WCBP 2025

Schedule

Monday, 27 January, 2025

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

Registration for Pre-Conference Workshop Only

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.

08:00-09:00 2nd Floor Foyer

Breakfast for Pre-Conference Workshop Only

Breakfast will be available for workshop attendees only, and it will be open until 09:00

09:00-10:15 South Carolina Room

Workshop I Part A: Introduction to Bioassay Development: CMC Strategy and Practical Application

Workshop Facilitators: Patrick Hussmann, *AstraZeneca* and Scott Umlauf, *AstraZeneca*

The workshop will provide practical knowledge on Bioassay method development, with a particular emphasis on Potency Assays. Method development and lifecycle management will be covered in the context of the unique role of Bioassays in CMC control strategy of Biopharmaceuticals, including monoclonal antibodies, antibody-drug conjugates, fusion proteins, such as T cell engagers, vaccines and cell and gene therapy.

10:15-10:45

Networking and Coffee Break

10:45-12:30 South Carolina Room

Workshop I Part B: Introduction to Bioassay Development: CMC Strategy and Practical Application

Workshop Facilitators: Patrick Hussmann, *AstraZeneca* and Scott Umlauf, *AstraZeneca*

The workshop will provide practical knowledge on Bioassay method development, with a particular emphasis on Potency Assays. Method development and lifecycle management will be covered in the context of the unique role of Bioassays in CMC control strategy of Biopharmaceuticals, including monoclonal antibodies, antibody-drug conjugates, fusion proteins, such as T cell engagers, vaccines and cell and gene therapy.

12:30-13:30

Lunch

13:30-15:00 South Carolina Room

Workshop II Part A: Practical Applications for Method Design and Performance

Workshop Facilitators: Colleen Santoro, *Bristol-Myers Squibb Company* and Tara Stauffer, *Bristol-Myers Squibb Company*

In this interactive session, participants will work collaboratively on case studies relevant to current challenges in bioassay development, deployment, and lifecycle. This session will expand on the morning session and is recommended for both novice and experienced attendees.

15:00-15:30

Networking and Coffee Break

15:30-17:00 South Carolina Room

Workshop II Part B: Practical Applications for Method Design and Performance

Workshop Facilitators: Colleen Santoro, *Bristol-Myers Squibb Company* and Tara Stauffer, *Bristol-Myers Squibb Company*

In this interactive session, participants will work collaboratively on case studies relevant to current challenges in bioassay development, deployment, and lifecycle. This session will expand on the morning session and is recommended for both novice and experienced attendees.

Tuesday, 28 January, 2025

05:00-06:00

Visit the WCBP 2025 Virtual Poster Gallery

Enhance your Symposium experience and visit the WCBP virtual poster gallery featuring poster submissions on a wide range of topics from industry leaders and innovators in our global community. Chat with the presenters and view supplemental video presentations from each presenter. The gallery will be accessible pre- and post-Symposium via the online Scientific Program. You can view the gallery here: https://virtual.oxfordabstracts.com/event/73479/poster-gallery/grid
Visit the WCBP 2025 Virtual Poster Gallery

06:00-07:00

WATCH NOW: How to Maximize Value from Protein Metrics' New Multi-Protein Quantitation Workflows | Presented by Protein Metrics, LLC

This Technical Seminar will be available to watch on demand 24/7 before and during the Symposium. Click on this session to access the presentation video.

NOTE: If prompted to login to view the video, enter your CASSS member credentials.

Presented by: Protein Metrics, LLC
Click to Watch Video

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

Continental Breakfast

Breakfast is available until 09:00

08:00-08:30 Grand Ballroom

CASSS Welcome and the 13th Annual Hancock Award

Live Streamed

08:30-08:45 Grand Ballroom

WCBP 2025 Introduction

Live Streamed

08:45-10:00 Grand Ballroom

Keynote Presentation - The Road to Preventing Prion Disease: Opportunities, Challenges, and My Personal Mandate

Live Streamed
Keynote Speaker: Sonia Vallabh, Ph.D., *Broad Institute*

10:00-10:30 East/State Rooms

Networking Break

10:30-12:00 Grand Ballroom

Parallel Session 2A - Science vs the Fear Factor: Alternative Potency Assays for Recombinant Biologics and Vaccines

Marla Abodeely, Svetlana Bergelson, Jayda Siggers, Dean Smith
Live Streamed

Potency analytical control strategies are critical to support biopharmaceutical drug and vaccine development throughout the product lifecycle. For biopharmaceutical drugs, it is generally expected that a quantitative potency assay be included in the control strategy and that the assay adequately reflects the physiological Mechanism of Action (MOA). Most often these assays are developed using cell lines that mimic MOA-relevant, physiological responses. However, the development, validation, and transfer of cell-based potency assays can be challenging due to multiple factors inherent to working with living systems/live cells. Therefore, non cell-based alternatives are of great interest to the more complex cell-based potency assays to ensure the consistent generation of accurate results for drug substance/drug product release and stability specifications.
Current day vaccine potency analytical control strategies typically do not involve cell-based assays, but generally rely on binding, chromatographic or physical chemical methods. However, many legacy vaccines still utilize in vivo potency assays; these assays are inherently more variable, require weeks to perform, and are more prone to invalid test results, necessitating repeat testing. The transition to in vitro alternatives has been challenging due to less robust characterization of vaccine products, compounding the establishment of in vitro alternatives, as well as regulatory acceptance of new methods. Fortunately, recent industry driven collaboration and novel regulatory approaches have accelerated the development of in vitro alternative assays and regulatory acceptance.
In this session, we plan to discuss the following topics:
- Successful and/or failed biopharmaceutical case studies regarding strategies used to support the phase-appropriate introduction of a new non-cell-based potency assay as a replacement to an existing cell-based potency assay in the lot release and stability program,
- Successful and/or failed biopharmaceutical case studies regarding strategies used to support the phase-appropriate removal of an existing cell-based potency assay from the lot release and stability program while leveraging an existing non-cell-based potency assay.
- Vaccine industry collaboration and regulatory innovation that has accelerated the transition from in vivo to in vitro potency and safety assays for legacy vaccines.

