Results: Degenerate PCR & Fragment Sequencing Assay for Biosafety Testing** Afshin Sohrabi, *BioReliance Corporation, Rockville, MD USA*
15:20 – 15:35	**Panel Discussion - Questions and Answers**
15:35 – 16:00	**Networking Break** – Visit the Exhibits in the East / State Rooms

TUESDAY, JANUARY 29 *continued*

16:00 – 17:00 **Roundtable Session 1**

Select Your Table Topic in One of the Following Rooms

- Cabinet Room
- Chinese Room
- Palm Court Ballroom
- Pennsylvania Room (located on the second floor)
- Rhode Island (located on the second floor)
- South Carolina (located on the second floor)
- Virginia Room (located on the second floor)

Please refer to table topics listed in the back of this program book.
Table seats are on a first-come, first-serve basis.

16:00 – 17:15

Prior Knowledge: What Is In It for Me?
CMC Strategy Forum Global Topic Update in the Grand Ballroom
Co-leaders: Markus Goese, *F. Hoffmann-La Roche Ltd.;* Mats Welin, *Medical Products Agency (MPA);* Kimberly Wolfram, *Biogen*

17:00 – 17:30 **Networking Break** – Visit the Exhibits in the East / State Rooms

17:30 – 18:45 **Workshop Session 1**

Particles in Injectable Formulations: Risks and Control Strategies
Standard **Chinese Room**
Shawn Cao, *Amgen Inc.;* Merry Christie, *CDER, FDA;* Ewa Marszal, *CBER, FDA;* Samir Sane, *Genentech, a Member of the Roche Group*

Multi-attribute Methods: Now That We Can Measure It, What Does It Mean?
Standard **District Ballroom**
Nobuko Katagiri, *CBER, FDA;* Frances Namuswe, *CDER, FDA;* Jason Rouse, *Pfizer, Inc.;* Liqiang (Lisa) Zhou, *AbbVie, Inc.*

Regulatory Considerations for Advances in Technologies like mRNA Vaccines
Plen-shop **Palm Court Ballroom**
Kimberly Duffy, *Merck & Co., Inc.;* Keith Peden, *CBER, FDA;* Allison Wolf, *Eli Lilly and Company*

19:00 – 23:00 **Welcome Reception** at the Washington National Cathedral
Transportation will be provided

WEDNESDAY, JANUARY 30, 2019

07:00 – 08:30 **Continental Breakfast** in the East / State Rooms

08:00 – 17:00 **Registration** in the Senate Room

Keynote Speaker in the Grand Ballroom
Introduction By: Stefanie Pluschkell, *Pfizer, Inc.*

08:15 – 09:15 **Infectious Disease – Designing Biological Therapies for Global Patient Access**
Michael Kamarck, *Vir Biotechnology, San Francisco, CA USA*

09:15 – 09:30 Transition Time

The Use of Advanced Computational Tools in the Biopharmaceutical and Vaccine Industries
Parallel Session in the Grand Ballroom
Session Chairs: Julia O'Neill, *Direxa Consulting* and Timothy Schofield, *CMC Sciences, LLC*

09:30 – 09:35 **Introduction**

09:35 – 10:00 **Estimation of Platform Process Variation from Large Portfolio Datasets**
Roger Hart, *Amgen Inc., Cambridge, MA USA*

10:00 – 10:25 **An Advanced Process Control Framing to the Application of Analytics and Modeling for Biopharm Manufacturing Processing**
Robert Guenard, *Biogen, Cambridge, MA USA*

10:25 – 10:50 **Unsupervised Machine Learning for Improved Understanding, Optimization, Process Monitoring and Fault Diagnosis in Early Development**
Nelson Afanador, *Merck & Co., Inc., West Point, PA USA*

10:50 – 11:05 **Panel Discussion - Questions and Answers**

New Technologies for New Modalities
Parallel Session in the District Ballroom
Session Chairs: Andrew Weiskopf, *Biogen* and Heidi Zhang, *Juno Therapeutics, A Celgene Company*

