The Scientific Organizing Committee gratefully acknowledges the pharmaceutical and biotechnology industry for their generous support of WCBP 2020:

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<tr>
<th>Strategic Diamond Program Partners</th>
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<td>F. Hoffmann-La Roche Ltd.</td>
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<td>Genentech, a Member of the Roche Group</td>
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<th>Strategic Platinum Program Partners</th>
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<td>Merck &amp; Co., Inc.</td>
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<th>Strategic Gold Program Partners</th>
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<td>AbbVie Bioresearch Center, Inc.</td>
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<td>Eli Lilly and Company</td>
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<td>Novo Nordisk A/S</td>
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<th>Strategic Silver Program Partner</th>
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<td>Bristol-Myers Squibb Company</td>
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## Gold Program Partners
- Bill and Melinda Gates Foundation
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## Silver Program Partners
- BioMarin Pharmaceutical Inc.
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- Seattle Genetics, Inc.

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- Janssen Pharmaceutical R&D, LLC
- Omeros Corporation
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The Scientific Organizing Committee gratefully acknowledges the program partners and exhibitors for their generous support of WCBP 2020:

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<td>Thermo Fisher Scientific</td>
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<td>BioAnalytix, Inc. / Protagen Protein Services GmbH</td>
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The Scientific Organizing Committee gratefully acknowledges the exhibitors for their generous support of WCBP 2020:

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<th>Exhibitor Partners</th>
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<td>Agilent Technologies, Inc.</td>
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<td>KBI Biopharma, Inc.</td>
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The Scientific Organizing Committee gratefully acknowledges the following media for their promotional consideration of WCBP 2020:

Leading Media Partners

BioProcess International
International Pharmaceutical Quality
Acknowledgements

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Cecilia Tami, CDER, FDA

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Michael Kunitani, Marin Analytical Consulting
Thomas Layloff, Supply Chain Management System

Special thanks to all the Workshop Session Co-leaders

Special thanks to all the Roundtable Facilitators and Scribes
Acknowledgements continued

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American Chemical Society, Division of Analytical Chemistry (ACS, DAC)
Chinese Biopharmaceutical Association (CBA)
MASSSEP.org
National Institute of Standards and Technology (NIST)
Pharmaceutical & BioScience Society (PBSS)
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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 National Portrait Gallery. Guest tickets to the Welcome Reception may be purchased at the registration desk at a cost of $125.00.

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:

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>Tuesday, January 28</td>
<td>7:00 to 17:00</td>
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<tr>
<td>Wednesday, January 29</td>
<td>8:00 to 17:00</td>
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<tr>
<td>Thursday, January 30</td>
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Roundtable Sessions:
This year at WCBP 2020, there are two roundtable sessions that will consist of a total 48 topics. The first session will be held on Tuesday, January 28 from 16:00 to 17:15 and the second session will be held on Wednesday, January 29 from 11:30 to 12:45.

The sessions will last 75 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 were such a success in 2019 that we’re bringing them back this year. The Roundtable MiniCases are a new format at 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 2020 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!

Knowledge Circle
NEW! WCBP 2020 continues to offer engaging content for all levels of experience. This year join us for the Knowledge Circle, a new format that will explore topics of interest that would not traditionally be included in the program. Listen and interact with experts and newcomers alike as they share their stories related to:
   • Green Biotech: Progress is Sustainability
   • Giving Back to the Community
   • The CASSS Mentorship Program
   • Career Paths through Industry, Academia and Regulatory
   • Crowd-sourced “HOT” Topic Workshop
The Knowledge Circle will be held in the State Room, parallel with the roundtable and workshop sessions.

Technical Seminars:
Luncheon technical seminars will be held on Tuesday, January 28 from 12:50-13:50; Wednesday, January 29 from 13:15-14:15; and Thursday, January 30 from 12:45-13:45. Lunch will be available 30 minutes prior to the start of the technical seminar and will be provided for the first 100 attendees.

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.
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 Training on Tuesday, January 28 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 28, 2020
19:00 – 23:00  Welcome Reception  National Portrait Gallery
NOTE: Transportation will be provided.

Wednesday, January 29, 2020
07:15 – 08:30  New Member Breakfast  District Ballroom
Access to this event requires a “New Member” ribbon on the badge.

Wednesday, January 29, 2020
18:00 – 19:30  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 17:20 in the Grand Ballroom. You must be present to win.
We are pleased to once again offer the CASSS Mobile App for the CMC Strategy Forum January and WCBP 2020!