Session Speakers:

Successful Implementation of Potency Control Strategy - Two Binding Assays Rather Than One Cell-based Assay
Catherine Shoemaker-Ramsey, *Biogen*

How Industry and Regulatory Innovation and Collaboration Can Promote the Transition From in Vivo to In Vitro Potency Testing for Human Legacy Vaccines
Emmanuelle Coppens, *Sanofi*

Replacement of in Vivo Immunogenicity Assay With in Vitro Antigenicity ELISA for Pertactin Antigen in Acellular Pertussis Combination Vaccines
Belma Ljutic, *Sanofi*

Additional Panelists:

Elena Grabski, *Paul-Ehrlich-Institut*

Emily Shacter, *ThinkFDA LLC*

Jayda Siggers, *Health Canada*

Yasuhiro Kishioka, *Pharmaceuticals and Medical Devices Agency (PMDA)*

10:30-12:00 District Ballroom

Parallel Session 2B- LER 2025: Strategies Today for Overcoming Low Endotoxin Recovery

Minh Luu, Zahra Shahrokh, Arne Staby
Live Streamed

Monitoring and control of endotoxin are critical aspects of an overall microbial control strategy necessary to ensure drug product quality and patient safety. It has been over a decade since Low Endotoxin Recovery (LER) came into prominence as a major challenge in biologics manufacturing, due to the common use of formulation excipients such as polysorbate, phosphates, etc. that have been shown to interfere with the compendial endotoxin detection methods. Since then, industry and regulators have made gains in understanding LER and developing standardized approaches for evaluating and overcoming it. However, there still is much progress to be made. Developing alternative methods that address LER is sometimes a labor intensive task and may result in complicated methods that lack robustness or are difficult to implement, in some occasions leaving Sponsors with the Rabbit Pyrogen Test as the "only option" for endotoxin detection. This is further complicated as some health authorities and industry take steps towards removing animal testing. The purpose of this session is to provide an overview of endotoxin methods and microbial controls to mitigate LER and discuss evolving regulatory expectations, challenges, and potential solutions.

Session Speakers:

Overcoming Low Endotoxin Recovery from Theory to Practice
Jessica Hankins, *Bristol-Myers Squibb Company*

Defining the Microbial Control Strategy for Low Endotoxin Recovery Impacted Biologics
Lindsey Silva, *Genentech, a Member of the Roche Group*

Additional Panelists:

Jay Bolden, *Eli Lilly and Company*

Claudia Müller, Swissmedic

Jody Peraino, *Pfizer, Inc.*

12:00-13:45

Lunch Break

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

12:15-13:30 Cabinet Room

First Time Attendee Lunch

In-Person

12:25-13:25 Grand Ballroom

Advances in Capillary Electrophoresis for Biotherapeutic Development | Presented by Bio-Techne

Live Streamed
Session Speakers:

Xiaoping He, *Pfizer, Inc.*

Peter Johnson, *Bio-Techne*

12:25-13:25 District Ballroom

Critical Attributes Analysis and Method Lifecycle Management for Biologics and ATMPs – Selection of Assay Platforms and Data Processing Methods for Potency Assurance | Presented by BioAgilytix Labs

Live Streamed
Session Speakers:

Jeff Patrick, *BioAgilytix Labs*

Shiqian Zhu, *BioAgilytix Labs*

12:25-13:25 Palm Court Ballroom

Quantitative Cell Characterization Using Laser Force Cytology™ (LFC): The Future of Precision Analytics for Improved Manufacturing Success | Presented by LumaCyte, Inc.

In-Person

Session Speaker:

Colin Hebert, *LumaCyte, Inc.*

12:25-13:25 Chinese Room

Digital Transformation in Bioprocessing: Managing Data for Better Outcomes | Presented by Genedata Inc.

In-Person

Session Speaker:

Jana Hersch, *Genedata Inc.*

13:45-15:00 Chinese Room

Workshop Session 1 - Endotoxin Testing: The Future and the Past are Living Together

In-Person

Topic Scope and Discussion Points

- When LER testing and mitigation might be needed; potential for a white paper to discuss specifics
- Global alignment around LER assessment and mitigation does not exist. Some expectations in place for US and EU only.

- Uncertainty regarding the endotoxin standards to be used in LER testing: highly purified? Based on naturally occurring organisms? Commercial standards?

- If real uncertainty exists, and pyrogen testing may be helpful, how can an alternate to rabbit pyrogen testing (RPT), such as the monocyte activation test (MAT) be applied? And overall, how can MAT be applied in any situation where RPT may be needed or required by regulations?

13:45-15:00 District Ballroom

Workshop Session 1 - Unlocking the Secrets of Platform Analytical Procedures with a Dash of ICH Q2(R2)/Q14 Magic

In-Person

The recent adoption of ICH Q2(R2) and ICH Q14 has further enabled the application of platform analytical procedures through an increased focus on the use of prior knowledge. In this session, regulatory leaders alongside Industry Experts with direct involvement in the development of ICH Q2(R2) / Q14 will lead a discussion on the practical implementation of platform analytical procedures utilising the concepts of ICH Q2(R2)/Q14.

Join us as we explore approaches to the development, validation and registration of platform analytical procedures, enabling efficiencies such as abbreviated analytical procedure validations and streamlined laboratory implementation. We will tackle pertinent topics such as:

When can an analytical procedure be designated as platform and how does it apply to your next product?

What is the latest thinking on platform analytical procedure validation requirements?

What are the potential advantages and/or challenges faced during regulatory submission?

During the session, we invite attendees to actively participate in the discussion and to share your most pressing challenges, concerns, and aspirations in relation to the implementation of platform analytical procedures. This session promises to be an exciting and collaborative discussion, blending industry and regulatory insights, with your input ensuring that this will be a fruitful and enlightening workshop

13:45-15:00 Grand Ballroom

Workshop Session 1- Back to the Future and the Future is Predictive Stability

In-Person

Setting a shelf-life for biological medicinal products can be on the critical path for the CMC package required for the approval of new, innovative or improved medicines and thereby can delay the availability of these products to the patients that need them. Predictive stability models are seen as a solution for some drugs to optimize product development, for which there are many possible applications throughout development.

Many types of stability model for biologics are being developed, including those based on complex derivatives of the Arrhenius equation, while others are based on prior knowledge. Indeed, stability models for certain 'well characterized' biologics have now evolved to the extent that the biopharma industry is confident in their applicant in the product control strategy. Meanwhile the ICH Stability guidelines are under revision and the concept paper includes the use of stability models as part of the modernization of the stability regulatory environment.

This Plenshop intends to discuss the 'why, when and how' to development predictive stability models, the risk considerations for biologic products and how they could be successfully used across the product lifecycle while meeting global regulatory expectations of quality, safety and efficacy. The audience will gain appreciation of the following questions: What does predictive stability aim to achieve? What is the ICH revision intended to achieve? What products could be appropriate to employ a predictive stability model? What are the challenges and regulatory expectations for a credible predictive stability model for shelf-life setting? How do the challenges differ across different applications of predictive stability through product development?