09:30 – 09:35 **Introduction**

09:35 – 10:00 **Gene Therapy and AAV: Advancing Analytical Characterization and Product Understanding for Late-state and Lifecycle Success**
Herbert Runnels, *Pfizer, Inc., Chesterfield, MO USA*

10:00 – 10:25 **Leveraging Bioprocessing Technologies and Product Insight for Next Generation CAR-T Production**
Matthew Westoby, *Juno Therapeutics, A Celgene Company, Seattle, WA USA*

10:25 – 10:50 **ProteinMentor: A Breakthrough Platform Technology for Developability and Comparability Assessment Providing a Transforamtive Solution for the Study of Therapeutic Proteins**
Belinda Pastrana, *Protein Dynamic Solutions, Wakefield, MA USA*

WEDNESDAY, JANUARY 30 *continued*

10:50 – 11:05 **Panel Discussion - Questions and Answers**

11:05 – 11:15 **Networking Break** – Visit the Exhibits in the East / State Rooms

11:15 – 12:30

Current Regulatory Trends and Hot Topics Around the Globe
Panel Discussion in the Grand Ballroom
Session Chairs: Carmilia Jiménez-Ramirez, *Ajinimoto Bio-Pharma Services* and Thomas Schreitmüller, *F. Hoffmann-La Roche Ltd.*

Panel Members:
Shatha Zevad Mohammed Al qur'an, *Jordan Food and Drug Administration, Jordan*
Vered Ben-Naim, *Ministry of Health, Israel*
Penny Kusumastuti Lukito, *National Agency of Drug and Food Control, Indonesia*
Patrick Owusu-Danso, *Food and Drug Authority, Ghana*
Gilia Pines, *Ministry of Health, Israel*
Claudia Saidman, *ANMAT-National Administration of Medicines, Food and Medical Technology, Argentina*

11:30 – 12:30 **Roundtable Session 2**
Select Your Table Topic in One of the Following Rooms

- Cabinet Room
- Chinese Room
- Palm Court Ballroom
- Pennsylvania Room (located on the second floor)
- Rhode Island (located on the second floor)
- South Carolina (located on the second floor)
- Virginia Room (located on the second floor)

Please refer to table topics listed in the back of this program book.
Table seats are on a first-come, first-serve basis.

12:30 – 14:15 **Lunch Break** – Participants on their own

13:00 – 14:00 **Technical Seminars**

N-Glycan Sample Preparation and Analysis Workflows for Screening and Characterization of Biotherapeutics
Sponsored by ProZyme, A part of Agilent **Cabinet Room**
NOTE: Lunch is provided for first 100 attendees

Recent Advances in Trapped Ion Mobility Mass Spectrometry (TimsTOF) and High Field NMR for the Evaluation of Biotherapeutics Sequence and Higher Order Structure
Sponsored by Bruker Corporation **Chinese Room**
NOTE: Lunch is provided for first 100 attendees

WEDNESDAY, JANUARY 30 *continued*

13:00 – 14:00 **Technical Seminars** *continued*

Strategies for Profiling, Characterization and Quantitation of N-Linked Glycans
Sponsored by SCIEX **District Ballroom**
NOTE: Lunch is provided for first 100 attendees

Host Cell Protein (HCP) Immunoassays and Integration of Orthogonal Methods for Determination of HCP Impurities in Downstream Samples
Sponsored by Cygnus Technologies **Grand Ballroom**
NOTE: Lunch is provided for first 100 attendees

Advancing Biopharmaceutical Discovery, Development and Manufacturing: A High Resolution Accurate Mass MAM Workflow
The Evolution of MAM
Sponsored by Thermo Fisher Scientific **Palm Court Ballroom**
NOTE: Lunch is provided for first 100 attendees

14:15 – 15:30 **Workshop Session 2**

CQA and Process Characterization: Are You Doing What Everyone Else is Doing? Output from an IQ Consortium Working Group
Standard **Chinese Room**
Michael Kennedy, *CBER, FDA;* Melody Schmidt, *Genentech, a Member of the Roche Group;* Philip Tsai, *Seattle Genetics, Inc.*