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 CMC Strategy Forum and WCBP 2020 Mobile App is coming in January 2020. 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 28 at 10:15 in the Cabinet Room. You can also contact CASSS’ Exhibitor and Technology Coordinator, Isolde Honoré (ihonore@casss.org) or stop by the registration office in the Senate Room.
TUESDAY, JANUARY 28, 2020

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

07:00 – 17:00 Registration in the Promenade Foyer / Senate Room

08:00 – 08:15 CASSS Welcome in the Grand Ballroom
Nadine Ritter, Global Biotech Experts, LLC

08:15 – 08:30 9th Annual William S. Hancock Award Announcement – Sponsored by CASSS in the Grand Ballroom
Wassim Nashabeh, Genentech, a Member of the Roche Group

08:30 – 08:45 WCBP 2020 Introduction in the Grand Ballroom
Jamie Moore, Genentech, a Member of the Roche Group

08:45 – 10:15 US Food and Drug Administration Regulatory Panel Discussion in the Grand Ballroom
Moderator: Joseph Kutza, AstraZeneca
Session Chair: Jamie Moore, Genentech, a Member of the Roche Group

Panel Members:
Marion Gruber, CBER, FDA
David Keire, CDER, FDA
Zhihao (Peter) Qiu, CDER, FDA
Zenobia Taraporewala, CBER, FDA
Joel Welch, CDER, FDA

10:15 – 10:45 Networking Break – Visit the Exhibits in the East / State Rooms

10:15 – 10:45 Mobile App Training
Mobile App training in the Cabinet Room

An Antibody, a Vaccine and a Blood Product Walk into a Bar…Challenges and Solutions in the Development of Novel Modalities Plenary Session in the Grand Ballroom
Session Chairs: John (JR) Dobbins, Eli Lilly and Company and Marjorie Shapiro, CDER, FDA

10:45 – 10:50 Introduction
TUESDAY, JANUARY 28 continued

Pedro Alfonso, Janssen Pharmaceutical R&D, LLC, Malvern, PA USA

11:15 – 11:40  The Good and the Not-So-Good When It Comes to Accelerated Development and Registration of a Vaccine  
Kimberly Duffy and Kimberly Hassis, Merck & Co., West Point, PA USA

11:40 – 12:05  Development of rFVIIIfc-VWF-XTEN (BIVV001): Novel FVIII Based Fusion Protein for the Treatment of Hemophilia A  
Ekta Seth Chhabra, Bioverativ Inc., A Sanofi Company, Waltham, MA USA

12:05 – 12:20  Panel Discussion - Questions and Answers

12:20 – 14:00  Lunch Break – Participants on their own

12:50 – 13:50  Technical Seminars

Meet the Blaze™ Imaged cIEF-MS System for Rapid Analysis of Intact Biotherapeutic Charge Variants  
Sponsored by Intabio  
NOTE: Lunch is provided for first 100 attendees  
Cabinet Room

Powering Up Maurice with Waters™ Empower® Software  
Sponsored by ProteinSimple, a Bio-Techne brand  
NOTE: Lunch is provided for first 100 attendees  
Chinese Room

Conversion of a Potency Assay from Cell-based Binding to AlphaLISA  
Sponsored by Catalent, Inc.  
NOTE: Lunch is provided for first 100 attendees  
District Ballroom

Developing the Analytics and Analytical Workflows Supporting the Analysis of the Next Generation of Biotherapeutic and Gene Therapies  
Sponsored by Waters Corporation  
NOTE: Lunch is provided for first 100 attendees  
Palm Court Ballroom
TUESDAY, JANUARY 28 continued

Analytical Method Modernization for Biologics and Vaccines – Mitigating the Risks Associated with the Introduction of Advanced Technologies

Parallel Session in the Grand Ballroom

Session Chairs: Nomalie Jaya, Seattle Genetics, Inc. and Sonya Kennedy-Gabb, GlaxoSmithKline

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<td>14:00 – 14:05</td>
<td>Introduction</td>
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| 14:05 – 14:30 | Multi-attribute Analytical Method Advancing in Viral Release Testing: “All-In-One” Identity, Infectivity and Transgene Expression Quantification for Virus-vectored Vaccines  
Marc Fiorucci, GlaxoSmithKline Vaccines, Rixensart, Belgium |
| 14:30 – 14:55 | From Profile-based Assays to Attribute-focused Analysis: A Case Study of Analytical Method Modernization  
Da Ren, Amgen Inc., Thousand Oaks, CA USA |
| 14:55 – 15:20 | A Path Forward: Establishing New NMR Analytical Protocols to Assure the Quality of Biologics  
David Keire, CDER, FDA, St. Louis, MO USA |
| 15:20 – 15:35 | Panel Discussion - Questions and Answers                               |
| 15:35 – 16:00 | Networking Break – Visit the Exhibits in the East / State Rooms        |

Connecting CQAs to Process Parameters and Materials

Parallel Session in the District Ballroom

Session Chairs: Valerie Tsang, Biogen and Li Zang, AbbVie Bioresearch Center, Inc.