13:45-15:00 Palm Court Ballroom

Workshop Session 1 - Managing Product-Specific Reference Standards: Challenges and Best Practices

In-Person

Reference standard (RS) is crucial for biotherapeutic development, quality control, and regulatory compliance. ICH Q6B and ICH Q7 provides some general descriptions about reference standards, their uses and basic requirements. While Pharmacopoeia/WHO standards provide additional guidance on the RS management, product-specific reference standards require specialized management and control. This workshop focuses on the unique challenges and best practices for managing in-house reference standards. Key challenges include (1) Lack of clear regulatory guidance on preparation, qualification, storage, and management (2) Lack of harmonization in reference standard management practices.

Foundational Principles:
1. Reference standards are stored in non-reactive containers.
2. Temperature-controlled storage and proper handling [SV1] ensures stability.
3. Single-use vial volumes minimize contamination and potential degradation[SV2] .
4. Sufficient and appropriate qualification of the reference standards ensure the suitability for their intended uses and prevent potential drifting of the product's quality attributes.
5. Periodic re-qualification (re-evaluation) verifies stability of the reference standards.

Workshop Objectives:
Share experiences and discuss best practices for:
1. Establishing reference standards for early-phase and late-phase products.
2. Selecting optimal storage and handling conditions (vial configuration, temperature and freeze thaws etc.).
3. Ensuring reference standard's stability throughout the product lifecycle (RS stability monitoring plan and RS data trending analysis).
4. Managing lifecycle changes across product reference standards, including implementation of a two-tier reference standard strategy (Primary RS and Working RS).

Join the discussion to:
- Explore strategies for managing product-specific reference standards.
- Share expertise and learn from industry peers.
- Develop practical solutions for reference standard challenges.

15:00-15:30 East/State Rooms

Networking Break

15:30-17:00 Grand Ballroom

Plenary Session 3 - Navigating the Regulatory Landscape: Global Convergence and Innovation in Biopharmaceutical Manufacturing

Sarah Miksinski Pope, Cecillia Tami, Kim Wolfram
Live Streamed

In this session, regulatory leaders from the EMA, Health Canada, PMDA, Health Canada, and international health authorities including WHO will delve into the challenges hindering the path to regulatory reliance and approval of advanced technologies. By sharing their insights and experiences, they will illuminate potential solutions to overcome these obstacles and accelerate the journey towards a unified "One Submission/One inspection/One Assessment" approach.
Join us as we explore the latest advancements in technology and reliance that are reshaping the regulatory landscape. Together, we can foster a collaborative environment that benefits all companies and countries.
Ahead of and during the session, we invite attendees to share their most pressing challenges and transformative solutions. Your contributions will help shape a more productive and insightful discussion.
Key Highlights:
- Regulatory Reliance Progress: Are recent advancements in reliance tools and pilots being shared across all regions and companies?
- Future of Biopharmaceutical Manufacturing: What does the future hold for biopharmaceutical manufacturing, and how can regulators support these changes?
- Advanced Technologies: How are regulators incorporating advancements in technology to improve efficiency and speed to patient?
- Global Convergence: What steps can be taken to promote greater convergence and collaboration among regulatory authorities?

Session Panelists:

Rogério Gaspar, *World Health Organization*

Akihiro Ishiguro, *Pharmaceuticals and Medical Devices Agency (PMDA)*

Yasuhiro Kishioka, *Pharmaceuticals and Medical Devices Agency (PMDA)*

Anabela Marçal, *European Medicines Agency (EMA)*

Claudia Müller, *Swissmedic*

Sophie Sommerer, *Health Canada*

18:00-21:00 Planet Word Museum

Welcome Reception - Planet Word Museum

In-Person

Join us for the WCBP Welcome Reception! The welcome reception will be held at the Planet Word Museum. The museum is located at 925 13th St NW, Washington DC 20005

Don't forget to bring your conference badge, as it is required to attend.

Wednesday, 29 January, 2025

05:00-06:00

Visit the WCBP 2025 Virtual Poster Gallery

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06:00-07:00

WATCH NOW: How to Maximize Value from Protein Metrics' New Multi-Protein Quantitation Workflows | Presented by Protein Metrics, LLC

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Presented by: Protein Metrics, LLC
Click to Watch Video

07:00-08:15 Promenade Foyer / Senate Room

Registration

Registration is open until 17:00

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07:00-08:00

NEW Wellness Walks

Start the day with your fellow attendees and take advantage of the surroundings of the centrally located Mayflower Hotel, by stepping outside for a brisk morning walk. Walks are self-led and depart from the Desales entrance of the Mayflower Hotel on Wednesday and Thursday morning at 7:10 am.

View details about a suggested walking route here.

07:00-08:15 East/State Rooms

Continental Breakfast

Breakfast is available until 09:00

07:00-08:15 District Ballroom

Community Voices: Sunrise Chats

Live Streamed

Featured Panelists:

Kavita Aiyer, *Teva Pharmaceuticals USA, Inc.*
Sydia Dunkley, *Hoffmann-La Roche Limited*
Marjorie Shapiro, *Retired*
Kim Wolfram, *Biogen*

08:15-08:30 Grand Ballroom

Welcome Day 2 & CASSS Distinguished Fellow Presentation

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 4 - Old Dog, New Tricks: Harnessing the Hidden Potential of Established Analytical Technologies to Drive Complex Product Characterization

Nomalie Jaya, John Orlet, Yi Zhang
Live Streamed

Innovations in therapeutic modalities are continually emerging as viable treatment options for a multitude of disease indications. These novel therapies can be complex biologics with multiple product components such as bioconjugates, volume limited therapies where the suit of established characterization and release testing cannot be performed due to low volumes as in the case of certain Cell and Gene therapies or molecules that are invisible by established analytical tools. Re-evaluation of established analytical technologies or reimagining the use of established analytical tool kits to provide novel characterization approaches can accelerate and enhance product understanding.
In this session we will explore case-studies where established technologies are enhanced or leveraged in a novel manner to characterize complex therapeutic modalities. Additionally, we will explore the current state of the art analytical tools utilized for process analytical technologies and release testing. We will discuss which technologies are QC ready and which remain as characterization tools in the development labs. This session will highlight the evolving trend of reimagining established analytical technologies to tackle the characterization and product release challenges posed by the modern-day innovative therapies.

