CMC WCBP 2024

Schedule

Monday, 22 January, 2024

07:00-07:15 Palm Court Ballroom

Sunrise Social: Breakfast

Breakfast will be served until 09:00.

07:15-08:30 Promenade Foyer / Senate Room

Registration for Securing Patient Well-being: Best Practices for In-Use Stability and Compatibility Studies and Establishing and Leveraging Platforms to Support Product Development

Track: Securing Patient Well-being: Best Practices for In-Use Stability and Compatibility Studies

Registration is open from 07:00 to 17:00
Pre-registered attendees should go to the Foyer. If you are registering onsite, please make your way to the Senate Room.

08:30-08:50 Grand Ballroom

CASSS Welcome and CMC Strategy Forum 2024 Introductory Comments

Chair: Markus Blümel, Félix Jules, Jing Liu, Jennifer Swisher
Presentation type: Live Streamed
Track: Securing Patient Well-being: Best Practices for In-Use Stability and Compatibility Studies

Health care providers and patients are frequently required to manipulate biological drugs prior and during administration. This might include procedures such as dilution of the drug into admixtures for infusion, limited storage, transportation to the hospital or exposure to new contact materials, such as intravenous bags.
The instructions for use are provided by the drug manufacturer and are based on studies to support in-use stability and compatibility with administration components, simulating drug handling and hold times throughout the defined in-use period. The studies are challenging, because there is a wide range of in-use conditions and administration components used globally. In addition, only limited guidance is available from regulators on expected in-use stability data.
In four workshops we will present and discuss industry approaches to assess in-use stability and compatibility for classic biological products as well as emerging trends. Each workshop is scheduled for 90 minutes, and includes 2 presentations followed by a discussion with the presenters and additional panel members.

08:30-08:50 District Ballroom

CASSS Welcome and CMC Strategy Forum 2024 Introductory Comments

Chair: Tura Camilli, Jason Starkey, Nailing Zhang
Presentation type: Live Streamed
Track: Establishing and Leveraging Platforms to Support Product Development

Platform technologies are used extensively across the biopharmaceutical industry to develop drugs efficiently and effectively. The application of prior knowledge and platforms from established products lays a strong foundation to guide development and advance new medicines to the patients. From cell line development, upstream and downstream operations, formulation development, devices, and analytical methodologies, platforms have proven that they work and are a powerful tool. However, there are no universal standards on how to create, justify and maintain platforms. The inclusion of platform information and the level of detail in the dossier is key for regulatory agencies to evaluate the applicability of the platform using a risk-based assessment. Moreover, the rationale and justification on how prior knowledge and platform data are suitable for the intended product is essential in a review. This session will look at the application of platform approaches and technologies and how they can be applied to programs to support development and registration. Insight into how prior knowledge for a platform is fully leverage across products and supporting rationale will be presented in case studies. The objective from the session should help developers and health authorities better align on expectations and paths to use platforms for clinical development through commercialization.

08:50-10:20 Grand Ballroom

Workshop I: Established Best Practices for In-Use Stability Study Design and Testing

Chair: Félix Jules, Jing Liu
Presentation type: Live Streamed
Track: Securing Patient Well-being: Best Practices for In-Use Stability and Compatibility Studies

Session Speakers:

How to Design and Perform In-Use Stability and Compatibility Studies?
Markus Blümel, ***Novartis Pharma AG***

In-Use Stability Study Design: A Regulatory Perspective
Paula Russell, *Health Canada*

Additional Panelist:
Ankit Patel, *Denali Therapeutics*
Isabella de Jong, *Genentech, a Member of the Roche Group*

08:50-10:20 District Ballroom

Workshop I: Analytical

Chair: Karen Rule
Presentation type: Live Streamed
Track: Establishing and Leveraging Platforms to Support Product Development

Session Speakers:
Platform Technologies Designation Program: Highlights of Statutory Language
Phillip Kurs, *CBER, FDA*

Leveraging Prior Knowledge for Practical Application of Platform Analytical Procedures in Late-Stage Development of Monoclonal Antibodies
Hetalben Patel, *Pfizer, Inc.*

Platform Approaches in Analytics for rAAV based Gene Therapies
Van Hoang, Spark Therapeutics, Inc.

Planning Platform Analytical Approaches for Cell Therapy
Emily English, *Cartesian Therapeutics, Inc.*

10:20-10:50 Palm Court Ballroom

Coffee Connection: Networking Break

10:50-12:20 Grand Ballroom

Workshop II: Microbial In-Use Studies and Closed System Transfer Devices

Chair: Jennifer Swisher, Sarah Weiser
Presentation type: Live Streamed
Track: Securing Patient Well-being: Best Practices for In-Use Stability and Compatibility Studies

Session Speakers:

In-Use Studies Microbial Challenge Studies: Cross-Industry Efforts to Harmonize Strategies in Collaboration with Health Authorities
J. Paul Kirwan, Amgen Inc.

Pharmaceutical Industry Perspective on Closed System Transfer Devices (CSTDs): Balancing Overfill, Evaluating, Communicating
Christian Lehermayr, Novartis Pharma AG

Additional Panelists:

Virginia Carroll, CDER, FDA

Nicholas Clark, Amgen Inc.

John Metcalfe, CDER, FDA

10:50-12:20 District Ballroom

Workshop I: Panel Discussion: Analytical

Chair: Karen Rule
Presentation type: Live Streamed
Track: Establishing and Leveraging Platforms to Support Product Development

Panelists:

Emily English, *Cartesian Therapeutics, Inc.*
Phillip Kurs, *CBER, FDA*
Van Hoang, *Spark Therapeutics, Inc.*
Hetalben Patel, *Pfizer, Inc.,*
Da Ren, *BioTherapeutics Solutions, Inc.*

12:20-13:20 Palm Court Ballroom

Midday Meetup: Hosted Lunch

13:20-14:50 Grand Ballroom

Workshop III: Product In-Use: Meeting Patient and User Needs

Chair: Jennifer Litowski, Martin Nemec
Presentation type: Live Streamed
Track: Securing Patient Well-being: Best Practices for In-Use Stability and Compatibility Studies

Session Speakers:

Patient and User-Centric Considerations on In-use Study Design
Sarah Weiser, *Pfizer, Inc*

Leveraging AI to Meet Patient Needs: Improving Product Quality in Biotechnology
Prashanth Chodagiri, *Amgen Inc.*

Additonal Panelist:
Sarah Donegan*, AstraZeneca*

13:20-14:50 District Ballroom

Workshop II: Process

Presentation type: Live Streamed
Track: Establishing and Leveraging Platforms to Support Product Development

Session Speakers:

Incorporation of Platform Based Approaches and Prior Knowledge Leveraging Into the Recently Revised ICH Q5A (R2) Guideline
Kathryn King, *CDER, FDA*

Power of Platform to Accelerate Therapies Beyond a Pandemic
Ronan Kelly, *Eli Lilly and Company*

Leveraging Platforms to Accelerate ADC Formulation and Drug Product Development
Karen Rutherford, Pfizer I*nc.*

Continuous Platform Improvement to Propel Drug Substance Development,
Heather Nunn, *Amgen Inc.*

14:50-15:15 Palm Court Ballroom

Coffee Connection: Networking Break

15:15-16:45 Grand Ballroom

Workshop IV: Emerging Trends in Compatibility and In-Use Stability Studies

Chair: Isabella de Jong, Michael Moses
Presentation type: Live Streamed
Track: Securing Patient Well-being: Best Practices for In-Use Stability and Compatibility Studies

Session Speakers:

In-Use Compatibility Testing of Cell and Gene Therapies (CGT)
Philip Grossen, F. Hoffmann-La Roche Ltd.
Abbygail Foster, Genentech, a Member of the Roche Group

Challenges of In-Use of Low – Dose High Potent Product- Case Studies and Potential Mitigations
Basma Ibrahim, AbbVie Inc.