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| 14:05 – 14:30 | Leveraging Material Attribute Knowledge as the Foundation for a Predict and Prevent Raw Material Control Strategy  
Susan Burke, Amgen Inc., Thousand Oaks, CA USA |
| 14:30 – 14:55 | Holistic Control Strategy – From Molecular Design to Combination Product  
Chandra Webb, Pfizer, Inc., Andover, MA USA |
| 14:55 – 15:20 | Understanding the Critical Quality Attributes of a mAb and an ADC and Their Relationship to Reduction and Conjugation Parameters  
Hillary Schuessler, GlaxoSmithKline, King of Prussia, PA 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 28 continued

16:00 – 17:15

**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

**Current Regulatory Trends and Hot Topics Around the Globe: Part One**

**Plen-shop Discussion** in the Grand Ballroom

**Session Chairs:** Andrew Chang, *Novo Nordisk Inc.* and Markus Goese, *F. Hoffmann-La Roche Ltd.*

- **Biologics in Brazil: Overview and Perspectives**
  Elkiane Rama, *ANVISA-Brazilian National Health Surveillance Agency, Brazil*

- **Health Canada: Update on Regulatory Activities and Priorities**
  Anthony Ridgway, *Health Canada, Ottawa, ON Canada*

- **Title TBD**
  Patricia Aprea, *ANMAT-National Administration of Medicines, Food and Medical Technology, Argentina*

- **Recent Trends in the Regulation of Biopharmaceutical Products – A European Update**
  Steffen Gross, *Paul-Ehrlich-Institut, Germany*

16:00 – 17:15

**Green Biotech: Progress is Sustainability**

**Knowledge Circle** in the State Room

**Chair:** Jamie Moore, *Genentech, a Member of the Roche Group*

**Presenters:**
- William Cooper, *Agilyx*
- Sally Kline, *Genentech, a Member of the Roche Group*
- Ken Silverman, *AstraZeneca*

17:15 – 17:30

**Transition Time**
### Workshop Session 1

**Accelerating the Implementation of New Technologies – Are We Having Fun Yet?**  
**Standard Chinese Room**  
Rana Chattopadhyay, *CBER, FDA*; Jeff Davis, *Genentech, a Member of the Roche Group*; Riley Myers, *CDER, FDA*; Emily Shacter, *ThinkFDA, LLC*

**Enabling Real Time Release – Strategic Approaches to Design the PAT Roadmap**  
**Standard District Ballroom**  

**Perspectives on Q12 Lifecycle Management and Established Conditions / Approved Matters**  
**Plen-shop Grand Ballroom**  
Jennifer Eck, *AstraZeneca*; Minh Luu, *Genentech, a Member of the Roche Group*; Chikako Torigoe, *CBER, FDA*; Qing (Joanna) Zhou, *CDER, FDA*

**Can We Really Control Polysorbate?**  
**Standard Palm Court Ballroom**  

### 17:30 – 18:45

**Giving Back to the Community**  
**Knowledge Circle** in the State Room  
**Chair:** Shawn Novick

**Presenters:**  
Nina Cauchon, *Amgen Inc.*  
William Hancock, *Northeastern University*  
Edwin Moore, *University of Illinois*  
Robert Sitrin, *PATH*

### 19:00 – 23:00

**Welcome Reception** at the National Portrait Gallery  
Transportation will be provided
WEDNESDAY, JANUARY 29, 2020

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

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

08:30 – 09:15  Featured Keynote Speaker

**Fireside Chat** in the Grand Ballroom
Moderator: Nadine Ritter, *Global Biotech Experts, LLC*

Amy P. Abernethy, M.D., Ph.D., Principal Deputy Commissioner
*Food and Drugs, Silver Spring, MD USA*

09:15 – 09:30  Transition Time

Industry and Regulatory Perspectives on Challenges and Opportunities of Cell & Gene Therapy Product Development

**Parallel Session** in the Grand Ballroom

**Session Chairs:** Ingrid Markovic, *Genentech, a Member of the Roche Group* and
Francis Poulin, *Sanofi*

09:30 – 09:35  Introduction

09:35 – 10:00  ATMPs – New Concepts and the Existing Regulatory Framework
Ilona Reischl, *BASG-Federal Office for Safety in Health Care, Vienna, Austria*