Session Speaker:

A Novel, High-Throughput Imaged Capillary Isoelectric Focusing (iCIEF)-Western Method to Characterize Charge Heterogeneity of Monoclonal Antibody (mAb) Heavy and Light Chains
Gangadhar Dhulipala*, Regeneron Pharmaceuticals Inc.*

Genetic Medicine Characterization via 2nd and 3rd Generation Sequencing Tools
Beth Ostrander, Pfizer, Inc.

Carly Daniels, *Pfizer, Inc.*

Additional Panelists:

Methal Albarghouthi, *AstraZeneca*

Da Ren*, BioTherapeutics Solutions*

Nadine Ritter, *Global Biotech Experts, LLC*

10:00-10:30 East/State Rooms

Networking Break

10:30-12:00 Grand Ballroom

Parallel Session 5A - Integrated Control Strategy for Combination Products

Wayne Kelley, Andrea Redd, Chin-Wei Soo
Live Streamed

Drug-device combination products such as prefilled syringes, autoinjectors, etc. can play an important role to ensure patient convenience, compliance, and enhance therapeutic impact of the drug. An integrated control strategy for combination products is critical to ensure that the products are designed, manufactured, and released with the desired product quality and robustness. Building an integrated control strategy starts with a thorough understanding of the materials, components, product design, and the associated processes; this understanding usually begins early during clinical development. The extent of the control strategy should be risk-based and assessed throughout the product lifecycle. This session will cover the following topics: (a) development and implementation of an integrated control strategy throughout clinical development, commercial marketing authorization, and post-approval life cycle management and (b) effective use of design controls framework, prior knowledge, and risk management process to implement an effective control strategy. In this session, the audience will have the opportunity to learn from real-world case studies as well as interact with industry-leading experts and key regulatory opinion leaders.

Session Speakers:

Considerations for Developing an Autoinjector Control Strategy: A Case Study
Kristin Benokraitis, *Biogen*

Maintaining an Integrated Control Strategy Throughout Combination Product Lifecycle Changes
Amir Tabaian, *Pfizer, Inc.*

Additional Panelists:

Ben Stevens, *GlaxoSmithKline*

Chin-Wei Soo, *Genentech, a Member of the Roche Group*

10:30-12:00 District Ballroom

Parallel Session 5B - Immunogenicity Risk and Control

Douglas Roepke
Live Streamed

Peptides, proteins and oligonucleotide are becoming essential medical treatments for many progressive, debilitating, or life-threatening diseases. However, the development of these potential therapies can be derailed by product immunogenicity as it can impact on safety and efficacy. Establishment of validated methods to measure anti-drug antibody responses during clinical trials is currently used to identify potential immunogenicity-related adverse outcomes and intervene early on. However, this approach is limited by incidence and study size particularly when there is low frequency of occurrence for many unwanted immunogenic outcomes. As a result, understanding of product immunogenicity risk is often still incomplete late in development and during early commercialization. Moreover, this also limits the information yielded by abbreviated regulatory paths for follow-on products such as complex generics and biosimilars. To mitigate this risk, sponsors are increasingly utilizing analytical, in silico, and in vitro tools to compare and control product attributes such as propensity to aggregate, likelihood to undergo post-translational modifications, and presence of product and process related impurities that could act as adjuvants to reduce the failure risk in their product target selection. Unfortunately, studies linking the result of these studies in the context of clinical results are rarely shared, even with the regulatory agencies, which is an important missed opportunity to connect critical quality attributes with clinical outcomes. Thus, currently, our understanding of the levels of product and process related impurities that can impact on immunogenicity risk are frequently based on analytical and process capabilities rather than safety considerations, which can result in unnecessary burdens on development and lead to delay in getting potential therapies to patients. This session will focus on emerging strategies to connect product quality attributes to immunogenicity risk, and how they could inform not only product selection and development but also the regulatory process for new products as well as for follow on products such as complex generic peptides, oligonucleotides and biosimilars.

Session Speakers:

Tiered, Data-driven Approach for Assessing the Safety of Product-Related Impurities in Support of Commercial Control Strategy Development
Robert Siegel, *Eli Lilly and Company*

Additional Panelists:

Andrea Ferrante, *Eli Lilly and Company*

Mark Schenerman, *CMC Biotech-MAS Consulting*

Jayda Siggers, *Health Canada*

12:00-13:45

Lunch Break

Attendees on own

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

12:25-13:25 Grand Ballroom

Comprehensive Characterization of Biotherapeutics Using Orthogonal Capillary Electrophoresis (CE), Liquid Chromatography-Mass Spectrometry (LC-MS) and Imaged Capillary Isoelectric Focusing (icIEF)-UV/MS Workflows | Presented by SCIEX

Live Streamed

Session Speaker:

Greg Roman, *SCIEX*

12:25-13:25 District Ballroom

Best Practices in Host Cell Impurity Analytics – Using Advanced Technologies and Methods to Monitor and Control Host Cell Proteins and Host Cell DNA | Presented by Cygnus Technologies, LLC

Live Streamed

Session Speaker:

Eric Bishop, *Cygnus Technologies, LLC*

12:25-13:25 Palm Court Ballroom

Integrating LC, MALS, and MS for Compliance and Connectivity in GMP Labs | Presented by Waters Corporation

In-Person

Session Speaker:

Yuwei Wu, *Regeneron Pharmaceuticals Inc.*

12:25-13:25 Chinese Room

Evaluating the Stability of Monoclonal Antibodies: The Role of Forced Degradation Conditions in Method Development, Manufacturability, Aggregation, and other Critical Quality Attributes | Presented by Catalent, Inc

In-Person

Session Speaker:

Brent Kennedy, *Catalent, Inc*

12:30-13:30 Pennsylvania Room

CASSS Consultants' Network

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, 2025. Light lunch will be provided!

13:45-14:45 Palm Court Ballroom

Roundtable Session 1

In-Person

Table 1 - Setting Specification (Including Potency) for Not Well-Characterized Biological Products, e.g., Cell and Gene Therapy Products

Table 2 - CMC Challenges With Complex Formulation: Excipient Selection and Impact on Product Stability and Process Consistency

Table 3 - Recent Trends in Questions from Health Authorities

Table 4 - Moving Away from Animal Testing and Animal Derived Components Including Alternate Endotoxin Test

Table 5 - The Road to One Global CMC Dossier

Table 6 - Relevance of Accelerated and Forced Degradation Studies for a Frozen DS/DP

13:45-14:45 Chinese Room

Roundtable Session 1

In-Person

Table 7 - Managing/Leveraging CMOs and CTOs for Marketing Application Success

Table 8 - Between 2 Worlds: Regulatory & Development Strategies for Peptide Therapeutics > 40 Amino Acids

Table 9 - Advanced Manufacturing Technology

Table 10 - What Does Potency Mean for mRNA?

