WCBP 2026

Schedule

Sunday, 25 January, 2026

08:00-09:00 Promenade Foyer

Registration for Pre-Conference Short Course Attendees Only

Registration is open until 17:00

Pre-registered attendees should go to the Foyer.

08:00-09:00 2nd Floor Foyer

Breakfast for Pre-Conference Short Course Only

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

09:00-10:30 Cabinet Room

Short Course I: Regulatory Frameworks and Guidance | Part 1

Track: Short Course: Comparability of Biologicals

This session will provide a comprehensive overview of comparability in biological products, highlighting its definition, importance, and role in ensuring patient safety throughout the product lifecycle. Speakers will discuss the key drivers of comparability assessments, including manufacturing changes and lifecycle management.

A global regulatory perspective will be presented, covering international guidelines such as ICH Q5E and WHO recommendations, along with regional frameworks from the FDA (U.S.), EMA (EU), PMDA (Japan), and regulatory authorities in emerging markets including China, India, and Brazil.

Scientific and technical considerations will be explored in detail, with emphasis on analytical similarity assessments, non-clinical and clinical requirements, and risk-based approaches.

The session will conclude with a Q&A and discussion, offering insights into common regulatory expectations, pitfalls to avoid, and lessons learned from real-world experience

Short Course Instructors:

Anthony Mire-Sluis, *SVP Global Quality, Gilead Sciences, Inc.*

Nadine Ritter, *Global Biotech Experts, LLC*

Mark Schenerman, *President, CMC Biotech-MAS Consulting, LLC*

Scott Nichols, *Kite, a Gilead Company*

09:00-10:30 South Carolina Room

Short Course II: Fundamentals of Mass Spectrometry in the Analysis of Protein Therapeutics

Track: Short Course: Mass Spec

This introductory course will provide an overview of the fundamentals of Mass Spectrometry, including the history of Mass Spectrometry, terminology, data interpretation and sample handling. We will include a discussion on modes of operation (parent versus fragment ion analysis), components of a current MS system, and selected applications of Mass Spec as it applies to protein analysis in the biotechnology industry. A discussion on software (basic interpretation and operation) will be presented along with a hardware discussion (strengths for various applications). A limited discussion on small molecule analysis will be presented.

Short Course Instructor:
Chris Chumsae, *Bristol-Myers Squibb Company*

10:30-10:45

Networking and Coffee Break

10:45-12:15 Cabinet Room

Short Course I: Regulatory Frameworks and Guidance | Part 1

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Short Course Instructor:
Chris Chumsae, *Bristol-Myers Squibb Company*

12:15-13:15

Lunch

13:15-14:45 Cabinet Room

Short Course I: Applied Case Studies | Part 2

Track: Short Course: Comparability of Biologicals

This session will explore how comparability is approached across different product types, highlighting both common principles and unique challenges.

Speakers will address key considerations for therapeutic biologics such as monoclonal antibodies, including manufacturing change scenarios, the role of advanced analytics, and clinical bridging requirements. For vaccines, the focus will turn to comparability in multivalent formulations, process scale-up, technology transfer, and case studies drawn from seasonal influenza and COVID-19 vaccines.

The discussion will then shift to cell and gene therapies, where comparability presents distinct complexities—ranging from autologous versus allogeneic approaches to the impact of raw material and process changes, alongside evolving regulatory guidance.

The session will conclude with an interactive group discussion, offering lessons learned from case studies and sharing best practices to help participants more effectively plan comparability exercises for diverse product types.

Short Course Instructors:

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Scott Nichols, *Kite, a Gilead Company*

13:15-14:45 South Carolina Room

Short Course II: Applications of Mass Spectrometry to Characterize Biotherapeutics

Track: Short Course: Mass Spec

The afternoon section will focus on practical industrial uses of Mass Spectrometry in the analysis of protein therapeutics as well as in Cell and Gene Therapy. The specific topics will be Intact Mass Analysis, Structural MS, Host Cell Protein ID and Peptide Mapping and Multi-Attribute Method and protein post translational modifications: detection and quantitation. The discussions will be driven by industry leaders. Two interactive segments will cover live data analysis demos of both Intact and Reduced Mass Analysis as well as Peptide Mapping Data Analysis in variety of vendors software products.