10:00 – 10:25  Specifications for Cell & Gene Therapy Products: Maximizing Patient Access to a Safe & Effective Quality Product
Neil Haig, *Juno Therapeutics, A Bristol-Myers Squibb Company, Seattle, WA USA*

10:25 – 10:50  Adaptive, Flexible or Novel: Regulatory Frameworks for Advanced Therapies – Case Study: Individualized Neoantigen-specific Therapy (iNeST)
Kathleen Francissen, *Genentech, a Member of the Roche Group, South San Francisco, CA USA*

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

11:05 – 11:30  Networking Break – Visit the Exhibits in the East / State Rooms

Connecting Critical Quality Product Attributes to Patients’ Outcomes

**Parallel Session** in the District Ballroom

**Session Chairs:** Guoying Jiang, *Genentech, a Member of the Roche Group* and
Wayne Kelley, *GlaxoSmithKline*

09:30 – 09:35  Introduction
WEDNESDAY, JANUARY 29 continued

09:35 – 10:00  Considering Impurity Specifications in the Context of Immunogenicity Risk
Daniela Verthelyi, CDER, FDA, Silver Spring, MD USA

10:00 – 10:25  Product Understanding: Connecting the Dots
Claire Davies, Sanofi, Framingham, MA USA

10:25 – 10:50  Establishing Patient-centric Specifications by Connecting Product Quality
and Clinical Outcomes
Richard Beardsley, Genentech, a Member of the Roche Group, South San
Francisco, CA USA

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

11:05 – 11:30  Networking Break – Visit the Exhibits in the East / State Rooms

11:30 – 12:45  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.

11:30 – 12:45  Current Regulatory Trends and Hot Topics Around the Globe: Part Two
Discussion in the Grand Ballroom
Session Chairs: Susanne Ausborn, F. Hoffmann-La Roche Ltd. and Anthony Ridgway,
Health Canada

Title TBD
Esra’a abedelrahman Alzubi, JFDA-Jordan Food and Drug Administration,
Jordan

Trends in Regulatory Convergence / Harmonization in West Africa
Eric Karikari-Boateng and Patrick Owusu-Danso, Food and Drugs Authority,
Ghana

Challenges and Priorities in Paraguayan Regulatory Agency
Julio Rolón, National Directorate of Health Surveillance, Ministry of Public
Health and Social Welfare, Paraguay,
Regulation of Biological Products in Peru: The Current Situation  
Susan Zavala Coloma, DIGEMID-General Directorate of Medicines, Supplies and Drugs, Peru

Accelerated Approval for Medicines in Rare and Serious Diseases  
Claudia Saidman, ANMAT-National Administration of Medicines, Food and Medical Technology, Argentina

11:30 – 12:45

**The CASSS Mentorship Program**  
**Knowledge Circle** in the State Room  
**Chairs:** Edwin Moore, *University of Illinois* and Mark Schenerman, *CMC Biotech-MAS Consulting*

**Presenters:**  
Maura Kibbey, *U.S. Pharmacopeia*  
Mark Schenerman, *CMC Biotech-MAS Consulting*

12:45 – 14:30  
**Lunch Break** – Participants on their own

13:15 – 14:15  
**Technical Seminars**

**Host Cell Protein (HCP) Immunoassays and the Role of Mass Spectrometry in Identification of HCP Impurities in Downstream Samples**  
Sponsored by Cygnus Technologies  
**NOTE:** Lunch is provided for first 100 attendees  
*Cabinet Room*

**Characterization of Critical Quality Attributes Using State-of-the-art Analytical Technologies: A Focus on Sample Preparation and Automation**  
Sponsored by Agilent Technologies  
**NOTE:** Lunch is provided for first 100 attendees  
*Chinese Room*

**Identification and Tracking of Problematic Host Cell Proteins Through Downstream Bioprocessing of Monoclonal Antibodies**  
Sponsored by Thermo Fisher Scientific  
**NOTE:** Lunch is provided for the first 100 attendees  
*District Ballroom*

**Development of On-line Hydrophobic Interaction Chromatography Method for Therapeutic Proteins Characterization using Native Mass Spectrometry**  
Sponsored by SCIEX  
**NOTE:** Lunch is provided for the first 100 attendees  
*Palm Court Ballroom*

14:15 – 14:30  
**Networking Break** - Visit the Exhibits in the East / State Rooms
WEDNESDAY, JANUARY 29 continued