Table 11 - Fix-Dose Co-Formulated Protein Product in Liquid or Solid

Table 12 - Navigating 2-Tier Reference Standard Strategy for Biologics

13:45-14:45 Cabinet Room

Roundtable Session 1

In-Person

Table 13 - Practical Applications of AI / ML in Discovery, Development and Platform Establishment Including CQA Controls

Table 14 - Applications of Artificial Intelligence / Machine Learning and Automation

Table 15 - Wide-Spread Adoption of High Volume Delivery Subcutaneously Delivery - What's the Hold Up?

Table 16 - Molecule-Agnostic Drug-Delivery Device Bridging (an approach to streamline clinical development to serve patients)

Table 17 - What Are the New Alternate Lipids for Lipid Nanoparticles?

Table 18 - Global Access to Medicines in Underserved Regions

13:45-14:45 Rhode Island Room

Mini Case Session 1 - Digital Solutions (Data Management, Modeling, Submissions, etc.)

In-Person

13:45-14:45 South Carolina Room

Mini Case Session 1 - Use of Predictive Stability for Shelf-Life Extension

In-Person

13:45-14:45 Virginia Room

Mini Case Session 1 - Accelerating Post Approval Changes

In-Person

13:45-14:45 Grand Ballroom

Bridging Session - Leveraging Contract Organization Networks to Enhance Patient Access in Lower and Middle-Income Countries

Vandana Chauhan, John Kim, Ken Miller
Live Streamed

Access to advanced medical treatments remains a significant challenge in lower and middle-income countries (LMICs), often due to barriers in manufacturing, distribution, and regulatory complexities. This plenary session explores how Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs) can play a pivotal role in bridging these gaps and enhancing patient access to essential therapies in LMICs.

CMOs and CDMOs are instrumental in the pharmaceutical supply chain, providing expertise in the development, production, and scaling of medicines. Their extensive networks and operational capabilities offer unique opportunities to address the access disparities faced by LMICs. The session will delve into strategies for leveraging these networks to overcome common obstacles, such as high production costs, limited local manufacturing infrastructure, and regulatory hurdles.

Key topics will include:

1. Optimizing Production and Distribution: Exploring how CMOs and CDMOs can help reduce costs and streamline production processes to make medicines more affordable and accessible. Case studies will highlight successful collaborations that have led to the establishment of local manufacturing facilities and improved distribution channels in LMICs.
2. Regulatory and Quality Assurance: Addressing the challenges related to meeting diverse regulatory standards and ensuring consistent quality across different markets. Discussion will focus on best practices for navigating regulatory environments and implementing robust quality assurance measures to ensure compliance and safety.
3. Innovative Partnerships and Collaborations: Examining partnerships between CMOs, CDMOs, governments, and non-governmental organizations (NGOs) that have facilitated patient access to life-saving treatments. The session will showcase examples of successful models and explore opportunities for scaling these approaches.
4. Capacity Building and Knowledge Transfer: Highlighting initiatives that focus on building local capabilities through knowledge transfer and training programs. This will cover how CMOs and CDMOs can support capacity building efforts to empower local stakeholders and enhance self-sufficiency in drug production.

By the end of the session, participants will gain insights into effective strategies and actionable frameworks for leveraging the strengths of CMOs and CDMOs to improve healthcare outcomes in LMICs. The discussion will emphasize the importance of collaborative efforts and innovative solutions to ensure that more patients in underserved regions receive timely access to essential medicines and treatments.

Session Speakers:

Accelerating Access to Essential Medicines by Maximizing the Benefits of Contract Manufacturing
Ken Kent, *Gilead Sciences, Inc.*

Virtual Presentation
Boitumelo (Tumi) Semete-Makokotlela, *South African Health Products*

MRNA Technology Transfer Programme: Towards a Better Prepared Global South
Antonio Grilo, *Medicines Patent Pool (MPP)*

Additional Panelists:

Dean Smith, *Health Canada*

14:45-15:15 East/State Rooms

Networking Break

15:15-16:30 Chinese Room

Workshop Session 2 - Revolutionizing Biopharmaceuticals with AI: From Soup to Nuts

In-Person

This workshop will explore how Artificial Intelligence (AI) is transforming the biopharmaceutical industry across various stages, from drug development and clinical trials to Chemistry, Manufacturing, and Controls (CMC), regulatory submissions, and interactions with health authorities. We will examine both the opportunities and challenges of deploying AI in these contexts, sharing practical insights into current applications, common pitfalls, best practices, and emerging roles. Attendees will gain an understanding of what is possible with AI, how to best navigate its implementation, and what risks and considerations need to be managed to ensure successful outcomes.

Discussion Questions:

1. What are the most exciting applications of AI across different stages of biopharmaceuticals (e.g., development, clinical, CMC, regulatory)? And what tools and software are being used to develop applications?

A. What areas of AI do you think present the highest potential risks or need the most caution in biopharmaceutical applications?

2. What specific problems have organizations encountered when implementing AI solutions, and how have they addressed them?

A. How do you balance the benefits of AI tools with the risks of over-reliance on automation in critical decision-making processes?

3. What best practices have emerged for building AI systems in biopharma?

A. How can organizations ensure that their AI systems undergo rigorous testing, validation, and monitoring throughout their entire lifecycle to maintain high standards of quality and reliability (human-in-the-loop, new roles)?

4. What considerations are most important for integrating AI into the regulatory landscape, and how can companies work effectively with health authorities?

A. How might regulatory agencies adapt to the use of AI in the biopharmaceutical industry? What challenges could arise?

B. What metrics can be used to evaluate the safety, efficacy, and generalizability of AI models in the industry?

15:15-16:30 District Ballroom

Workshop Session 2 - Patient Centric Specifications: How Can They Be Established and Maintained, or if Justified Amended

In-Person

An appropriately supported and justified patient centric specification (PCS) can provide enhanced access to biologics of high quality. Whereas, an overly stringent specification, or the tightening of a specification based on improvements in manufacturing capability or assay performance in the context of a robust PCS, may lead to the reduced product availability, as well as potentially increase the cost of those drugs. Cleary, neither of those latter two outcomes is in the interest of patients.