Additional Panelists:

Andrew Chang, *Novo Nordisk Inc.*
Martin Nemec, *Health Canada*
Jennifer Swisher, *CDER, FDA*

15:15-16:45 District Ballroom

CMC Workshop II: Panel Discussion: Process

Chair: Tura Camilli
Presentation type: Live Streamed
Track: Establishing and Leveraging Platforms to Support Product Development

Panelists:

Ronan Kelly, *Eli Lilly and Company*
Kathryn King, *CDER, FDA*
Heather Nunn, *Amgen Inc.*
Karen Rutherford, *Pfizer Inc.*
Dean Smith, *Health Canada*

16:45-17:00 Grand Ballroom

Closing Remarks: Invitation to CMC Strategy Forum Summer 2024

Presentation type: Live Streamed
Track: Securing Patient Well-being: Best Practices for In-Use Stability and Compatibility Studies

16:45-17:00 District Ballroom

Closing Remarks: Invitation to CMC Strategy Forum Summer 2024

Presentation type: Live Streamed
Track: Establishing and Leveraging Platforms to Support Product Development

17:00-18:30 Palm Court Ballroom

Science and Social Networking Event

Tuesday, 23 January, 2024

07:00-08:00 Promenade Foyer / Senate Room

Registration

Registration is open until 17:00

Pre-registered attendees should go to the Foyer. If you are registering onsite, please make your way to the Senate Room.

07:00-08:45 East/State Rooms

Sunrise Social: Breakfast

Breakfast is available until 09:00

08:00-08:30 Grand Ballroom

CASSS Welcome and Introduction to WCBP 2024

Chair: Kevin King, Jamie Moore
Presentation type: Live Streamed

08:30-08:45 Grand Ballroom

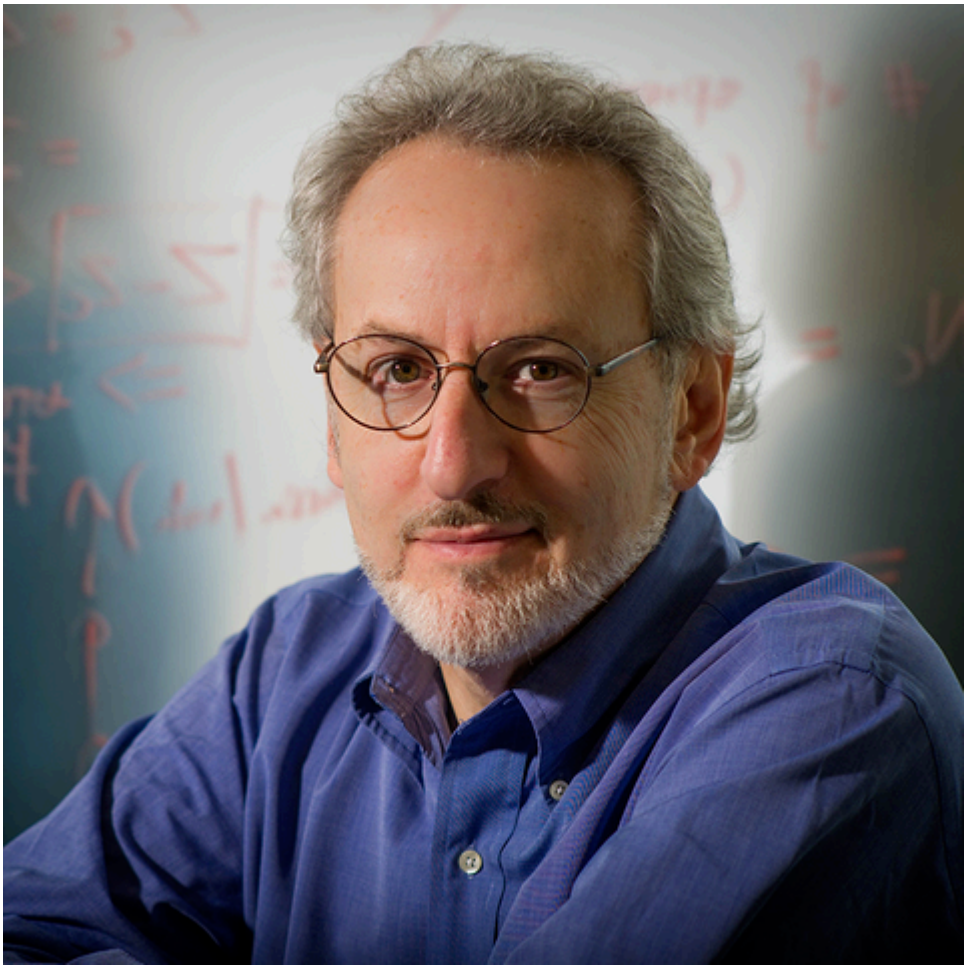
12th Annual William Hancock Award

Chair: Kevin King
Presentation type: Live Streamed

08:45-10:00 Grand Ballroom

Keynote Presentation: Disruptive Innovation in Drug Development and Personalized Medicine: Human Organ Chips and Beyond

Presentation type: Live Streamed



Donald E. Ingber, *Wyss Institute for Biologically Inspired Engineering, Harvard University*

The large number of failures observed in human clinical trials is a problem that must be overcome for the benefit of patients and the survival of the pharmaceutical industry. Failure of animal models to predict therapeutic responses in humans is a major part of the problem. In this presentation, I will describe Organ-on-a-chip (Organ Chip) microfluidic devices lined with living human tissues that form tissue-tissue interfaces, reconstitute vascular perfusion and organotypic mechanical cues, integrate immune cells, contain living microbiome, and recapitulate organ-level physiology and pathophysiology with high fidelity. Work will be presented describing how single human Organ Chips and multi-organ human Body-on-Chips systems have been used to model complex diseases and rare genetic disorders, study host-microbiome interactions, quantitatively predict drug pharmacokinetic and pharmacodynamic parameters, recapitulate whole body inter-organ physiology, and reproduce human clinical responses to drugs, radiation, toxins, and infectious pathogens. We also have used human Organ Chips to gain new insight into mechanisms of host immunity to viral infections and to develop new therapeutics for potential pandemic respiratory viruses, including influenza and SARS-CoV-2. My message is that the possibility that human Organ Chips can be used in lieu of animal models for drug development and as living avatars for personalized medicine is coming ever closer to becoming a reality. In addition, I will briefly review new technologies being pursued at the Wyss Institute at Harvard that I lead, including artificial intelligence approaches for accelerated drug discovery, novel drug shuttles that cross the blood-brain barrier with high efficiency, and handheld multiplexed companion diagnostic devices for clinical trials and home healthcare.