This course will review the role MS has in newer therapeutic modalities such as multi-specific, antibody-drug conjugates, cell and gene therapy (AAV, oligonucleotides). Additionally, there will be sections covering mass spec techniques which evaluate protein structure such as hydroxy radical foot-printing, cross-linking, hydrogen-deuterium exchange, top down and middle down methods and ion mobility. The increasing use of Native MS in the analysis if mis-paired Multispecifics as well as investigation of non-covalent interaction will be covered. The 2nd part of the afternoon session focuses on Multi-Attribute Method (MAM), MS in QC, PTM quantitation as well as Sequence Variant Analysis and the role of MS in Cell Line Selection.

Short Course Instructors:

Andrew Mahan, *Johnson & Johnson*
Rich Rogers, *Umoja Biopharma*

14:45-15:00

Networking and Coffee Break

15:00-16:30 Cabinet Room

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Short Course Instructors:

Andrew Mahan, *Johnson & Johnson*
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Tuesday, 27 January, 2026

06:00-07:00

Visit the WCBP 2026 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.

View the poster abstracts below.

Virtual posters will be available to view on Tuesday, January 20.

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

Registration

Registration is open until 17:00

Pre-registered attendees should go to the Foyer.

07:00-08:45 East/State Rooms

Continental Breakfast

Presentation type: In-Person

Breakfast is available until 09:00

08:00-08:30 Grand Ballroom

CASSS Welcome and the 14th Annual Hancock Award

Presentation type: Live Streamed

08:30-08:45 Grand Ballroom

WCBP 2026 Introduction

Presentation type: Live Streamed

08:45-10:00 Grand Ballroom

Keynote Presentation I - Moving a Genome Edited Stem Cell Based Therapy from the Bench to the Bedside

Presentation type: Live Streamed

Keynote Speaker:
Matthew Porteus, *Stanford University*

10:00-10:30 East/State Rooms

Networking Break

10:30-12:00 Grand Ballroom

Parallel Session 2A - AI in Development and Manufacturing – New Era in Well Characterized Biologics

Alla Polozova, Arne Staby, Gert Thurau
Presentation type: Live Streamed
Track: Digitalization - AI, Predictive Modeling, Automation, Data Management

Artificial intelligence (AI) is accelerating the journey from bench to bedside for therapeutic proteins, vaccines, cell and gene-based therapies, and other well characterized biologics. This plenary session will showcase how in the later stages of product development and in commercial manufacturing the state-of-the-art digital technologies can transform every stage of biotherapeutic manufacturing and control.

AI powered process development platforms combine mechanistic and machine learning models to shrink experimental design spaces, improve predictions, shorten tech transfer timelines, and derisk commercial scaleup.

Digital twin high fidelity, data driven replicas of upstream and downstream unit operations are now enabling predictive engines for critical quality attribute (CQA) monitoring and forecasting, providing early-warning soft-sensors, real-time what if scenario testing and closed loop control with an outlook to delivering adaptive processes that learn and self-optimize across scales.

On the analytical front, AI augmented methods development and validation leverage advanced chemometrics, pattern recognition, and generative algorithms to automate workflows, harmonize transfers between global sites, and enable rapid methods deployment.

Machine-learning enhanced visual inspection methods continue to progress. Conventional automated visual inspection of parenteral products can be significantly improved by image analysis powered with machine learning/deep learning, reducing the misidentification of defects and accelerating the production process by minimizing additional manual inspections.

For all these aspects integrated data pipelines are enablers that stream continuous process and product data into predictive models.

This session will present recent breakthroughs and applications of AI/ML, followed by a panel discussion on current challenges and future directions. Attendees will gain actionable insights into deploying AI responsibly to improve efficiency, robustness and agility in the manufacture of biologics.

Session Speakers:

Designing the AI-Enabled CMC Ecosystem for Drug Development and Manufacturing
Pablo Rolandi, Amgen Inc.

Machine Learning-Supported (Process) Models: Promises and Practical Regulatory Challenges
Christina Heinlein, F. Hoffmann-La Roche Ltd

Integrating Artificial Intelligence into Pharmaceutical Manufacturing
Tina Kiang, *CDER, FDA*

Additional Panelist:

Jayda Siggers, *Health Canada*

10:30-12:00 District Ballroom

Parallel Session 2B - What's New in the World of Stability: Navigating the New ICH Q1 Landscape

Elizabeth Krug, Linda Lemieux, Ashutosh Rao, Paula Russell
Presentation type: Live Streamed
Track: Regulations - International Harmonization and Collaboration

As the regulatory and scientific landscape evolves, the stability of well-characterized biological products remains a cornerstone of product quality, patient safety, and global access. This plenary session, What's New in the World of Stability: Navigating the New ICH Q1 Landscape, explores the latest developments and forward-looking strategies in stability science, with a focus on the emerging expectations surrounding ICH Q1 revisions and their implications for biologicals.