The discussion in the workshop will focus on three situations:

- What are manufacturer's experiences when proposing a "robust" PCS in a commercial license application, with acceptance criteria beyond manufacturing experience?
- What are successful strategies to expand a specification post-authorization?
- Post-authorization and in the absence of safety or manufacturing issues, is there scientific justification for tightening a specification based on increased manufacturing consistency or assay performance?

Participants are invited to share examples and their experiences that address the above or related PCS topics.

15:15-16:30 Grand Ballroom

Workshop Session 2 - Interpreting and Applying the Platform Designation Guidance and Advanced Technologies

In-Person

Discussions with the audience will be guided by the following questions:

What are the challenges that industry sees in the implementation of the designation programs?

Where do we think that the greatest opportunities lay for each program?

When do we think is the optimum time for first interaction with the agency for each program?

Appropriate data packages are not defined as such in the guidelines, what is expected from the agency?

Next steps: the programs relate to one agency and one market, how do we expand opportunities to other markets?

15:15-16:30 Palm Court Ballroom

Workshop Session 2 - Microbiology Topics: Sterilization Validation and Aseptic Topics in Biologics

In-Person

This workshop will delve into key microbiological considerations and the evolving landscape of sterile validation and aseptic processing for biologics. Participants will discuss the current expectations for sterile validation data, environmental monitoring, and contamination control, as well as the challenges posed by products under accelerated development programs, newer biologic modalities, and addressing review issues related to sterility assurance. The session will also explore the complexities of validating manufacturing operations, exploring practical strategies for ensuring sterility and quality in flexible, multi-product facilities, as well as explore considerations related to the use of emerging technologies and AI.
Industry and Regulators are encouraged to share perspectives, including how companies are adapting to regulatory changes (particularly Annex 1 of the EU GMP guidelines), and addressing emerging questions in sterile validation. The discussion is intended to focus on how to better navigate the regulatory landscape and manage the risks and complexities of modern aseptic manufacturing.

16:30-16:45

Transition Time

Attendees can take this time to check emails, use the restroom and prepare for Plenary Session 6.

16:45-18:15 Grand Ballroom

Parallel Session 6A - Prior Knowledge to Support Clinical and Marketing Applications

Linda Lemieux, Charles Morgan
Live Streamed

Prior knowledge is fundamental for the progression of science and critical for efficient product development and informed regulatory assessments of product safety and quality. In this session, a variety of case studies will be presented touching on aspects of modeling, extrapolation, analysis of structured and unstructured datasets and the application to product development and the assessment of regulatory submissions. The panel will discuss successful applications of prior knowledge and explore the challenges and areas for improvement.

Session Speakers:

How to Incorporate Prior Knowledge: What Are Bayesian Statistics and Why Non-Statisticians Should Be Interested
Christopher Thompson, *AstraZeneca*

Predictive Stability for Biologics Using Kinetic Modeling
Michael Dillon, *Merck & Co., Inc.*

Leveraging Prior Knowledge for Efficient mRNA Vaccine Drug Product Development
Bob Walters, *Pfizer, Inc.*

Additional Panelist:

Jayda Siggers, *Health Canada*

Jason Warfel, *Bristol-Myers Squibb Company*

16:45-18:15 District Ballroom

Parallel Session 6B: The Critical Need to Protect the Horseshoe Crab: Initiatives from Industry, Suppliers and Regulators to Replace the LAL Assay

Sarah Argoud, Varnika Roy, Ben Stevens
Live Streamed

The pharmaceutical industry is increasingly viewed as a key sector systemically important in reversing nature loss. One of the sector's key dependencies is on the horseshoe crab , a species that is vital to marine ecosystems only located in a few locations globally. In 2023, the Pharmaceutical Supply Chain Initiative (PSCI) published a shared commitment that only the US based species will be used because of the critical status of those in Asia . Populations are declining due to various complex factors with the exploitation for our sector's use playing a significant role . The decline of horseshoe crabs also adversely impacts other species within the ecosystems, including the Red Knot, a critically endangered bird which feeds on their eggs in the Delaware Bay. Increasing calls to protect the horseshoe crabs to halt and reverse this loss poses a significant risk for supply continuity and ultimately for our patients - The crab's blue blood contains coagulation factors critical for use in the Limulus Amebocyte Lysate (LAL) assay, which is widely used for detecting bacterial endotoxins as a release assay to ensure safety of pharmaceutical and vaccine products.
This session will explore the urgent need for regulators, suppliers, and industry leaders to collaborate in replacing the LAL assay with in vitro alternatives, such as recombinant Factor C (rFC). Experts will discuss case studies that share the ecological impact of current practices, advancements in alternative assays, and the regulatory frameworks needed to facilitate the transition to a new release assay for supply chains to ensure endotoxin free products. Attendees will gain insights into how a united collaborative effort can ensure the preservation of horseshoe crabs while maintaining the safety and efficacy of medical release testing.

Session Speakers:

Sarah Argoud, *AstraZeneca*

What Do Birds Have to Do with Crabs Have to Do with People?
Holly Bamford, *National Fish and Wildlife Foundation*

Initiatives from Industry: An Update from the PSCI Horseshoe Crab Blood Working Group
Phil Duncanson, *AstraZeneca*

Bacterial Endotoxin Testing: Progressive Science and Sustainability
Jay Bolden, *Eli Lily and Company*

18:15-19:30 East/State Rooms

Exhibitor Reception

Thursday, 30 January, 2025

05:00-06:00

Visit the WCBP 2025 Virtual Poster Gallery

Enhance your Symposium experience and visit the WCBP virtual poster gallery featuring poster submissions on a wide range of topics from industry leaders and innovators in our global community. Chat with the presenters and view supplemental video presentations from each presenter. The gallery will be accessible pre- and post-Symposium via the online Scientific Program. You can view the gallery here: https://virtual.oxfordabstracts.com/event/73479/poster-gallery/grid
Visit the WCBP 2025 Virtual Poster Gallery

06:00-07:00

WATCH NOW: How to Maximize Value from Protein Metrics' New Multi-Protein Quantitation Workflows | Presented by Protein Metrics, LLC

This Technical Seminar will be available to watch on demand 24/7 before and during the Symposium. Click on this session to access the presentation video.

NOTE: If prompted to login to view the video, enter your CASSS member credentials.

Presented by: Protein Metrics, LLC
Click to Watch Video

07:00-08:00

NEW Wellness Walks

Start the day with your fellow attendees and take advantage of the surroundings of the centrally located Mayflower Hotel, by stepping outside for a brisk morning walk. Walks are self-led and depart from the Desales entrance of the Mayflower Hotel on Wednesday and Thursday morning at 7:10 am.