10:00-10:30 East/State Rooms

Coffee Connection: Networking Break

10:30-12:00 Grand Ballroom

Plenary Session 1 - Novel Modalities

Chair: Kavita Aiyer, Marjorie Shapiro
Presentation type: Live Streamed

Technological innovation and advancements have enabled novel designs for antibody-based products, vaccines, blood products, gene and cell therapy candidates. While mAB conjugates like ADCs and novel mAB constructs like bispecifics molecules have been maturing as approved therapies for unmet medical needs, additional molecules like mAb fragments, trispecifics, cocktails, bifunctional (e.g., mAb-cytokine fusion proteins), and non-IgG isotype molecules are in development. Novel approaches to vaccine design include the expression of antigen to elicit a protective immune response and development of universal vaccines for flu and SARS-CoV-2. Gene and cell therapies continue to evolve, including new designs for CAR-T cell constructs to decrease side effects, improve proliferation and cytotoxicity, and increase specificity of therapeutic targets. The emerging allogenic/ Induced Pluripotent Stem Cells (IPSC) CAR-T cells will further the reach of CAR-T applications. In addition, macrophage CAR which are in development may better target solid tumors. This springs the questions, do novel modalities warrant novel product quality controls because of product quality concerns? It is acknowledged that based on the modality, additional testing based on novel analytical techniques, control and characterization may be recommended and should be determined on an individual case basis. This should be informed by scientific knowledge and risk-based approach aligned with guidance documents. In this session we will discuss the industry's current trend and application of innovative approaches for new modalities, with a focus on the success, challenges, and lessons learned during product development.

Session Speakers:

Enhanced Quality Attribute Understanding Enabled Accelerated Development of a RSV Vaccine
John Davis, Pfizer, Inc.

Analytical Considerations in the Development of Engineered Therapeutic IgM Antibodies
Devinder Ubhi, IGM Biosciences, Inc.
Jaime Marach, IGM Biosciences, Inc.

6+ Years of Autologous CAR-T Therapy
Mehrshid Alai-Safar, **Kite, a Gilead Company**

12:00-14:00

Lunch Break

Attendees on own
Attendees not participating in one of the Technical Seminars are on their own for lunch.

12:15-13:30 Cabinet Room

New Member Lunch

Presentation type: In-Person

12:30-13:30 Grand Ballroom

Even More Maurice Innovation as Shared by Your Colleagues – Protein Isoform Characterization Using MauriceFlex | Presented by Bio-Techne

Presentation type: Live Streamed
Session Speakers:

Even More Maurice Innovation as Shared by Your Colleagues – Protein Isoform Characterization Using MauriceFlex
Xiaoping He, *Pfizer*
Qurrat (Anny) Ui-Ain, *Sanofi*
Zishuo (Toby) Cheng, *Sanofi*

12:30-13:30 Chinese Room

USP - US Pharmacopeia and ATCC® Resources that Support Monitoring of Impurities in Biologics | Presented by USP - US Pharmacopeia

Presentation type: In-Person
Session Speakers:

USP - US Pharmacopeia and ATCC® Resources that Support Monitoring of Impurities in Biologics
Kevin Carrick, *USP - US Pharmacopeia*
Leka Papazisi, *ATCC*

12:30-13:30 District Ballroom

From High Order Aggregates to Peptide Maps: Comprehensive Protein Characterization Using Advanced UHPLC-HRAM MS Platforms | Presented by Thermo Fisher Scientific

Presentation type: Live Streamed

Session Speakers:

From High Order Aggregates to Peptide Maps: Comprehensive Protein Characterization Using Advanced UHPLC-HRAM MS Platforms
Andrew Mahan, *Janssen Research & Development, LLC*

12:30-13:30 Palm Court Ballroom

New Technologies for Rapid Characterization of Biologics: From R&D to Manufacturing | Presented by Refeyn Inc.

Presentation type: In-Person

Session Speaker:
Amanda St. Paul, *Refeyn Inc.*

14:00-15:15 Chinese Room

Workshop Session 1: Innovations Today for the Factory of the Future

Chair: Riley Myers, Belinda Pastrana, Arne Staby, Graham Tulloch
Presentation type: In-Person

Workshop Presenters:
Belinda Pastrana, *Protein Metrics Inc.*
Lisa Vetter-Joss, *Novo Nordisk A/S*
Jason Walther, *Sanofi*

Since the approval of the first biosynthetic protein in 1982 more than 100 monoclonal antibodies and other recombinant therapeutic proteins have been approved for human use. Over the following 40+ years there has been a significant evolution in manufacturing and analytical technologies as the industry has worked to keep pace with increasing market demand. Innovations in cell line cloning techniques, bioreactor design and cell culture media have led to notable increases in upstream productivity. High-capacity resins, multi-column purification systems, and connected operations have enabled partial and fully continuous facility designs. Advances in analytical technologies such as on-line and at-line instruments and muti-attribute methods are reducing turn-around times in testing of therapeutic proteins while providing in-depth understanding of both the manufacturing process and drug substance. Together these innovations can decrease time to market and reduce manufacturing costs all while ensuring safety and efficacy of the therapeutic protein of interest. In this session we will review innovations in facility design, manufacturing and analytical technologies, and discuss how these can be used to enable Factories of the Future.

14:00-15:15 District Ballroom

Workshop Session 1: ICH Regulatory Updates and FDA Meetings - Lessons Learned

Chair: Andrew Chang, Yasuhiro Kishioka, Sarah Pope Miksinski
Presentation type: In-Person

ICH delivers guidance on science- and risk-based strategies and is an enabler of greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner.
The ICH Q12 Lifecycle Management guideline provides a framework for managing post-approval changes. Global adoption and implementation of ICH Q12 provides opportunities to maximize flexibility in product lifecycle management for both industry and regulators. Attendees will learn about the status of the implementation ICH Q12 from USFDA and PDMA. The ICH M4Q(R1) guideline on the Common Technical Document (CTD) in 2002 harmonized the format of quality information for registration of pharmaceuticals. Attendees will learn about important revisions to M4Q(R1) including improvements in registration and lifecycle management efficiency and accelerating patient and consumer access to pharmaceuticals.
This workshop session will explore implementation experiences for ICH Q12 as well as perspectives on ICH M4Q, followed by an interactive panel discussion that includes industry and regulatory agency subject matter experts.

14:00-15:15 Grand Ballroom

Workshop Session 1: Back From the Future - Let's Make the AI/ML Machines Work for Us!