Key aspects of the draft revision to the ICH Q1 guideline include streamlining the existing stability series (ICH Q1A-F and Q5C) into a single guideline, promoting a harmonized interpretation by addressing identified gaps and ambiguities, strengthening the application of risk management with innovative tools and strategies, introducing new topics and considerations for advanced therapies. The main goal of these revisions was to provide modernized guidance for a standard/traditional approach to stability while also providing details on the familiar refrain 'alternative risk-based approaches were scientifically justified'.

This session will look to develop an understanding of the revised guideline and its potential application when finalized. An overview of the guideline, highlighting core, revised, and new content will provide an awareness of the overall document while highlighting the goals of the revision. A regulator's perspective on the guideline will provide an overview of the risk-based approaches included in the guideline while identifying what is being considered to support regulatory-readiness ahead of implementation of the guideline.

Finally, the session will address the opportunity and challenge of enabling these innovations across international markets, focusing on the role of primary stability studies in generating product knowledge and establishing a scientifically justified shelf-life. Through case studies and global perspectives, participants will leave with a deeper understanding of how to harmonize stability strategies with evolving expectations, while maintaining scientific integrity and regulatory standards.

Session Speakers:

ICH Q1 Stability Guideline Revision- What's New?
Linda Lemieux, *Merck & Co., Inc.*

Predictive Stability for Biopharmaceuticals: Accelerating Patient Access through Industry Recommendations and Stakeholder Alignment
Daniel Skomski, *Merck & Co., Inc.* and Andrea Ji, Genentech, *a Member of the Roche Group*

ICH Q1 Guideline Revisions: Risk Frameworks and Regulatory Readiness
Paula Russell, *Health Canada*

Additional Panelists:

Ashutosh Rao, *CDER, FDA*
Adam Rauk, *Eli Lilly and Company*

12:00-13:45

Lunch Break

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

12:25-13:25 Grand Ballroom

The Road Ahead - What's Next for Host Cell Protein Analytics? | Presented by Cygnus Technologies, LLC

Presentation type: Live Streamed
Session Speaker:

The Road Ahead - What's Next for Host Cell Protein Analytics?
Eric Bishop, *Cygnus Technologies*

12:25-13:25 District Ballroom

Transforming QC with MAM: High-Resolution LC–MS for Product Quality Monitoring | Presented by Agilent Technologies, Inc.

Presentation type: Live Streamed
Session Speaker:

Transforming QC with MAM: High-Resolution LC–MS for Product Quality Monitoring
Melissa Sato, *Agilent Technologies, Inc.*

12:25-13:25 Palm Court Ballroom

Technical Seminar | Palm Court Ballroom | Presented by BioAgilytix Labs, LLC

Presentation type: In-Person

12:25-13:25 Chinese Room

Regulatory-Ready Characterization: From IND to BLA | Presented by KBI Biopharma, Inc.

Presentation type: In-Person

Session Speaker:

Kelly Donovan, *KBI Biopharma*

13:45-15:00 Grand Ballroom

Workshop Session 1 - Shaken, Stirred, and Stable? Tales from a CMC Multivalent Cocktail Party

Presentation type: In-Person

Track: Science - Novel Modalities and Manufacturing Innovations

Multivalent products (e.g., vaccines, well-characterized biological drugs) utilizing co-formulation and co-administration increase efficiency while potentially broadening protection and therapeutic capabilities. However, development of these products brings unique CMC challenges related to various modalities, specific considerations for formulation and stability studies, as well as adequate control strategies. This workshop will discuss those CMC challenges and the relevant best practices to facilitate the development of multivalent products.