To view a suggested walking route, click here.

07:00-08:25 East/State Rooms

Continental Breakfast

Breakfast is available until 09:00

07:30-08:25 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.

08:25-08:30 Grand Ballroom

Welcome Day 3 & Morning Announcements

Live Streamed

08:30-10:00 Grand Ballroom

Plenary Session 7 - Navigating the Small and Virtual Business Landscape: Managing More with Less

Bharat Dixit, Cindy Riggins
Live Streamed

In the rapidly evolving biotechnology sector, small and virtual companies play pivotal roles in innovation and development. However, these organizations face unique challenges that necessitate strategic navigation to ensure successful product development, partnership, collaborations, and commercialization. This session will address the key considerations when working in small and virtual biotech companies, focusing on analytical and process development challenges, CROs and CDMOs management, tech transfer, and supply chain issues, including raw materials.

Small and virtual biotech companies often encounter significant hurdles in analytical and process development due to limited internal resources and infrastructure. These companies must balance the need for robust analytical methods, process development, and quality oversight with the constraints of smaller budgets and personnel. Small companies frequently lack the extensive in-house capabilities required to develop methods and manufacturing processes for hands-on product understanding. They must carefully design and optimize analytical methods and processes to ensure that they are both efficient and compliant with regulatory requirements, all while managing the inherent risks of manufacturing.

CROs and CDMOs are essential partners for small and virtual biotech companies, providing critical expertise and infrastructure that these companies may lack. Effective CDMO management is crucial to the success of a biotech project. Small companies need to navigate complex agreements and ensure that CDMOs meet their specific needs, including timelines, quality standards, and cost constraints. Establishing clear communication channels, setting well-defined expectations, and maintaining rigorous oversight are vital for mitigating risks and ensuring alignment with project goals.

Supply chain management is another critical area where small and virtual biotech companies face unique challenges. Ensuring a reliable supply of raw materials and components is fundamental to maintaining uninterrupted development and manufacturing processes. Small companies may struggle with procurement issues, such as securing high-quality raw materials at competitive prices and managing supply chain disruptions. They must develop contingency plans to address potential shortages or delays, which can impact project timelines and costs.

This session will share learnings, offer practical guidance, and discuss strategies to address the critical issues or product development, out-sourcing management, and supply chain management while maintaining regulatory compliance.

Session Speakers:

Troublesome Issues Seen in Biologics Development in Academic Spaces and Small Startup Companies
Mark Levi, *RTI International*

Managing More With Less – the Power of Platforms
Isabelle Lequeux, *BioPhorum*

CMC Paths to Patients for Small & Virtual Biotechs
Stephen Sofen, *Sofen Consulting LLC*

Key Considerations for Startups (And Established Innovators) to Efficiently Engage and Partner With a Contract Development and Manufacturing Organization (CDMO)
Bruce Thompson, *Kincell Bio*

Additional Panelist:

Da Ren, *Biotherapeutics Solutions*

10:00-11:45 District Ballroom

Turning Mandates into Momentum: How CASSS Can Help Sonia Vallabh?

Live Streamed

As a follow-up to Tuesday's very impactful Keynote presentation, join us in-person or online as we come together as a community and brainstorm ways to further Sonia's mission to prevent prion disease.

10:00-10:45 East/State Rooms

Networking Break

10:45-11:45 Palm Court Ballroom

Roundtable Session 2

In-Person

Table 1 - Setting Specification (Including Potency) for Not Well-Characterized Biological Products, e.g., Cell and Gene Therapy Products

Table 2 - CMC Challenges With Complex Formulation: Excipient Selection and Impact on Product Stability and Quality

Table 3 - Recent Trends in Questions from Health Authorities

Table 4 - Moving Away from Animal Testing and Animal Derived Components including alternate Endotoxin Test

Table 5 - The Road to One Global CMC Dossier

Table 6 - Relevance of Accelerated and Forced Degradation Studies for a Frozen DS/DP

10:45-11:45 Chinese Room

Roundtable Session 2

In-Person

Table 7 - Managing/Leveraging CMOs and CTOs for Lifecycle Success

Table 8 - Success Stories When Implementing Predictive Stability Models

Table 9 - Shelf-Life Claims for Products at Submission: How to Navigate Challenges

Table 10 - Microbiological Submission Roadblocks

Table 11 - Lifecycle Approach to Raw Materials/Critical Materials Attributes

Table 12 - AI and Application to Analytical Development for Vaccines and Therapeutics

10:45-11:45 Cabinet Room

Roundtable Session 2

In-Person

Table 13 - Method Transfer Challenges at CMOs/CROs

Table 14 - Allowable Excess Volume and Gross Content Requirements for Injectable Drug Products Filled in Vials or Ampules

Table 15 - Vaccine Manufacturing New Technologies for mRNA Production

Table 16 - Host Cell Protein Assays - Are We Still Relying on ELISA

Table 17 - Tech-Transfer Challenges and How to Avoid Common Mistakes

Table 18 - Adoption of Non-Animal Derived Reagents/Associated Assays

10:45-11:45 Rhode Island Room

Mini Case Studies Session 2 - M4Q(R2): The Future (of Quality Submissions) is Here!

In-Person

10:45-11:45 South Carolina Room

Mini Case Studies Session 2 - Challenges and Strategies for Assessment of Visible Particles in C&GT and High Concentration Products

In-Person

10:45-11:45 Virginia Room

Mini Case Studies Session 2 - Applying Prior Knowledge to Accelerate CMC Development

In-Person

11:45-13:30

Lunch Break

Attendees on own

12:10-13:10 Grand Ballroom

Coupling Mass Spectrometry (MS) with non-MS Assays for Automated Profiling of Antibody Impurities | Presented by Agilent Technologies

Live Streamed

Session Speaker:

Harsha Gunawardena, *Johnson & Johnson Innovative Medicine*

12:10-13:10 District Ballroom

Unmatched Capability to Elucidate the Complex Size and Charge Variants of Protein Therapeutics using Native Mass Spectrometry with the Orbitrap Ascend Biopharma Tribrid MS | Presented by Thermo Fisher Scientific

Live Streamed

Session Speakers:

Elucidation of a Unique High Molecular Mass Species in a Bispecific Antibody Using Native Electrospray Ionization Orbitrap Mass Spectrometry
Andrew Saati, *Pfizer, Inc.*

Improving Proteoform Specific Microheterogeneity Assessment of Biopharmaceuticals Using an Orbitrap Ascend BioPharma Mass Spectrometer
Corentin Beaumal, *National Institute for Bioprocessing Research and Training (NIBRT)*

12:10-13:10 Palm Court Ballroom

Digital Transformation and Data Integrity in GMP Manufacturing with Phizzle's Digital Solutions | Presented by Phizzle, Inc.