Chair: Bradley Dworak, Ben Stevens, Gert Thurau
Presentation type: In-Person

Worried that your regulatory authority may say “hasta la vista, baby” to your AI/ML application? This plenshop will gather regulatory and technical experts to discuss the use of these applications, including their modeling aspects in the development, manufacture, and control of regulated products. Several brief introductory presentations will be provided. There will be particular focus on audience engagement by polling for consensus on model impact level per ICH Q8/9/10 Q&A Points to Consider for several case studies. Filing and dossier strategy will be discussed, with a particular emphasis on lifecycle management approaches such as use of PACMPs. Participants will share prior experience to help identify some common approaches that may be beneficial for future regulatory filings. By the end of the session, you’ll confidently tell your regulators “I’ll be back!”

14:00-15:15 Palm Court Ballroom

Workshop Session 1: Current Challenges in Manufacturing of Cell and Gene Therapy Products

Chair: Charles Kline, Janus Krarup, Haritha Vallabhaneni, Zhaohui Ye
Presentation type: In-Person

Cell and Gene therapy products continue to grow in importance as part of the constellation of treatments for serious diseases including ones which can progress rapidly with high morbidity. Many of these treatments are by nature individualized to the patient, whether they contain autologous materials or not. Individualized medicinal products generally cannot be manufactured in bulk in advance of identifying the patient, therefore minimizing the turn-around time (the time from assessment of the patient through treatment decision to administration of the medicinal product) is important for positive patient outcomes. These two factors, the individualized nature of the treatment and the need for minimal turn-around time, have profound impacts on the manufacturing and control strategy for the drug product, which will be the focus of this workshop. Attendees will be posed questions on the following topics for discussion at the workshop: challenges with implementation of alternative, rapid test methods vs standard compendial test methods; challenges with developing a meaningful potency assay, ideally linked to mechanism of action of the medicinal product; decisions on control strategy for manufacturing including when to employ in process measures versus end of production batch release testing; effective control strategies for raw materials, to balance the need for appropriate quality while ensuring stable supply; other means of controlling and reducing turn-around time.

15:15-15:45 East/State Rooms

Coffee Connection: Networking Break

15:45-17:30 Grand Ballroom

Plenary Session 2 - Transforming Global Regulatory CMC Practices in an Age of Revolutionary Innovation

Chair: Nina Cauchon, Maria Gutierrez Lugo, Maria Cecilia Tami
Presentation type: Live Streamed

This regulatory panel will bring together regulators from several global regions for an interactive discussion about evolving practices and initiatives.

Current trends in agency-agency and agency-industry collaborations, including:
- Discussions on the role of regional and international harmonization and regulatory convergence initiatives, including ICH, WHO, and regional initiatives
- Sharing experiences from collaborative reviews, e.g., ICMRA pilots, Project Orbis/Access Consortium and other collaborative and reliance pathways

Accelerating the pace of acceptance for innovative solutions, including:
- Achieving the blue-sky vision “One dossier, one submission, one review, one inspection, one approval”, e.g., ICH M4Q revision, CMC dossier content alignment, ICH Q12 benefits, Accumulus
- Addressing how rapid advances in pharmaceutical science, novel technology, new modalities analytics, data management, and regulatory concepts can be accepted globally.

Session Speakers:

Update From WHO: Global Perspective on Regulatory Harmonization and Convergence to Support Reliance
Samvel Azatyan, *WHO - World Health Organization*

Additional Panelists:

Nelio Aquino, *ANVISA*

Yasuhiro Kishioka, *PMDA - Pharmaceuticals and Medical Devices Agency*

Steve Kozlowski, *CDER, FDA*

Ingrid Markovic, *CBER, FDA*

Nino Mihokovic, EMA - *European Medicines Agency*

Theresa Mullin, *CDER, FDA*

18:00-22:00

Welcome Reception

Presentation type: In-Person

Join us for the WCBP Welcome Reception!

All Symposium attendees are invited to attend this off-site welcome reception at **The International Spy Museum** (700 L'Enfant Plaza SW, Washington, DC 20024). Transportation will be provided to-and-from the museum. Bus loading will begin at 5:30pm outside the Desales Street entrance of the Mayflower. Return trips to the hotel will begin at 7:30pm.
Don't forget to bring your conference badge, as it is required to attend.

Wednesday, 24 January, 2024

07:00-08:15 East/State Rooms

Sunrise Social: Breakfast

Breakfast is available until 09:00

07:00-08:15 Palm Court Ballroom

Community Voices: Breakfast Chats

Presentation type: In-Person

Session Speakers:

The Accidental CMC Analytical Chemist
Benjamin Barnhill, *aTyr Pharma, Inc.*

From the Lab to Data & Digital: My Journey to Becoming Head of Scientific Engagement at Genedata
Jana Hersch, *Genedata Inc.*

A Journey Through the Biopharmaceutical Industry

Ken Miller, *BioMarin Pharmaceutical Inc.*

Mass Spectrometry for Pharmaceutical Quality Research: In-Depth Understanding Mechanism of Methods and Content of Use
Jinhui Zhang, *CDER, FDA*

08:00-08:15 Promenade Foyer / Senate Room

Registration

Registration is open until 17:00

Pre-registered attendees should go to the Foyer. If you are registering onsite, please make your way to the Senate Room.

08:15-08:30 Grand Ballroom

Welcome Day 2 & CASSS Distinguished Fellows Awards

Presentation type: Live Streamed

The designation of CASSS Distinguished Fellow is designed to recognize individuals noted for their outstanding contributions to CASSS, our community and the industry overall. These individuals are honored with the title of Distinguished Fellow, bestowed on less than 1% of our members, and offered lifetime membership in CASSS. Join us this morning as we recognize two deserving individuals as new CASSS Distinguished Fellows.

08:30-10:00 Grand Ballroom

Plenary Session 3 - State of the Art, Science-Based Comparability Strategies and Novel/Platform Technologies

Chair: Richard Beardsley, Wayne Kelley, Rachel Novak, Sabina Sheikh
Presentation type: Live Streamed

Throughout the life cycle of a biotherapeutic it is often necessary to make changes to the manufacturing process and control system. These changes may improve the consistency of the process, increase the scale or yield to meet supply needs, involve improvements to analytical methods, transfer to a new facility or equipment, and/or be designed to improve product quality. When these changes occur it is necessary to demonstrate that product quality is not adversely impacted, and that the safety and efficacy established with prior process versions will be maintained with material from the post-change process. This plenary session will focus on state of the art, science-based and regulatory strategies that enable process changes to be executed successfully and efficiently. In scope topics may include comprehensive comparability strategies guided by patient-centric considerations, lean technical transfers enabled by the use of platform technologies, and perspectives on the use of regulatory tools to support changes.

