

## July 20, 2022

08:30-08:45	<b>CASSS Welcome and Introductory Comments</b> Washingtonian Ballroom D-G Bhavin Parekh, <i>Eli Lilly and Company</i>
08:45-10:30	<b>Workshop Session One: The Nuts and Bolts of Bioassays</b> Washingtonian Ballroom D-G Session Chairs: Katrin Buss, <i>BfArM</i> , <i>Federal Institute for Drugs and Medical Devices</i> , Jill Crouse-Zeineddini, <i>Amgen Inc.</i> , and Thomas Millward, <i>Novartis Pharma AG</i>  Session Speakers: <b>Characterizing Antibody Fc Effector Functions by Using SPR and Cell-Based Assays</b> Alexander Berger, <i>Boehringer Ingelheim Pharma GmbH &amp; Co. KG</i>  <b>A Better Understanding of Bioassays – How Suitable are Primary Cell Based Assays for the Evaluation of Product Quality</b> Florian Cymer, <i>F. Hoffmann-La Roche Ltd</i>  <b>Bioassay Strategies for Challenging Biologics</b> Ganesh Shankarling, <i>Bristol-Myers Squibb Company</i>  <b>An Alternative Influenza Vaccine Potency Assay: Assessing Receptor-Binding Hemagglutinin by a Coupled Receptor-binding/RP-HPLC Assay</b> Huixin Lu, <i>Health Canada</i>
10:30-11:15	<b>Networking Break</b> Washingtonian Ballroom A-C <b>New Member Networking Event</b> Lakeside Ballroom 1
11:15-12:15	<b>Workshop Session I - Panel Discussion</b> Washingtonian Ballroom D-G
12:15-13:30	<b>Lunch and Learn: Vendor Showcase</b> Washingtonian Ballroom D-G
13:30-14:30	<b>Poster Session</b> Washingtonian Ballroom A-C
14:30-16:15	<b>Workshop Session Two: Bioassays for Cell and Gene Therapies</b> Washingtonian Ballroom D-G Session Chairs: Marina Feschenko, <i>Biogen</i> , Xu-Rong Jiang, <i>AstraZeneca BioVentures</i> , Bhavin Parekh, <i>Eli Lilly and Company</i> , and Michael Sadick, <i>Precision Biosciences</i>  Session Speakers: <b>Resetting Expectations for CAR-T Potency Assessment</b> Avinash Chinthala, <i>Precision Biosciences</i>  <b>Challenges of Developing Potency Assays for Critical Materials Used in Cell and Gene Therapy Products</b> Amanda Dios, <i>Beam Therapeutics</i>  <b>Evolution of Potency Strategy for Gene Therapies</b> Edith Nalbandian, <i>Tune Therapeutics</i>  <b>Platforms to Accelerate Gene Therapy, Cell-Based Assay Development</b> Katelyn Mansfield, <i>Biogen</i>  Additional Panel Member:

	Ramjay Vatsan, <i>CBER, FDA</i>
16:15-16:30	<b>Networking Break</b> Washingtonian Ballroom A-C
16:30-17:30	<b>Workshop Session Two - Panel Discussion</b> Washingtonian Ballroom D-G
17:30-18:30	<b>Exhibitor and Poster Reception</b> Washingtonian Ballroom A-C

## July 21, 2022

08:30-09:15	<b>Keynote Presentation</b> Washingtonian Ballroom D-G <b>Bioassays Throughout Drug Development and the Product Life Cycle</b> Marjorie Shapiro, <i>CDER, FDA</i>
09:15-09:30	<b>Networking Break</b> Washingtonian Ballroom A-C
09:30-11:15	<b>Workshop Session Three: Bioassays for Vaccines</b> Washingtonian Ballroom D-G Session Chairs: David Cirelli, <i>Pfizer, Inc.</i> and Martin Nemec, <i>Health Canada</i>  Session Speakers: <b>Bioassay Technologies for mRNA Vaccines</b> Emma Reyes, <i>Pfizer, Inc.</i>  <b>Improving a Vaccine Potency Assay – A Real World Regulatory Implementation Saga</b> Kimberly Duffy, <i>Merck &amp; Co. Inc.</i>  <b>From Bioassay Method Development to Commercial Testing at Pandemic Speed: The Story of AZD1222 (ChAdOx1 nCoV-19)</b> Scott Umlauf, <i>AstraZeneca</i>  <b>Bioassay Points to Consider During a Pandemic: A Regulator's Perspective</b> Jason Fernandes, <i>Health Canada</i>
11:15-11:45	<b>Networking Break</b> Washingtonian Ballroom A-C
11:45-12:45	<b>Workshop Session Three - Panel Discussion</b> Washingtonian Ballroom D-G
12:45-13:45	<b>Hosted Lunch</b> Washingtonian Ballroom Foyer
13:45-15:30	<b>Workshop Session Four: Process Improvements &amp; Innovation in Bioassays</b> Washingtonian Ballroom D-G Session Chairs: Chana Fuchs, <i>CDER, FDA</i> , Stephen Hartman, <i>AbbVie Inc.</i> and Adelheid Rohde, <i>F. Hoffmann - La Roche Ltd.</i>

	<p>Session Speakers:</p> <p><b>Phase-Appropriate Potency Assay Development Strategies for Gene Therapy Products</b> Arkadi Manukyan, <i>Sanofi</i></p> <p><b>Selection of Optimal 4PL Dose Response Curves Using a Computational Simulation Method</b> Ahmad Ebtikar, <i>Genentech, a Member of the Roche Group</i></p> <p><b>Characterization of Dual AAV Vector Otoferlin</b> Christine Le Bec, <i>Sensorion</i></p> <p><b>CD107a Degranulation Assay to Measure CAR-T Potency</b> Cynthia Bamdad, <i>Minerva Biotechnologies</i></p>
<p>15:30- 15:45</p>	<p><b>Networking Break</b> Washingtonian Ballroom Foyer</p>
<p>15:45- 16:45</p>	<p><b>Workshop Session Four - Panel Discussion</b> Washingtonian Ballroom D-G</p>
<p>16:45- 17:00</p>	<p><b>Closing Remarks</b> Washingtonian Ballroom D-G David Cirelli, <i>Pfizer, Inc.</i></p>