In-Person

Session Speaker:

Michael Patrick, *Phizzle, Inc*

13:30-14:45 Chinese Room

Workshop Session 3 - Bridging the Gap: Harmonizing EMA Annex I and Regulatory Guidance While Understanding the Differences

In-Person

The revised Annex 1 to the EU GMP, covering the manufacture of sterile medicinal products became mostly effective Aug 25, 2023, with the last requirement regarding sterilization of manually loaded lyophilizers effective as of Aug 25, 2024. This revision was a complete re-write of the annex and was considerably longer (59 vs. 16 pages) than the 2008 version The rewrite was a joint EU, PIC/S and WHO project, with US regulatory agencies actively involved. This workshop will discuss areas of harmonization between this annex and the guidelines, mainly the September 2004 guideline on Sterile Drugs Products Produced by Aseptic Processing. The workshop will also discuss as differences between the two guidelines and how these impact the aseptic process design. Participants are urged to come to the workshop with examples of how they could design the aseptic process and its controls to ensure that the process is compliant with both the EMEA Annex 1 and additional guidelines.

13:30-14:45 District Ballroom

Workshop Session 3 - Hitchhikers Guide to the Galaxy of Prior Knowledge – What Makes Sense for the More Efficient Development of Biologics

In-Person

The speed and efficiency of development are critical success factors for the next generation of biological therapeutics. While there is an abundance of prior knowledge that can facilitate accelerated development, it is essential to understand how best to apply this knowledge. This workshop will concentrate on prior knowledge related to the established and accepted scientific principles that can serve as guidance to mitigate risks and/or expedite development. The emphasis will be on protein-based modalities, including monoclonal antibodies (MAbs), multi-specifics, and conjugates; however, many aspects of this discussion are anticipated to be universally applicable to other biologics.

13:30-14:45 Grand Ballroom

Workshop Session 3 - Analytical Method Bridging Pre- and Post- Approval

In-Person

The need to adapt and update analytical methods is critical to ensure the accuracy and reliability of product testing. Analytical methods are changed to accommodate technological advances, simplify test schemes, and address equipment or reagent availability issues. The workshop will cover assumptions and considerations involved in switching to new analytical methods, including the ability of methods to distinguish acceptable from unacceptable materials and the implications for clinical and post-approval batches. The importance of assay bridging studies in informing specification updates and the various approaches required for different methods will be discussed.

13:30-14:45 Palm Court Ballroom

Workshop Session 3 - Hot Topic – FDA MAPP 5019.1 “Allowable Excess Volume/Content in Injectable Drug and Biological Products” - a.k.a. deliverable volume/gross content

In-Person

The Hot Topic workshop is intended to provide a forum for timely, interactive discussion of a topic currently impacting or likely to impact our industry. This topic will be selected by vote of all conference participants from a ballot developed using industry and health authority input. The goal of this workshop is sharing of information, experiences, strategies, questions, concerns, solutions, etc. to support paths forward for all.

Submit Your Vote for the Hot Topic Workshop!

Voting for the Hot Topic, topic selection is now open. Cast your vote for the session topic here: https://www.surveymonkey.com/r/SLH6BMG

Voting will end on Tuesday, January 28 at 6:00 pm EST.
Submit Your Vote for the Hot Topic Workshop!

14:45-15:15 Promenade Foyer

Networking Break

15:15-16:45 Grand Ballroom

Plenary Session 8 - Strength in Partnership: Bringing Reliance into Action Globally

Kavita Aiyer, Susanne Ausborn, Martin Harvey Allchruch
Live Streamed

Bringing new medicinal products to patients worldwide and ensuring uninterrupted supply of high-quality medicines can involve complex and lengthy processes. Timely approval of marketing authorization applications is critical for facilitating access of patients to new medicinal products, including innovative therapies for many rare diseases. Additionally, timely approval of variations is critical for ensuring continuity of the supply of quality medicinal products in the global market. Both industry and regulatory authorities both can play a role in increasing efficiencies that would promote more timely access for patients to new and improved medicinal products.

Submission of the same application can facilitate collaborative review among National Regulatory Agencies (NRAs) and opportunities for full or partial reliance to increase efficiency. Implementation of risk-based approaches while ensuring scientific rigor can speed product development and promote continuity of patient access to essential medicines. The World Health Organization (WHO) strongly encourages the use of informed reliance as a 21st century regulatory solution to leverage the work of trusted partners (e.g., more advanced regulatory authorities, WHO PQ program) to facilitate product approval, especially in low-and-middle-income countries (LMICs). NRAs can rely on assessments performed by a reference regulatory authority (e.g., a WHO Listed Authority) to streamline the review and authorization process while maintaining national autonomy to make regulatory decisions. Promoting the practice of evidence-based reliance can build efficiencies for both health agencies and industry.

Several existing programs and pilot projects that use work-sharing models or unilateral reliance based on reference agency assessment are ongoing. A well-designed program for work-sharing and reliance can promote global alignment, increase regulatory efficiencies, and allow regulators and industry to utilize resources more effectively by eliminating redundancies. The experiences to date demonstrate that ‘reliance pathways’ hold the potential to increase efficiencies and could be considered, where appropriate, for mainstream operation.

This Plenary Session aims to understand opportunities and challenges of utilizing ‘Reliance’ as a mechanism to facilitate regulatory decision-making and explore practical aspects of how industry and regulators can help this to become a common practice globally. Evidence-based reliance can be one tool in ‘smart’ regulation which could enhance regulatory efficiencies and bring quality medicines to patients in a timely manner.

Session Speakers:

Rogério Gaspar, *World Health Organization*

How to Effectively Manage CMC Post-Approval Changes
John Armando, *Genentech, a Member of the Roche Group*

Strength in Partnership: Bringing Reliance into Action Globally
Cynthia Ban, *Sanofi*

José Crisóstomo Landeros, *ISP Chile*

Additional Panelists:

Anabela Marçal, *EMA-European Medicines Agency*

Mark Pellet, *AstraZeneca*

Lawrence Starke, *Novartis Pharmaceuticals Corporation*

16:45-17:00 Grand Ballroom

Acknowledgements, Closing Remarks & Invitation to WCBP 2026

Live Streamed