Session Speakers:

Building a Comparability Strategy for a Major Post-Approval Manufacturing Change
Nathan Mcknight, *Genentech, a Member of the Roche Group*

An Industry Perspective on the Use of Forced Degradation Studies to Assess Comparability of Biopharmaceuticals
Kasia Nowinski, *Pfizer Inc.*

Accelerating Biopharmaceutical Development: Data-Driven Strategies, Platforms, and Technologies
Nitin Rathore, *Amgen Inc.*

Additional Panelis:
Leslie Rivera Rosado, *CDER, FDA*

10:00-10:30 East/State Rooms

Coffee Connection: Networking Break

10:30-11:45 Chinese Room

Workshop Session 2: Antibody-Drug Conjugates: Sharing Best CMC Practices Based On Advanced Scientific Understanding

Chair: Nathan Ihle, Charles Morgan, Paresma Patel, Marjorie Shapiro
Presentation type: In-Person

Antibody-drug conjugates (ADCs) are inherently complex molecules combining attributes of small molecule and large molecule therapeutics in addition to attributes associated with their conjugation. Advances in this field resulting from intense research in recent years have produced important new anti-cancer therapeutics with major clinical benefits. As these programs advanced, new insights into the properties impacting their activity and safety, as well as deeper understanding of the associated manufacturing processes have developed. This knowledge presents the opportunity to refine the systems used in their manufacture and testing in a manner that will speed development of additional ADCs and other types of bioconjugates.

In this workshop participants will have the opportunity to share their experience working on the technical development, manufacturing and regulatory oversight of bioconjugates.

The goal is to identify best practices in the field, understand remaining challenges, and look for areas where harmonization of strategy may be beneficial. Discussion topics will include science-based comparability strategies, utilization of advanced analytical methodologies, and how approaches may need to be adapted for the novel molecular designs and conjugation technologies in development today.

10:30-11:45 District Ballroom

Workshop Session 2: Comparability: Technical Challenges and Regulatory Considerations

Chair: Leiyun Boone, Babu Kunnel, Ivy Lin, Elizabeth Schmidt, Ramakrishna Valicheti, Hsialong Wang
Presentation type: In-Person

During the development of recombinant therapeutic proteins, changes to the manufacturing process, site and scale are inevitable. Some of the changes, such as manufacturing site changes and replacement of same equipment, lead to minimum impact to product quality attributes, whereas some of the changes may have potentially more significant impact to product quality such as cell line change, formulation change etc. Regardless of the extent of changes, product quality needs to be compared between pre- and post-change processes to make sure that post change product quality is not adversely impacted and maintains safety and efficacy to the patient. There are several considerations for comparability assessment based on the extent of change, the potential risk to quality, amount of data serving as basis of comparison, and to ensure regulatory compliance. The discussion is meant to cover regulatory considerations and industry perspectives of comparability studies for recombinant proteins covering, early, late and post approval changes.

10:30-11:45 Grand Ballroom

Workshop Session 2: Platform Technologies (FDA Guidance)

Chair: Mike Smith, Allison Wolf, Nailing Zhang
Presentation type: In-Person

Platform technologies have been identified as a potential lever to speed the development and availability of therapeutics to patients. In 2022, the US government passed legislation establishing a platform technology designation program with the hope to improve the efficiency of the drug development and review process. This workshop will build on the concepts introduced and discussed in the CMC Strategy Forum on Establishing and Leveraging Platforms to Support Product Development. The interactive workshop format will allow for detailed group discussions of the benefits and challenges with leveraging platforms and will look to discuss how to best include platforms in regulatory submissions. Participants are encouraged to share their experiences with platform technologies (e.g., platform analytical methods, platform manufacturing processes, etc.) and discuss aspects of platforms that may be challenging for industry and/or regulatory agencies.

10:30-11:45 Palm Court Ballroom

Workshop Session 2: Predictive Stability for Biologics - The Discussion Continues

Chair: Kristi Griffiths, Jennifer Kirk, Linda Lemieux, Yideng Liang, Paula Russell, Boris Zimmerman
Presentation type: In-Person

Predictive stability methodologies for shelf-life setting have emerged as potential components of a comprehensive stability program for biologics. Traditional stability studies are routinely cited as rate limiting steps for product development and predictive stability can play a role to facilitate the accelerated availability of new medicines. The recent inclusion of stability modeling to support market authorization applications and post-approval changes for some vaccines and biotherapeutics, as well as recent publications detailing the feasibility of stability modeling to support shelf-life setting, have triggered broader discussions around the application of predictive stability for biologics. The objective of this session is to provide a facilitated discussion that develops the industry and regulatory perspectives relating to predictive stability for biologics. This session will begin with a brief introduction of predictive stability models, use of prior knowledge in modeling, and regulatory expectations. The discussion will focus on the opportunities and challenges on the application of predictive stability for biologics. Attendees can expect a robust and insightful discussion that looks to broaden the understanding of the application of predictive stability as a science and risk-based approach for biologics.

11:45-13:45

Lunch Break

Attendees on own

Attendees not participating in one of the Technical Seminars are on their own for lunch.

12:15-13:15 Grand Ballroom

Host Cell Protein ELISAs: The Scientific and Business Decisions to Ensure Successful Outcomes | Presented by Cygnus Technologies, LLC

Presentation type: Live Streamed

Session Speaker:

Host Cell Protein ELISAs: The Scientific and Business Decisions to Ensure Successful Outcomes
Eric Bishop, *Cygnus Technologies, LLC*

12:15-13:15 District Ballroom

Potency Assays for ATMPs – Selection of Assay Platforms and Data Processing Methods are Key Aspects for Successful Control Strategies | Presented by BioAgilytix Labs, LLC

Presentation type: Live Streamed

Session Speakers:

Potency Assays for ATMPs – Selection of Assay Platforms and Data Processing Methods are Key Aspects for Successful Control Strategies

Jeff Patrick, *BioAgilytix Labs, LLC*
Shiqian Zhu, *BioAgilytix Labs, LLC*

12:15-13:15 Palm Court Ballroom

Overcoming Bottlenecks in Biopharmaceutical Characterization Workflows with Microchip CE-MS | Presented by 908 Devices

Presentation type: In-Person

Session Speakers:

Overcoming bottlenecks in biopharmaceutical characterization workflows with Microchip CE-MS
Sara Carillo, *National Institute for Bioprocessing Research*
and
Zhijie Wu, *Regeneron Pharmaceuticals Inc.*

12:15-13:15 Chinese Room

Solving Problems That Matter | Presented by Waters Corporation

Presentation type: In-Person

Session Speakers:

Solving Problems That Matter
Nick Pittman, *Waters Corporation*
Ying Qing Yu, *Waters Corporation*

12:30-13:30 Pennsylvania Room

CASSS Consultants' Network

Presentation type: In-Person

Meet in the Pennsylvania Room from 12:30-1:30pm to meet and network with other consultants. Open discussion will include hot topics for the coming year of quarterly programming to begin in March, 2024. Grab some breakfast and head upstairs!

13:45-14:45 Palm Court Ballroom

Roundtable Session 1

Presentation type: In-Person

Table 1 - Setting Specifications on Limited Data, Clinically Relevant Specs/ Next Generation Control Strategies: Looking Ahead to Revision of ICH Q6B - What is Needed?