Linking Biology to Chemistry to Enable Process Optimization
Standard **District Ballroom**
Aston Liu, *GlaxoSmithKline;* Amy Morrison, *Biogen;* Jennifer Reed, *CBER, FDA;* Yan Wang, *CDER, FDA*

Qualification of New Working Cell Banks
Standard **Grand Ballroom**
Gerald DiDonato, *Bristol-Myers Squibb Company;* Kathryn King, *CDER, FDA;* Michael Laird, *Genentech, a Member of the Roche Group;* Haruhiko Murato, *CBER, FDA*

Blood Products – Issues Related to Potency Assay Standardization
Plen-shop **Palm Court Ballroom**
David Boerema, *CSL Behring;* Andrew Change, *Novo Nordisk Inc.;* Roman Drews, *Daiichi Sankyo, Inc.;* Wojciech Jankowski, *CBER, FDA;* Daniel Lagassé, *CBER, FDA;* Sanne Valentin, *Novo Nordisk Inc.*

15:30 – 16:30 **Networking Break** - Visit the Exhibits in the East / State Rooms
OR Attend One of the Technical Seminars

WEDNESDAY, JANUARY 30 *continued*

15:45 – 16:15 **Technical Seminars**

Not a Biosimilar or a Generic: Finding the Analytical Middle Ground for Complex Generic APIs
Sponsored by SGS Life Science Service **Chinese Room**

A Platform Approach to Manage Developability and Manufacturability Risks of Biologics Molecules
Sponsored by Genedata, Inc. **District Ballroom**

Light Scattering Tools for Rapid Screening and Deep Characterization of Therapeutic Nanoparticles
Sponsored by Wyatt Technology Corporation **Palm Court Ballroom**

Global Access through Transformative Technology
Parallel Session in the Grand Ballroom
Session Chairs: John Frenz and William Hancock, *Northeastern University*

16:30 – 16:35 **Introduction**

16:35 – 17:00 **Access-by-Design: Making Biologics Available to All and Advances in Diagnositc Technology to Support Global Access**
Rajeev Ram and Stacy Springs, *Massachusetts Institute of Technology, Cambridge, MA USA*

17:00 – 17:25 **The Development of Modular Manufacturing Systems that Would be Deployed to Africa for Local Production of Biologics**
Parrish Galliher, *GE Healthcare Life Sciences, Marlborough, MA USA*

17:25 – 17:50 **Perspectives on Access and Innovation Needs for Medical Products in MSF Contexts and Beyond**
Jennifer Reid, *Doctors Without Borders, New York, NY USA*

17:50 – 18:05 **Panel Discussion - Questions and Answers**

Advances in Process Control Plans and the Definition of CMC "Established Conditions"
Parallel Session in the District Ballroom
Session Chairs: Kristopher Barnthouse, *Janssen R&D, LLC* and Shannon Holmes, *Biogen*

16:30 – 16:35 **Introduction**

16:35 – 17:00 **Process Science to Regulatory Science: Control Strategy and Established Conditions 2019**
David Robbins, MedImmune, A member of the AstraZeneca Group

17:00 – 17:25 **Biopharmaceutical Process Model Evolution – Enabling Process Knowledge Continuum from an Advanced Process Control Perspective**
Saly Romero-Torres, *Biogen, Research Park Triangle, NC USA*

WEDNESDAY, JANUARY 30 *continued*

17:25 – 17:50 **Performance-based Approaches as an Enabler for Process Analytical Technologies**
Christine Moore, *Merck & Co., Inc., West Point, PA USA*

17:50 – 18:05 **Panel Discussion - Questions and Answers**

18:05 – 20:00 **Exhibitor Reception** in the East / State Rooms

THURSDAY, JANUARY 31, 2019

07:30 – 08:45 **Continental Breakfast** in the East/State Rooms

08:00 – 17:00 **Registration** in the Senate Room

08:45 – 09:00 **Acknowledgements** in the Grand Ballroom
Stefanie Pluschkell, *Pfizer, Inc.*