**Putting Prior Knowledge to Immediate Use: Knowledge Management and Digital Tools to Accelerate Development**

**Parallel Session** in the Grand Ballroom

**Session Chairs:** Shawn Novick, *BioPhia Consulting* and Stefanie Pluschkell, *Pfizer, Inc.*

14:30 – 14:35  **Introduction**

14:35 – 15:00  **Traversing the Pyramid: Data > Information > Knowledge > Wisdom**
Richa Sarin, *Biogen, Cambridge, MA USA*

15:00 – 15:25  **Been There, Done That: Applying Prior Knowledge in Process and Method Validation**
Melody Trexler Schmidt, *Genentech, a Member of the Roche Group, South San Francisco, CA USA*

15:25 – 15:50  **Leveraging Prior Knowledge for Marketing Approval Filings in Accelerated Settings**
Athena Nagi, *Merck & Co., Inc., West Point, PA USA*

15:50 – 16:05  **Panel Discussion - Questions and Answers**

**Factory of the Future: Considerations for Flexible Adaptive Manufacturing**

**Parallel Session** in the District Ballroom

**Session Chairs:** Kevin King, *Pfizer, Inc.* and A. Graham Tulloch, *Janssen Pharmaceutical R&D, LLC*

14:30 – 14:35  **Introduction**

14:35 – 15:00  **On Application of Multi-scale Modelling for Facility Simulation and Process Control Strategy: Moving from Reactive to Proactive Decision Making**
Deenesh Kavi Babi, *Novo Nordisk A/S, Kalundborg, Denmark*

Ping Huang, *AbbVie, Inc., Redwood City, CA USA*

Michael Jankowski, *Pfizer, Inc., Chesterfield, MO USA*

15:50 – 16:05  **Panel Discussion - Questions and Answers**

16:05 – 16:30  **Networking Break** - Visit the Exhibits in the East / State Rooms
**WEDNESDAY, JANUARY 29 continued**

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<th>Time</th>
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<td></td>
<td><strong>Career Paths through Industry, Academia and Regulatory Knowledge Circle</strong>&lt;br&gt;<strong>Knowledge Circle</strong> in the State Room&lt;br&gt;<strong>Chair:</strong> Kathy Lee, <em>Eli Lilly and Company</em>&lt;br&gt;<strong>Presenters:</strong>&lt;br&gt;Ingrid Markovic, <em>Genentech, a Member of the Roche Group</em>&lt;br&gt;Mark Scheneman, <em>CMC Biotech-MAS Consulting</em>&lt;br&gt;18:00 – 19:30 <strong>Exhibitor Reception</strong> in the East / State Rooms</td>
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THURSDAY, JANUARY 30, 2020

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
Jamie Moore, Genentech, a Member of the Roche Group

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<th>Solutions to Improve Global Access to Healthcare Through Transformative Technologies</th>
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<td><strong>Plenary Session</strong> in the Grand Ballroom</td>
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<td><strong>Session Chairs:</strong> Nina Cauchon, Amgen Inc. and Robert Sitrin, PATH</td>
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09:00 – 09:25  Commoditizing Manufacturing of Vaccines and Biopharmaceuticals for Global Health
Christopher Love, MIT, Cambridge, MA USA

09:25 – 09:50  CMC at the Bill & Melinda Gates Medical Research Institute: Cost to Serve Drives Manufacturing and Supply
Jorg Thommes, Bill & Melinda Gates Medical Research Institute, Cambridge, MA USA

09:50 – 10:15  Development of MIMIX Smart Release Patch Vaccines to Improve Compliance and Global Access
Michael Schrader, Vaxess Technologies, Inc., Cambridge, MA USA

10:15 – 10:30  Panel Discussion – Questions and Answers

10:30 – 11:00  Networking Break - Visit the Exhibits in the East / State Rooms

11:00 – 12:15  Workshop Session 3

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<th>Virtual Quality: Integrating Predictive Modeling Tools into Biologics Drug Design and Development as Part of Pharmaceutical Quality Control</th>
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<td>Chava Kimchi-Sarfaty, CBER, FDA; Olav Lyngberg, Janssen Pharmaceutical R&amp;D, LLC; Thomas O’Connor, CDER, FDA; Vikas Sharma, Genentech, a Member of the Roche Group</td>
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<th>Compliance Challenges and Opportunities in a New Regulatory Environment in China</th>
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<tr>
<td>Greg Gallegos, Genentech, a Member of the Roche Group; Min Jiang, AbbVie, Inc.; Christina Juli, Boehringer Ingelheim</td>
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</table>
11:00 – 12:15  Workshop Session 3 continued

Implementation of the BioPhorum Technology Roadmap
Plen-shop  Grand Ballroom
Audrey Chang, BioReliance/MilliporeSigma; Charlene Craig, Bristol-Myers Squibb Company; Isabelle LeQueux, BioPhorum Operations Group

In Preparation of New ICH Q14: Global Analytical Method Development Standard  Palm Court Ballroom
Marla Abodeely, Sanofi; Jee Chung, CDER, FDA; Muhammad Shahabuddin, CBER, FDA; Qian Wang, Pfizer, Inc.