Table 2 - Acceleration and CMC - Novel Approaches to Enabling Acceleration (Applying the EMA Toolbox and FDA MAPP); How to Manage Accelerated Programs and Changing Work Priorities

Table 3 - Comparability Approaches - Focus on Cell and Gene Therapies (see FDA Draft Guidance)

Table 4 - Regulator Review Preferences and Recent Review Trends: Questions and Key Issues - Focus on US FDA

Table 5 - Potency Assays / Use of Structure Function Models: MOA / Replace Biological / Cell-based Assays / Replacing in-vivo with in-vitro Potency Assays

Table 6 - Regulatory Considerations and Experiences for Control Strategies in Different Regions - Focus on General Challenges with Divergence

13:45-14:45 Chinese Room

Roundtable Session 1

Presentation type: In-Person

Table 7 - New Analytical Technologies Being Implemented for GMP Product Testing - Focus on Regulatory Challenges

Table 8 - When Simulation is Not Enough - When and Why Are Real Time Studies of Shipping Needed?

Table 9 - FDA's Request for Additional Tables in BLAs to Support KASA

Table 10 - Continuous Manufacturing - Continued Implementation of ICH Q13 Worldwide

Table 11 - In Use Stability and Compatibility Testing: Microbial Challenge Studies and Requirements

Table 12 - Regulatory Expectations and Challenges: Lessons Learned from Developing Countries

13:45-14:45 Cabinet Room

Roundtable Session 1

Presentation type: In-Person

Table 13 - Attracting Under-Represented Groups to Scientific Careers

Table 14 - Focus on FDA's Plans for Advanced Manufacturing and Platform Technology Designations

Table 15 - Recent Experiences with Regulation of Biosimilars at the FDA

Table 16 - Role of Cryo-TEM as an Orthogonal Method to Help Assess Formulation Purity, Potency for Nanoparticles.

Table 17 - Best Practices to Design and Submit Forced Degradation Studies

Table 18 - Bioconjugates - Filing Strategies for Manufacturing and Development

13:45-14:45 Rhode Island Room

Mini Case Session 1 - ICH Q12 - Practical Experience with Regulatory Acceptance of PACMPs and Established Conditions

Presentation type: In-Person

13:45-14:45 South Carolina Room

Mini Case Session 1 - RNA Vaccines and Therapeutics - Experience with Development and Commercialization

Presentation type: In-Person

13:45-14:45 Virginia Room

Mini Case Session 1 - Shelf Life Setting for Biologics: Approaches and Challenges Including Stability Modeling Approaches and Advanced Statistical Designs

Presentation type: In-Person

14:45-15:15 East/State Rooms

Coffee Connection: Networking Break

15:15-16:30 Chinese Room

Workshop Session 3: Navigating Regulation to Enable Environmental Sustainability

Chair: Sarah Argoud, Nicola Coles, Ben Stevens
Presentation type: In-Person

Climate change resulting from global warming is now widely recognized as the biggest threat to global health. Through increasing globalization, industry plays an ever more vital role in the response to the climate emergency.
With a growing healthcare sector responsible for 4–5% of global emissions, 71% of which are driven by supply chains, our industry must accelerate emission reduction in the pursuit of better global health. Consequently, pharmaceutical manufacturers are accelerating innovation to achieve sustainability goals focused on decarbonization, circularity and preserving nature.
Facilitated by BioPhorum, in this session representatives from AstraZeneca and GSK will present case studies of sustainability innovation across decarbonization, circularity and nature. In collaboration with the FDA, the industry representatives will discuss the regulatory challenges faced and what can be done in the future to support sustainability innovation.

15:15-16:30 District Ballroom

Workshop Session 3: Industry and Regulatory Authority Experience with International Coalition of Medicines Regulatory Authorities (ICMRA) Pilots: A Path Forward Towards Reliance

Chair: Ruth Cordoba-Rodriguez, Kristen Nickens, Srividya Srikant, Christine Wu
Presentation type: In-Person

The diverging requirements across Regulatory Authorities and supply chain complexities due to long lead times for approval of changes in many of the countries pose challenges in efficient implementation of Post Approval Changes (PAC) globally.
In June 2022, ICMRA announced the launch of two regulatory pilots on CMC PACs [Collaborative Assessments of CMC-Related PACs and PACMPs and Collaborative Hybrid Inspections (CHIPs) to Inform CMC Assessments]. Through these pilots ICMRA aims to showcase global collaboration among Regulatory Authorities fostering a unified approach to ensure the safety and efficacy of medical products worldwide and harmonization of regulatory processes, thus promoting consistency in evaluating and approving medical products across different regions, which can streamline market access. The initial focus of the collaborative assessment pilot and CHIP is on PACMP assessments and Pre Approval Inspections (PAI) of manufacturing facilities.
The plenshop will focus discussions around the ICMRA pilots where Industry and Regulatory participants will share their experiences during the pilot in interacting simultaneously with multiple agencies as part of the review/inspection process.

15:15-16:30 Grand Ballroom

Workshop Session 3: Delivering on the Vision: Developing and Applying the CMC Data Standard to Regulatory Submissions and Review

Chair: Rita Algorri, Craig Anderson, Sheetal Gaiki, Maria Sagoua, Geoffrey Wu
Presentation type: In-Person

Pharmaceutical Quality (PQ)/ Chemistry Manufacturing and Controls (CMC) data is a key source of information across the drug development lifecycle and is essential for regulatory review. Regardless of its importance, PQ is predominantly managed using unstructured documents (Microsoft Word and PDF). Several initiatives are under-way including the revision of ICH M4Q R2 and IDMP guidance updates. In the session, presenters will focus on two distinct yet complementary efforts to modernize the PQ space:

1. PQ/CMC, led by the US Food and Drug Administration (US FDA), is developing a framework for receiving electronic submission of structured PQ data to simplify the submission process, enable more efficient quality assessment, and lifecycle knowledge management.

2. DX-PQ, led by the biopharmaceutical industry, is developing a framework to support the exchange of structured PQ data in real-time within and between industry stakeholders.

Both initiatives leverage Health Level 7's (HL7) standard for Fast Healthcare Interoperability Resources (FHIR®). A modern web-based technology that supports rapid implementation, interoperability, and the use of advanced analytics to augment quality oversight throughout the product lifecycle.

During this session, you will hear be invited into a dialogue on the following:

1. Discover how FDA's progress on the PQ/CMC initiative has impacted its approach to enterprise digital transformation

2. Discover how Industry's progress on the DX-PQ initiative is expected to impact business efficiency and learn how it can be applied using a stability use case

3. Imagine how structured PQ data and real-time exchange could impact the post approval change regulatory review proces

15:15-16:30 Palm Court Ballroom

Workshop Session 3: Regulatory Reliance

Chair: John Armando, Patrick McGeehan, Richard Siggers, Martin Umhang
Presentation type: In-Person

In order to accelerate the review and approval of regulatory submissions, while making the best use of resources and expertise at both regulators and industry, the World Health Organization (WHO) is strongly supporting the concept of 'reliance' amongst National Regulatory Authorities. Reliance encourages NRAs to rely on the assessment completed by a recognized reference agency, thus enabling an efficient approach to regulation and ensure expedited and continued access to medicines for patients in need. While some promising developments have been made with the use of reliance pathways for initial marketing authorizations, they are still not widely used, especially for the review and approval of Post-approval changes. Collaboration and harmonization are required to achieve a blue-sky vision promoting regulatory convergence and to enhance greater transparency amongst global NRAs. In this session, we will explore industry and agency perspectives on how to facilitate and accelerate regulatory reliance approaches.