09:00 – 10:30

Improving Patient Access & Public Health: How Global Health Authorities and Industry Can Collaborate on CMC Expectations
Plenary Session in the Grand Ballroom
Session Chairs: J. Christopher Love, *Koch Institutue, MIT* and Robert Sitrin, *PATH*

Participants:
Eric Karikari-Boateng, *Food and Drug Authority, Accra, Ghana*
Ivana Knezevic, *World Health Organization, Geneva, Switzerland*
Sundaresan Ramanan, *Biocon, Bangalore, India*
David Robinson, *The Bill & Melinda Gates Foundation, New York, NY USA*

10:30 – 11:30 **Networking Break** - Visit the Exhibits in the East / State Rooms
OR Attend One of the Technical Seminars

10:45 – 11:15 **Technical Seminars**

Better, Faster, Stronger...Analysis. Expanding SPR Uses in Effector Function Determination
Sponsored by GE Healthcare Life Sciences **Chinese Room**

A View from the Top: Mass Analysis of Monoclonal Antibodies Using Various Liquid Chromatographic Separations and Mass Spectrometry
Sponsored by Eurofins BioPharma Product Testing **District Ballroom**

Addressing Requirements for Bioassay Cells as Critical Reagents from Development to QC Lot Release
Sponsored by Eurofins Pharma Discovery Services **Palm Court Ballroom**

11:30 – 12:45 **Workshop Session 3**

Qualification of Reference Materials to Sustain the Product Lifecycle
Standard **Chinese Room**
Brian Janelsins, *CDER, FDA;* Alexey Khrenov, *CBER, FDA;* Nancy Kirschbaum, *Syneos Health;* Shawn Novick, *Seattle Genetics, Inc.*

THURSDAY, JANUARY 31 *continued*

11:30 – 12:45 **Workshop Session 3** *continued*

Controlling Raw Material Variability – Do Today's Practices Meet Current & Future Challenges?
Standard **District Ballroom**
Arulvathani Arudchandran, *CDER, FDA;* Beth Junker, *BioProcess Advantage LLC;* Edwin Moore, *University of Illinois;* Ze Peng, *CBER, FDA*

Control Strategies for Cell and Gene Therapy Products
Standard **Grand Ballroom**
Jarrod Dean, *Sanofi;* Lily Koo, *CBER, FDA;* Herbert Runnels, *Pfizer, Inc.;* Sumona Sarkar, *NIST*

Patient-centric Stability and Expiration Dating - A Global View
Standard **Palm Court Ballroom**
Kavita Ramalingam Iyer, *Merck & Co., Inc.;* Mikhael Ovanesov, *CBER, FDA;* Tami Wu, *Seattle Genetics, Inc.*

12:45 – 14:15 **Hosted Lunch Break** in the East / State Rooms

14:15 – 15:30 **Workshop Session 4**

Crowd Sourced "Hot" Topic
Standard **Chinese Room**
Ingrid Markovic, *Genentech, a Member of the Roche Group;* Emily Shacter, *ThinkFDA*

Microbial Requirements for Marketing Applications
Standard **District Ballroom**
Hui Cai, *WuxiAppTec;* Reyes Candau-Chacon, *CDER, FDA;* James Kenney, *CBER, FDA;* Arne Staby, *Novo Nordisk A/S*

Closed System Transfer Device (CSTD) Use with Drug or Biological Product
Standard **Grand Ballroom**
Natalya Ananyeva, *CBER, FDA;* Sherri Biondi, *MedImmune, A member of the AstraZeneca Group;* Kathleen Hanley, *Genentech, a Member of the Roche Group*; *Linda Narhi, Amgen Inc.*; Lana Shiu, *Amgen Inc.*

Next Generation Sequencing: The Range of Applications of NGS Technology
Standard **Palm Court Ballroom**
Jeri Ann Boose, *Eurofins Lancaster Laboratories, Inc.*; Arifa Khan, *CBER, FDA;* Scott Kuhns, *Amgen Inc.;* Nasrin Salehi, *Pfizer, Inc.*