11:00 – 12:15

Crowd-sourced “HOT” Workshop Topic  Knowledge Circle in the State Room
Workshop Co-leaders: Kathy Lee, Eli Lilly and Company and Stefanie Pluschkell, Pfizer, Inc.

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

12:45 – 13:45  Technical Seminars

Emerging Applications of Electron Microscopy in Pharmaceutical Discovery and Development
Sponsored by NanoImaging Services  Chinese Room
NOTE: Lunch is provided for first 100 attendees

Challenge Analytical Complexity - Biacore™ SPR Systems for Candidate Selection, Characterization and Quality Control
Sponsored by GE Healthcare Life Sciences  District Ballroom
NOTE: Lunch is provided for the first 100 attendees

Measure AAV Quality Attributes with SEC-UV-MALS-dRI
Sponsored by Wyatt Technology Corporation  Palm Court Ballroom
NOTE: Lunch is provided for the first 100 attendees

14:00 – 15:15  Workshop Session 4

The Need to Update Vaccine Assays: Science Versus the Fear Factor  Chinese Room
Cristiana Campa, GSK Vaccines; Robin Levis, CBER, FDA; Todd Ranheim, Takeda Vaccines, Inc.; Dean Smith, Health Canada
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<td><strong>Workshop Session 4 continued</strong></td>
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<td>Demystifying and Staying Ahead of Current FDA Regulatory Expectations for Biologic-Device Combination Products</td>
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<td>Rosemary Gonzales, <em>Amgen Inc.</em>; Ze Peng, <em>CBER, FDA</em>; Leslie Rivera Rosado, <em>CDER, FDA</em>; Chin-Wei Soo, <em>Genentech, a Member of the Roche Group</em></td>
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<td>Long-term Care of Products: How to Develop a Sustainable Strategy for Post-approval Changes</td>
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<td>Digital Future</td>
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<td>15:15 – 15:45</td>
<td><strong>Networking Break</strong> in the Promenade Foyer</td>
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<td>15:45 – 15:50</td>
<td><strong>Rapid Analytics to Accelerate Process Development and Enable Real-time Release Test Plenary Session</strong> in the Grand Ballroom</td>
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<td>Session Chairs: Ping Hu, <em>Janssen Pharmaceutical R&amp;D, LLC</em> and Anthony Leone, <em>Bristol-Myers Squibb Company</em></td>
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<tr>
<td>15:50 – 16:15</td>
<td>Introduction</td>
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<td>15:50 – 16:15</td>
<td>Real-time Product Quality Assessment for Large Molecules Using Process Analytical Technologies</td>
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<td>Bhumit Patel, <em>Merck &amp; Co., Inc.</em>, <em>Kenilworth, NJ USA</em></td>
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<td>16:15 – 16:40</td>
<td>Rapid, Accurate and Precise Cell-based Potency Assays</td>
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<td>Arturo Orjalo, <em>Genentech, a Member of the Roche Group</em>, <em>South San Francisco, CA USA</em></td>
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<td>16:40 – 17:05</td>
<td>The Use of Label Free Raman Spectroscopy for Monitoring Manufacturing Performance and Product Quality</td>
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<td>Jeremy Springall, <em>AstraZeneca</em>, <em>Gaithersburg, MD USA</em></td>
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<td>17:05 – 17:20</td>
<td>Panel Discussion - Questions and Answers</td>
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<tr>
<td>17:20 – 17:30</td>
<td>Closing Remarks &amp; Invitation to WCBP 2021</td>
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<td>Julia Edwards, <em>Genentech, a Member of the Roche Group</em></td>
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Roundtable Information

Roundtable Session One
Tuesday, January 28, 2020
16:00 – 17:15

Roundtable MiniCases
Roundtable MiniCases 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: Reference Standards
FACILITATORS: Markus Blümel, Novartis Pharma AG and Kristi Griffiths, Eli Lilly and Company

In the Rhode Island Room
TOPIC: Post-Approval Changes
FACILITATORS: Kavita Ramalingam Iyer, GSK Biopharm and Sabina Sheikh, Celgene Corporation

In the South Carolina Room
TOPIC: Stability
FACILITATORS: Tami Wu, Seattle Genetics, Inc. and Michael Lynch, Alexion Pharmaceuticals, Inc.