13:45-15:00 District Ballroom

Workshop Session 1 - Leveraging Prior Knowledge for Setting Shelf-Life for Biologics

Presentation type: In-Person

Track: Science - Novel Modalities and Manufacturing Innovations

With the anticipated ICH Q1 revision, industry and regulatory must understand how prior knowledge can be integrated into shelf life setting for biologics. This workshop will focus discussion on what is appropriate prior knowledge for biologics, how it could be applied in modeling, and considerations for lifecycle management of filings using prior knowledge.

13:45-15:00 Palm Court Ballroom

Workshop Session 1 - From Batch Data to Patient Needs: Rethinking Specifications in ICH Q6

Presentation type: In-Person

Track: Regulations - International Harmonization and Collaboration

This workshop will focus on strategies for specification-setting, including discussion on ICH Q6 (R1) revision progress and comparison of traditional and enhanced approaches. Opportunity will be provided to discuss specific examples from industry to illustrate scenarios and rationales for justification of specifications using the principles of ICH Q8-Q14, covering different biologics modalities.

13:45-15:00 Chinese Room

Workshop Session 1 - Partnering With CMOs and CTOs - Opportunities and Challenges for Effective Collaboration and Lifecycle Success

Presentation type: In-Person

Track: Science - Novel Modalities and Manufacturing Innovations

Across the biopharma sector, the use of outsourced development and manufacturing partners has become a critical lever for flexibility, speed, and innovation. Large pharma organizations rely on external providers to expand capacity, while small and emerging biotech companies often depend on CDMOs to turn early concepts into viable products. Yet moving from partner selection through development, manufacturing, and ultimately regulatory submission presents both significant opportunities and operational challenges. This session will examine the realities of navigating outsourced models—highlighting issues such as misaligned KPIs, limited internal resources, differing expectations around timelines and risk, and the complexity of coordinating across multiple technical and operational interfaces. We will discuss practical strategies to strengthen collaboration, improve decision-making, and build more resilient, transparent, and effective working relationships with CDMOs to support lifecycle success

15:00-15:30 East/State Rooms

Networking Break

Presentation type: In-Person

15:30-17:30 Grand Ballroom

Plenary Session 3 - Global Regulatory Panel: Working Together to Do More with Less

Kavita Aiyer, Natalya Ananyeva, Nina Cauchon, Tere Gutierrez Lugo, Cecilia Tami, Leslie Wagner
Presentation type: Live Streamed
Track: Regulations - International Harmonization and Collaboration

Join regulatory leaders from around the world for an engaging panel discussion on the current and future of global regulatory practices. The session will address how rapid advances in pharmaceutical science, novel technology, new modalities, analytics, data management, and regulatory collaboration and submissions can be accepted globally and explore how experiences can inform a more agile, unified regulatory future.

- Agency Collaboration & Harmonization: Insights into regional and international efforts like ICH, WHO, ICMRA, and other pilot programs that are paving the way for increased regulatory alignment.

- Innovative Pathways: Discover strategies to accelerate acceptance of advanced technologies and novel modalities through streamlined submissions, inspections, and approvals.

- Vision for the Future: Progress toward the “One Dossier, One Submission, One Review, One Inspection, One Approval” model, with updates on ICH M4Q (R2), ICH Q12, PQKM, and CMC submission alignment.

Attendees are invited to share challenges, ideas and solutions to help build a more collaborative and efficient global regulatory ecosystem.

Session Panelists:

Ahmet Ayar, *Turkish Medicines and Medical Devices Agency (TITCK)*

Jorge Canales Pacheco, *ISP-Instituto de Salud Publica de Chile*

Elana Cherry, *Health Canada*

David Kaslow, *CBER, FDA*

Claudia Müller, *Swissmedic*

Theresa Mullin, *CDER, FDA*

Takashi Ogawa, *(PMDA) Pharmaceuticals and Medical Devices Agency*

Mphako Ratlabyana, *South African Health Products Regulatory Authority*

19:00-22:00 Capitol Turnaround

Welcome Reception - Capital Turnaround

Presentation type: In-Person

Join us for the WCBP Welcome Reception! The welcome reception will be held at the Capital Turnaround. Transportation will be provided, and buses will begin loading at 6:15 pm in the Mayflower lobby.

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

Wednesday, 28 January, 2026

06:00-07:00

Visit the WCBP 2026 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.