15:30 – 16:00 **Networking Break** in the Promenade Foyer

THURSDAY, JANUARY 31 *continued*

Manufacturing of the Future: The Journey to Flexible and Modular Facilities and the Use of PAT in Continuous Manufacturing
Plenary Session in the Grand Ballroom
Session Chairs: Rohini Deshpande, *Amgen Inc.* and Stacey Kaneshiro, *Eli Lilly and Company*

16:00 – 16:05 **Introduction**

16:05 – 16:30 **PAT Enabled Flexible Modular Biomanufacturing with Real Time PQA Monitoring and Control**
Gang Xue, *Amgen Inc., Lexington, MA USA*

16:30 – 16:55 **Enabling the Transformation of Biologic Manufacturing**
Brian Fahie, *Biogen, Cambridge, MA USA*

16:55 – 17:20 **Manufacturing of the Future is Becoming a Reality Today - Automated Sampling and PAT for Integrated Continuous Biomanufacturing Platform**
Aleksandar Cvetkovic, *Sanofi, Framingham, MA USA*

17:20 – 17:35 **Panel Discussion - Questions and Answers**

17:35 – 17:45 **Closing Remarks & Invitation to WCBP 2020**
Jamie Moore, *Genentech, a Member of the Roche Group*

Roundtable Information

Roundtable Session One
Tuesday, January 29, 2019
16:00 – 17:00

Roundtable MiniCases

Roundtable MiniCases are a new format to this year's WCBP that were developed to address the needs of attendees looking to learn more about a subject but don't have an extensive background in that area. These sessions will feature a brief introduction to the topic that will include data, examples or a case study intended to stimulate both discussion and learning. The subsequent discussion will be facilitated by experienced professionals and will focus on knowledge sharing.

In the Pennsylvania Room

TOPIC: **Method Validation Deliverables**
FACILITATORS: Nadine Ritter, *Global Biotech Experts, LLC* and Pinger Wang, *Janssen R&D, LLC*

In the Rhode Island Room

TOPIC: **Comparability Concepts and Case Studies**
FACILITATORS: Markus Blümel, *Novartis Pharma AG* and Reed Harris, *Genentech, a Member of the Roche Group*

In the South Carolina Room

TOPIC: **Setting Specifications – Review of FIH and Commercial Strategies**
FACILITATORS: Jochen Felix Kepert, *Roche Diagnostics GmbH* and Shawn Novick, *Seattle Genetics, Inc.*

In the Virginia Room

TOPIC: **Putting Together a "Quality" Dossier**
FACILITATORS: Michelle Frazier and Kathy Lee, *Eli Lilly and Company*

Standard Roundtables

In the Palm Court Ballroom

Table 1: Leveraging New Technologies to Get to Market Faster
Facilitator: Latonia Harris, *Janssen Pharmaceutical R&D, LLC*
Scribe: Jason Wood, *Bruker Corporation*

Table 2: Best Practices for QbD Development of Analytical Methods
Facilitator: Claudia Magagnoli, *GlaxoSmithKline*
Scribe: Joe Glajch, *JLG AP Consulting LLC*

Table 3: Practical Considerations: Mass Spec Based Multi-attribute Methods
Facilitator: Carly Daniels, *Pfizer, Inc.*
Scribe: John Kim, *Teva Pharmaceuticals*

Roundtable Session One *continued*

Table 4: Brexit
Facilitator: Joe Kutza, *MedImmune, A member of the AstraZeneca Group*
Scribe: Courtney Sawicki, *Merck & Co., Inc*

Table 5: Translating cGMPs Between Traditional Large-scale Modalities and Small-scale Personalized Medicines
Facilitator: Matt Kalo, *Genentech, a Member of the Roche Group*
Scribe: Rich Cornell, *Pfizer, Inc.*

Table 6: EU Clinical Trial Regulation and Impact to Clinical Trial Materials
Facilitator: Patsy Lewis, *Alpine Immune Services*
Scribe: Matt Campagna, *MedImmune, A member of the AstraZeneca Group*