In the Virginia Room
TOPIC: Comparability
FACILITATORS: James Carroll, Pfizer, Inc. and Ruth Cordoba-Rodriguez, AstraZeneca

Standard Roundtables

In the Palm Court Ballroom
Table 1: Linking CMC and Clinical
Facilitator: Charlene Craig, Bristol-Myers Squibb Company
Scribe: Mikayla Thompson, Biogen

Table 2: Predictive Analytics
Facilitator: Heather Hudson, Seattle Genetics, Inc.
Scribe: Ananya Dubey Kelsoe, IonDX Inc.

Table 3: Cell and Gene Therapy Products- Control Strategy
Facilitator: Zahra Shahrokh, ZDev Consulting and STC Biologics
Scribe: Megan Owen, Merck & Co., Inc.
Roundtable Session One continued

Table 4: Particles
Scribe: Carol Krantz, *Seattle Genetics, Inc.*

Table 5: Continued Process Verification (CPV) – Following the Data
Facilitator: David Robbins, *AstraZeneca*
Scribe: Sarah Aubert, *Janssen Pharmaceutical R&D, LLC*

Table 6: Accelerated Programs
Facilitator: Amy Morrison, *Biogen*
Scribe: Claire Davies, *Sanofi*

Table 7: Analytical QbD
Facilitator: Linda Yi, *Biogen*
Scribe: Neil Haig, *Juno Therapeutics, A Bristol-Myers Squibb Company*

Table 8: Structure-Function and MOA- When, What, How and How Much?
Facilitator: Peter Gray, *Janssen Pharmaceutical R&D, LLC*
Scribe: Bernice Yeung, *Biogen*

In the Chinese Room

Table 9: Host Cell Protein – Reagent Coverage, Identification and Risk Assessment
Facilitator: Carmelata Chitikila, *Janssen Pharmaceutical R&D, LLC*
Scribe: Suli Liu, *Biogen*

Table 10: Opportunities and Challenges of Regulatory Submissions in the Digital Age
Facilitator: Leslie Bloom, *Pfizer, Inc.*
Scribe: Mallory Scott, *Bayer HealthCare*

Table 11: Replacement of in vivo Assays
Facilitator: Emilia Bryne, *Pfizer, Inc.*
Scribe: Marla Abodeely, *Sanofi*

Table 12: Flu Vaccine
Facilitator: Brian Nunnally, *Seqirus, a CSL Company*
Scribe: David Cirelli, *Pfizer, Inc.*

Table 13: Biosimilars
Facilitator: Niomi Peckham, *U.S. Pharmacopeia*
Scribe: Chi-Ting Huang, *Surface Oncology*

Table 14: Quality Risk Management for Cross-Contamination in Multi-Product Facilities
Facilitator: Katherine Hsia, *Bayer HealthCare*
Scribe: Isabelle Lequeux, *Biophorum Operations Group (BPOG)*
Roundtable Session One continued

In the Cabinet Room
Table 15: Viral Clearance- Analytical Strategies
Facilitator: Bob Kozak, Bayer HealthCare
Scribe: Mark Paciga, Merck & Co., Inc.

Table 16: Endotoxin Testing
Facilitator: Stephen Gozo, Celgene Corporation
Scribe: Roman Drews, Daiichi Sankyo, Inc.

Table 17: Visual Inspection
Facilitator: Nomalie Jaya, Seattle Genetics, Inc.
Scribe: Francis Poulin, Sanofi

Table 18: NDA to BLA/Biosimilar – Are You Ready for the New Grey Zone?
Facilitator: John Kim, Teva Pharmaceuticals
Scribe: Lesley Redfern, AbbVie Inc.

Table 19: Is There a Problem Using Closed System Transfer Devices with Biological Products?
Facilitator: Stephen Chang, AstraZeneca
Scribe: Fadi Hakki, Viela Bio

Table 20: Trace Metals
Facilitator: Maura Kibbey, U.S. Pharmacopeia
Scribe: Hua Wang, U.S. Pharmacopeia
Roundtable Information

Roundtable Session Two
Wednesday, January 29, 2020
11:30 – 12:45

Roundtable MiniCases
Roundtable MiniCases 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: Reference Standards
FACILITATORS: Markus Blümel, Novartis Pharma AG and Kristi Griffiths, Eli Lilly and Company

In the Rhode Island Room
TOPIC: Post-Approval Changes
FACILITATORS: Kavita Ramalingam Iyer, GSK Biopharm and Sabina Sheikh, Celgene Corporation

In the South Carolina Room
TOPIC: Stability
FACILITATORS: Tami Wu, Seattle Genetics, Inc. and Michael Lynch, Alexion Pharmaceuticals, Inc.