Regulatory Reliance to Support Informed Decision Making
Samvel Azatyan, *WHO - World Health Organization*

16:30-16:45

Mini Break

Attendees can take this time to check emails, use the restroom and prepare for Plenary Session 4.

16:45-18:15 Grand Ballroom

Plenary Session 4 - Sustainable Biopharmaceutical and Vaccine Development – Strategies for Reducing Waste, Protecting the Environment, and Reaching Net-Zero

Chair: James Carroll, Shawn Novick, Varnika Roy
Presentation type: Live Streamed

Biopharmaceutical and vaccine development contribute significantly to global carbon emissions, plastic and chemical waste, water utilization, and animal testing. Strategies to implement sustainable practices can have a large positive impact on our environment, while still maintaining efficient development of critical and lifesaving drugs and vaccines for the benefit of society. New ways to streamline processes, optimize supply chains for raw materials and products, reduce testing on animals, substitute materials used in manufacturing and analytical assays, and to reduce solvent volumes through continuous manufacturing and real-time inline release testing can all be viable approaches for sustainable development. This session will focus on strategies and opportunities to incorporate reductions in resource utilization, energy, water and environmental impacts for more sustainable biopharmaceutical and vaccine development to reach net-zero carbon emission impact as an organization and then ultimately an industry.

Session Speakers:

Considerations for Animal Use and Sustainability – A Regulatory Perspective
Robin Levis, *CBER, FDA*

Designing and Manufacturing Medicines & Vaccines with Sustainability at the Core
Phil Dell'orco, *GlaxoSmithKline*

Enabling Sustainable and Predictable Bioprocessing Through Small-Footprint Automated Microbial Production
Chris Love, *Massachusetts Institute of Technology*

18:15-19:30 East/State Rooms

Exhibitor Reception

Thursday, 25 January, 2024

07:30-09:00 East/State Rooms

Sunrise Social: Breakfast

Breakfast is available until 09:30

08:15-09:00 Promenade Foyer / Senate Room

Registration

Registration is open until 16:00

Pre-registered attendees should go to the Foyer. If you are registering onsite, please make your way to the Senate Room.

09:00-10:30 Grand Ballroom

Plenary Session 5 - Drug Delivery Innovations for the Next Generation of Biologics and Vaccine Products: Smart Design, Smart Device

Chair: Cristiana Campa, Aparna Deora, Zahra Shahrokh, Thomas Wejs Møller
Presentation type: Live Streamed

The industry is committed to improving patient outcomes through the continuous development of innovative drugs, vaccines, and therapies. One area of focus for this innovation is drug delivery.
Administration of biological drugs and vaccines is challenged by painful methods using needles or invasive methods, often adversely affecting patient compliance. For CNS drugs, currently the most common method of delivery is through invasive intra-CNS devices. Additionally, efficacy of parenteral drugs and vaccines can be negatively affected by non-optimal targeting to sites other than that of the natural biological pathway (e.g., injecting intramuscularly, intravenously, or subcutaneously when the site of the target is mucosal or in the CNS space).
This session highlights innovations intended to enhance the effectiveness, uptake and compliance of injectable biological drugs. Topics include smart molecular designs for less frequent administration, novel technologies for less painful delivery (e.g., microneedles), more effective routes of administration (e.g., intra-nasal), and smart devices with feedback mechanisms to optimize dose and frequency.
The desired outcome for this session is to feature the latest trends in drug delivery and understand how far the challenges can be overcome towards improving patient outcomes and advancing the field.

Session Speakers:

From Blood-Brain Barrier to Blood-brain Interface: Strategies for Drug Delivery to the Brain
Bill Banks, *University of Washington*

Trends and Developments in Biopharmaceutical Delivery Innovations
Tine Zachariasen, *Novo Nordisk A/S*

Drug Delivery Innovations for CEPI's 100 Days Mission
Dimki Patel, *CEPI*

10:30-11:00 East/State Rooms

Coffee Connection: Networking Break

11:00-12:00 Palm Court Ballroom

Roundtable Session 2

Presentation type: In-Person

Table 1 - Setting Specifications on Limited Data, Clinically Relevant Specs/ Next Generation Control Strategies: Looking Ahead to Revision of ICH Q6B - What is Needed?

Table 2 - Acceleration and CMC - Novel Approaches to Enabling Acceleration (Applying the EMA Toolbox and FDA MAPP); How to Manage Accelerated Programs and Changing Work Priorities

Table 3 - Comparability Approaches in Development and Beyond - Focus on Traditional Biotherapeutics

Table 4 - Regulator Review Preferences and Recent Review Trends: Questions and Key Issues - Focus on Ex-US Regions

Table 5 - Potency Assays / Use of Structure Function Models: MOA / Replace Biological / Cell-based Assays / Replacing in-vivo with in-vitro Potency Assays

Table 6 - Regulatory Considerations and Experiences for Control Strategies in Different Regions (e.g. considerations for host cell proteins and how to justify attributes not on the C of A)

Table 7 - How Instrument Lifecycle Practices Can Facilitate the Best Technology While Ensuring Quality

11:00-12:00 Chinese Room

Roundtable Session 2

Presentation type: In-Person

Table 8 - New Analytical Technologies and Their Implementation in Advanced Manufacturing Including Continuous Manufacturing

Table 9 - Focus on Vaccines: Vaccine Adjuvants, Polysaccharide Conjugate Vaccines, Late Stage Characterization Packages

Table 10 - Technical Transfer of Analytical Procedures - Approaches for Streamlining and Discussion of Regulatory Submission Experiences

Table 11 - ICH Q12- Global Implementation Challenges with PACMPs and Established Conditions

Table 12- Supply Issues of New Medicines - Focus on Equitable Access in Third World Countries

Table 13 - Cell and Gene Therapy Products - Shared Experiences with Developing Manufacturing Control Strategy

Table 14 - Advanced Mass Spectrometry Methods in Biologics Characterization and Regulatory Filing

11:00-12:00 Cabinet Room

Roundtable Session 2

Presentation type: In-Person

Table 15 - Small Company CMC Challenges

Table 16 - Raw Material and Critical Reagent Management Strategies - Post Approval Challenges Including Shortages

Table 17 - NMR in Extended Characterization of Biologics

Table 18 - Visible and Sub-visible Particles: New Approaches and Requirements

Table 19 - Extractables and Leachables: New ICH Q3E Guidance, Common Practices and Challenges (single use)

Table 20 - Navigating the Complexities of EU EMA Annex 1: Overcoming Challenges in Sterile Pharmaceutical Manufacturing

Table 21 - Unlocking the Genetic Code: NGS Marvels in the Realm of Cell Therapy

11:00-12:00 Rhode Island Room

Mini Case Studies Session 2 - Platform Analytical - Applying Concepts in ICH Q2(R2) and Q14

Presentation type: In-Person

11:00-12:00 South Carolina Room

Mini Case Studies Session 2 - Could ADCs be the drug equivalent of Lego®?