Table 7: Continuous Manufacturing, RTRT, PAT
Facilitator: Markus Haindl, *Roche Diagnostics GmbH*
Scribe: Jason Starkey, *Pfizer, Inc.*

Table 8: Contractors and In-licensing: Working Effectively Across Companies
Facilitator: Megan Ward, *Bayer*
Scribe: Ian Meemaduma, *Biogen*

In the Chinese Room
Table 9: ICH Q12 and Life Cycle Management (LCM)
Facilitator: Gerald Gellerman, Novartis Pharma AG
Scribe: Ruth Cordoba, *AstraZeneca*

Table 10: Breakthrough Therapies
Facilitator: Bharat Dixit, *Finch Therapeutics Group*
Scribe: Bob Kozak, *Bayer*

Table 11: BioACCESS: Technology Based Solutions for Global Health Needs for Non-communicable Diseases
Facilitator: John Frenz
Scribe: Daniel Peng, *Merck & Co., Inc.*

Table 12: MCB and WCB Stability Testing
Facilitator: Fadi Hakki, *Viela Bio*
Scribe: Penelope Sharpe, *Pfizer, Inc.*

Table 13: Raw Materials
Facilitator: Amy St. Charles, *Pfizer, Inc.*
Scribe: Gerald DiDonato, *Bristol-Myers Squibb Company*

Table 14: Single Use and Extractables/Leachables
Facilitator: Katherine Hsia, *Bayer*
Scribe: Carsten Worsøe, *Novo Nordisk A/S*

Roundtable Session One *continued*

In the Cabinet Room

Table 15: Vaccines: Potency Assays
Facilitator: Julia O'Neill, *Direxa Consulting*
Scribe: Emilia Byrne, *Pfizer, Inc.*

Table 16: Knowledge Management - The Nuts and Bolts
Facilitator: Sofi Fexby, *Biogen*
Scribe: Catherine Eakin, *Seattle Genetics, Inc.*

Table 17: Cell and Gene Therapy Critical Quality Attributes
Facilitator: Phoebe Baldus, *Pfizer, Inc.*
Scribe: Mary Denton, *Pfizer, Inc.*

Table 18: Gene Therapy
Facilitator: Zahra Shahrokh, *STC Biologics*
Scribe: Ingrid Markovic, *Genentech, a Member of the Roche Group*

Table 19: BioPhorum Operations Group (BPOG): Rapid Methods for Adventitious Virus Detection and Sterility Assurance
Facilitator: Afahin Sohrabi, *BioReliance Corporation*
Scribe: Ken Miller, *AstraZeneca*

Table 20: Compatibility and Globally Relevant In-use Stability Testing
Facilitator: Isabelle Lequeux, *BioPhorum Operations Group*
Scribe: Trevor Swartz, *Genentech, a Member of the Roche Group*

Roundtable Information

Roundtable Session Two
Wednesday, January 30, 2019
11:30 – 12:30

Roundtable MiniCases

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In the Rhode Island Room

TOPIC: Comparability Concepts and Case Studies

FACILITATORS: Markus Blümel, *Novartis Pharma AG* and Reed Harris, *Genentech, a Member of the Roche Group*

In the South Carolina Room

TOPIC: Setting Specifications – Review of FIH and Commercial Strategies

FACILITATORS: Jochen Felix Kepert, *Roche Diagnostics GmbH* and Shawn Novick, *Seattle Genetics, Inc.*

In the Virginia Room

TOPIC: Putting Together a "Quality" Dossier

FACILITATORS: Michelle Frazier and Kathy Lee, *Eli Lilly and Company*

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In the Palm Court Ballroom

Table 1: Leveraging New Technologies to Get to Market Faster

Facilitator: John Armando, *Biogen*
Scribe: Eileen Berkay, *Janssen Biologics*

Table 2: Best Practices for QbD Development of Analytical Methods

Facilitator: Jason Starkey, *Pfizer, Inc.*
Scribe: Bharat Dixit, *Finch Therapeutics Group*