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TOPIC: Comparability
FACILITATORS: James Carroll, Pfizer, Inc. and Ruth Cordoba-Rodriguez, AstraZeneca

Standard Roundtables

In the Palm Court Ballroom
Table 1: Linking CMC and Clinical
Facilitator: Catherine Eakin, Seattle Genetics, Inc.
Scribe: Richard Pelt, Pfizer, Inc.

Table 2: Predictive Analytics
Facilitator: Joe Studts, Boehringer Ingelheim Pharma GmbH & Co. KG
Scribe: Scott Henry, Seattle Genetics, Inc.

Table 3: Cell and Gene Therapy Products- Control Strategy
Facilitator: Julia O’Neill, Direxa Consulting
Scribe: Zahra Shahrokh, ZDev Consulting and STC Biologics
Roundtable Session Two continued

Table 4: Particles
Facilitator: Carol Krantz, Seattle Genetics, Inc.
Scribe: Cindy Wu, Merck & Co., Inc.

Table 5: Continued Process Verification (CPV)- Following the Data
Facilitator: Joslyn Brunelle, Amgen Inc.
Scribe: David Robbins, AstraZeneca

Table 6: Accelerated Programs
Facilitator: John Amery, Pfizer, Inc.
Scribe: Bharat Dixit, ClearB Therapeutics

Table 7: Analytical QbD
Facilitator: Michelle Thompson, Merck & Co., Inc.
Scribe: Mikayla Thompson, Biogen

Table 8: Structure-Function: When, What, How and How Much?
Facilitator: Emily Shacter, ThinkFDA, LLC
Scribe: Mike Nedved, Janssen Pharmaceutical R&D, LLC

In the Chinese Room

Table 9: Host Cell Protein – Reagent Coverage, Identification and Risk Assessment
Facilitator: Lisette Coye, Seattle Genetics, Inc.
Scribe: Danielle Murray, Merck & Co., Inc.

Table 10: Opportunities and Challenges of Regulatory Submissions in the Digital Age
Facilitator: Nicolai Listov-Saabye, Novo Nordisk A/S
Scribe: Patsy Lewis, Omeros Corporation

Table 21: Vaccine Regualatory
Facilitator: Leslie Wagner, CBER, FDA
Scribe: Jennifer Miller, Pfizer, Inc.

Table 22: New Challenges for an Old Problem: Tales of Subvisible Particles
Facilitator: Mike Lewis, Janssen Pharmaceutical R&D, LLC
Scribe: George Bou-Assaf, Biogen

Table 23: Biospecific Antibody
Facilitator: Kirby Steger, Janssen Pharmaceutical R&D, LLC
Scribe: Reed Harris, Genentech, a Member of the Roche Group

Table 24: Advanced Technologies
Facilitator: Yang Liu, GlaxoSmithKline
Scribe: Chongfeng Xu, Biogen
Roundtable Session Two continued

**In the Cabinet Room**

**Table 25: The Multi-Attribute Method: Best Practices for Continued Success**
Facilitator: Ying Zhang, Pfizer, Inc.
Scribe: Linda Yi, Biogen

**Table 26: Data Integrity**
Facilitator: David Good, Eli Lilly and Company
Scribe: Allison Lehtinen, Pfizer, Inc.

**Table 27: Shipping Studies- Analytical Strategies**
Facilitator: Jin Qian, Merck & Co., Inc.
Scribe: Sri Gunturi, Janssen Pharmaceutical R&D, LLC

**Table 28: Formulation Development**
Facilitator: Vincent Corvari, Eli Lilly and Company
Scribe: Tapan Das, Bristol-Myers Squibb Company

**Table 20: Extractables and Leachables- What’s Being Requested and What’s Everyone Doing?**
Facilitator: Neil Steinmeyer, Pfizer, Inc.
Scribe: Lesbeth Rodriguez, Bayer HealthCare

**Table 30: In the Driver’s Seat - CAR-T Product Development Challenges and Solutions**
Facilitator: David Colter, Celgene Corporation
Scribe: Bryan Silvey, Kite Pharma, Inc.