Presentation type: In-Person

11:00-12:00 Virginia Room

Mini Case Studies Session 2 - Experience with Decentralized Manufacturing - Cell and Gene Therapies or Other Modalities

Presentation type: In-Person

12:00-14:00

Lunch Break

Attendees on own

12:30-13:30 Grand Ballroom

Characterization of Complex cIEF Electropherograms From mAb and Antibody-Drug Conjugate (ADC) Using a Novel icIEF-UV/MS System | Presented by SCIEX

Presentation type: Live Streamed

Session Speaker:

Characterization of Complex cIEF Electropherograms From mAb and Antibody-Drug Conjugate (ADC) Using a Novel icIEF-UV/MS System
Mingjie Cui, *AstraZeneca*

12:30-13:30 District Ballroom

Untangling the Complexity Within Oligonucleotide Therapeutics | Presented by Agilent Technologies, Inc.

Presentation type: Live Streamed

Session Speaker:

Untangling the Complexity Within Oligonucleotide Therapeutics
Jace Jones, *University of Maryland School of Pharmacy*

12:30-13:30 Palm Court Ballroom

Automating Cell-Based Assays, Reducing Variability & Time to Results | Presented by Catalent Pharma Solutions

Presentation type: In-Person

Session Speaker:

Automating Cell-Based Assays, Reducing Variability & Time to Results
Luke Mercer, *Catalent Pharma Solutions*

12:30-13:30 Chinese Room

Structured Data Management in the Age of Digital Maturity | Presented by Genedata Inc.

Presentation type: In-Person

Session Speaker:

Structured Data Management in the Age of Digital Maturity
Jana Hersch, G*enedata Inc.*

14:00-15:15 Grand Ballroom

Workshop Session 4: Hot Topic

Chair: Kavita Aiyer, Nicole del Canto
Presentation type: In-Person

Vote Now for the ***HOT TOPIC***
Voting will close on Tuesday, January 23 at 6:00 pm EST.
Make your selection here or click the video link under "Resources" in the mobile app.
Vote Now for the *HOT TOPIC*

14:00-15:15 District Ballroom

Workshop Session 4: CMC Express: Navigating the Fast Lane of Drug Development

Chair: Vandana Chauhan, Bazzarragchaa Damdinsuren, Meghan Dewitt, Alexy Khrenov, Daniel Sayut, Joey Studts
Presentation type: In-Person

In the dynamic landscape of pharmaceutical development, the critical role of Chemistry, Manufacturing, and Control (CMC) processes cannot be overstated. This workshop aims to delve into the aspects of CMC strategies that contribute to the acceleration of pharmaceutical development, focusing on enhancing speed without compromising quality.
The workshop will bring together industry experts and regulators to explore innovative approaches and best practices aimed at expediting the drug development lifecycle.
Key Themes:
Regulatory Considerations: Navigating the evolving regulatory landscape and accelerating CMC development without compromising safety and efficacy to allow leveraging emerging pathways to accelerate regulatory approvals.
Active and Ongoing Risk Management: Using robust knowledge management, integrating product-specific data with platform, process and literature knowledge, to proactively identify potential hazards and manage associated risks, ensuring a robust and efficient process and product development.
Strategies for preparing and structuring that knowledge for use in regulatory decisions and discussions. Understanding the synergy between upstream and downstream manufacturing, formulation development, and analytical methods to create a cohesive and streamlined approach for faster drug development.
Collaboration and Communication: Emphasizing the importance of effective cross-functional communication and collaboration between CMC, regulatory affairs, and other stakeholders for holistic, seamless, and expedited development.
The workshop will combine expert presentations and interactive discussions, providing participants with valuable insights and actionable strategies to enhance the speed and efficiency of pharmaceutical development from a CMC perspective.

14:00-15:15 Palm Court Ballroom

Workshop Session 4: Preventing, Mitigating and Solving Drug Shortages to Get Medicines to Patients – Sponsor, Regulator and Supplier Perspectives

Chair: Didier Dayen, Gerald DiDonato, James Hathcock, Leslie Rivera Rosado, Emily Thakur
Presentation type: In-Person

14:00-15:15 Chinese Room

Workshop Session 4: Combination Products-bridging Studies

Chair: Prachi Bhoskar, Dez Crisolo
Presentation type: In-Person

15:15-15:45 Promenade Foyer

Coffee Connection: Networking Break

15:45-17:15 Grand Ballroom

Plenary Session 6 - Clearing the Fog: Particle Visibility and Regulatory Updates for Visual Inspection of Parenteral Drug Products

Chair: Patricia Cash, Sophia Levitskaya-Seaman, Ewa Marszal
Presentation type: Live Streamed

Visual inspection of parenteral drug products is a critical aspect of pharmaceutical development and manufacturing, subject to evolving regulatory standards. This session brings together experts to address the complex landscape of particle visibility and regulatory compliance, with a focus on enhancing product quality and patient safety. The session will provide attendees with a holistic view of the challenges, innovations, and best practices in visual inspection, offering an overview of the regulatory and compendial environment for visual inspection.
Two of the talks will present new data on defining particle visibility: the results from a cross-industry visible particle threshold study, as well as the results from a stand-alone study exploring the opportunities for standardization based on common features of human visual perception.
The session also examines the unique challenges posed by visual inspection for Cell and Gene Therapy (CGT) products, considering whether there are regulatory gaps in this rapidly advancing field.
Finally, the critical role of regulatory agencies in ensuring the safety and efficacy of injectable pharmaceuticals will be discussed, highlighting the collaborative efforts between industry and regulatory bodies in addressing visible particulates in injectable products.

Session Speakers:

The Visual Inspection Regulatory and Compendial Environment: Current Issues and Opportunities
John Shabushnig, *Insight Pharma Consulting*

Regulatory Considerations for the Assessment of Visible Particulates in Injectable Pharmaceuticals
Rukman De Silva, *CDER, FDA*

From Blur to Clarity: Definition of Participle Visibility Threshold in Parenteral Drug Products
Felix Nikels, *Boehringer Ingelheim Pharma GmbH & Co. KG*
Atanas Koulov, *Clear Solutions Laboratories*

Visual Inspection and Particle Life Cycle Management for CGT Products - Same, Same, but Different… Are There Gaps in the Current Regulations?
Antonio Burazer, *Takeda Austria GmbH*

Additional Panelists:

Patricia Cash, *Global Biotech Experts, LLC*

Maryam Mazaheri, *I-MAB Biopharma Co., Ltd.*
Patricia Cash Invites You to Plenary Session 6 at WCBP 2024

17:15-17:30 Grand Ballroom

Acknowledgements, Closing Remarks & Invitation to WCBP 2025

Presentation type: Live Streamed