Table 3: Practical Considerations: Mass Spec Based Multi-attribute Methods

Facilitator: Liqiang (Lisa) Zhou, *AbbVie Inc.*
Scribe: Tyler Carlage, *Biogen*

Roundtable Session Two *continued*

Table 4: Brexit
Facilitator: Jennifer Eck, *MedImmune, A member of the AstraZeneca Group*
Scribe: Carol Krantz, *Seattle Genetics, Inc.*

Table 5: Translating cGMPs Between Traditional Large-scale Modalities and Small-scale Personalized Medicines
Facilitator: Beth Anne Bort, *Pfizer, Inc.*
Scribe: Elizabeth Schmidt, *GlaxoSmithKline*

Table 6: EU Clinical Trial Regulation and Impact to Clinical Trial Materials
Facilitator: Melia Grim, *MedImmune, A member of the AstraZeneca Group*
Scribe: Joe Siemiatkoski, *J Siemiatkoski Consulting*

Table 7: Continuous Manufacturing, RTRT, PAT
Facilitator: Doug Richardson, *Merck & Co., Inc.*
Scribe: Lene Hørlyck, *Novo Nordisk A/S*

Table 8: Contractors and In-licensing: Working Effectively Across Companies
Facilitator: Houjun Yang, *Johnson & Johnson*
Scribe: Isabelle Lequeux, *BioPhorum Operations Group*

In the Chinese Room
Table 9: ICH Q12 and Life Cycle Management (LCM)
Facilitator: Joe Glajch, *JLG AP Consulting LLC*
Scribe: Ruth Cordoba, *AstraZeneca*

Table 10: Breakthrough Therapies
Facilitator: Emily Shacter, *ThinkFDA*
Scribe: Kimberly Wolfram, *Biogen*

Table 21: Vaccines: Control Strategy
Facilitator: Emilia Byrne, *Pfizer, Inc.*
Scribe: Rob Dufield, *Pfizer, Inc.*

Table 22: Current Hot Topics in Biologics Formulation
Facilitator: Kevin King, *Pfizer, Inc.*
Scribe: Mary Beth Pelletier, *Biogen*

Table 23: Practical Aspects of Particulate Testing
Facilitator: Chris Broomell, *Takeda Vaccines*
Scribe: Penny Sharpe, *Pfizer, Inc.*

Table 24: Non-standard mAbs: ADCs & Bispecifics
Facilitator: Jessika Feliciano, *Janssen Pharmaceutical R&D, LLC*
Scribe: Jeff Ryczek, *Pfizer, Inc.*

Roundtable Session Two *continued*

In the Cabinet Room

Table 25: Policy, Advocacy, and Industry Trends
Facilitator: Joseph Kutza, *MedImmune, A member of the AstraZeneca Group*
Scribe: Katherine Hsia, *Bayer*

Table 26: Regenerative Medicine, Stem Cells, and Tissue Engineered Products
Facilitator: TBD
Scribe: Roman Drews, *Daiichi Sankyo, Inc.*

Table 27: Immunogenicity: Impact on Therapeutic Proteins
Facilitator: John Alvino, *MedImmune, A member of the AstraZeneca Group*
Scribe: Linda Narhi, *Amgen Inc.*

Table 28: Multi-product Manufacturing and Chromatography Resins
Facilitator: Ekta Mahajan, *Genentech, a Member of the Roche Group*
Scribe: Angela Pishioneri, *MedImmune, A member of the AstraZeneca Group*

Table 29: Replacing *in vivo* with *in vitro* Safety Tests for Biological Products
Facilitator: William (Bill) Egan, *GlaxoSmithKline Vaccines*
Scribe: Lesbeth Rodriquez, *Bayer*

Table 30: Cell Therapy: Unique Challenges and Strategies to Meet Patient Needs
Facilitator: Wallace Kaserer, *Janssen Pharmaceutical R&D, LLC*
Scribe: Bob Kozak, *Bayer*