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07:00-08:00 East/State Rooms

Continental Breakfast

Presentation type: In-Person

Breakfast is available until 09:00

08:00-09:00 Grand Ballroom

Fireside Chat with Commissioner of Food and Drugs, Dr. Marty Makary

Presentation type: Live Streamed

We are pleased to welcome FDA Commissioner, Dr. Marty Makary, to WCBP 2026 for a fireside chat with Simon Hotchin, *Amgen Inc*. We look forward to hearing Dr. Makary's insights on the top reforms and modernization initiatives he's launched since taking office last year.

09:00-09:30 Grand Ballroom

Keynote Presentation II - Code, Care, and Conscience: How AI, Ethics, and Lived Experience Are Redefining the Future of Pharma

Presentation type: Live Streamed

In this keynote, Guadalupe Hayes-Mota shares a powerful personal journey from growing up with hemophilia in rural Mexico, where access to lifesaving treatment was uncertain, to leading global pharmaceutical supply chains and AI-driven digital transformation. His story anchors a bold vision for a more resilient, ethical, and human-centered pharmaceutical industry.

The talk highlights the most impactful applications of AI in pharma today, including quality systems, manufacturing optimization, predictive supply chains, and real-time risk management. Attendees will see how technologies such as machine learning and advanced analytics are already improving how medicines are produced, monitored, and delivered worldwide.

The keynote also addresses the ethical and regulatory challenges shaping the future of AI in pharma, from bias and accountability to data governance and trust. Hayes-Mota offers a practical roadmap for responsible AI adoption that puts patients, equity, and public trust at the center.

Keynote Speaker:
Guadalupe Hayes-Mota, *Santa Clara University*

09:30-09:45

Transition Time

Attendees can take this time to check emails, use the restroom and prepare for Workshop Session 2.

09:45-11:00 Grand Ballroom

Workshop Session 2 - Opportunities and Challenges of Expanding US-based Manufacturing

Presentation type: In-Person
Track: Science - Novel Modalities and Manufacturing Innovations

How do we optimize U.S. Manufacturing while enhancing global supply?
How might U.S. manufacturing on-shoring harmonize with the following?
Post approval changes
Site transfers
Other regulatory pathways
Other ways than only building out new manufacturing sites
Increased export from US manufacturing
CPPs following US approval may help global expansion

Can the following guidance facilitate U.S. manufacturing on-shoring?
Advanced manufacturing technology
Emerging Technology Program
ICH Q12

Key Considerations:
Construction permits
Approval inspections
FDA pre-check
Moving a process to the U.S. does not mean removal from other global sites

No requirement for US manufacturing to supply the US market:
Tariffs provide a driving force
FDA pre-check provides an incentive

FDA pre-check:
Voluntary approach to accelerate new U.S. facility construction/expansion
Earlier more frequent interactions
Pre-application CMC engagement
Needs to connect to permitting certainty, inspection predictability, and lifecycle change flexibility to be effective

09:45-11:00 District Ballroom

Workshop Session 2 - ICH M4QR2: Considerations and Expectations for Global Implementation

Presentation type: In-Person
Track: Regulations - International Harmonization and Collaboration

M4Q(R2) has now progressed to Step 2, and many stakeholders are beginning to wonder what implementation will look like. How will regulatory agencies adopt this revised guideline—will it be phased in, limited initially to new molecular entities, or applied more broadly? This session will explore the global implementation landscape for M4Q(R2), with a particular focus on ICH member regions.

09:45-11:00 Palm Court Ballroom

Workshop Session 2 - Latest Learning From AI as a Tool, Both From the Lens of Industry and Agency

Presentation type: In-Person
Track: Digitalization - AI, Predictive Modeling, Automation, Data Management

This workshop convenes industry and agency thought leaders to explore the latest learnings on AI/ML as a practical tool in pharmaceutical development and manufacturing (including CMC-relevant applications). We will discuss the current state of the art—capabilities, limitations, and where AI is (and is not) decision-grade today—grounded in real use cases.

The session will cover data strategy and governance, model lifecycle management, and approaches to validation/verification (including continuous verification concepts) that build trust and enable appropriate regulatory reliance. Participants will also examine institutional and workforce readiness, change management, and best practices for responsible deployment across global contexts.

The goal is to surface actionable lessons, clarify open issues for regulators and sponsors, and identify opportunities for alignment (e.g., standards, guidance, and collaborative pathways) that accelerate safe, high-quality adoption.

09:45-11:00 Chinese Room

Workshop Session 2 - Beyond the Molecule: Navigating Comparability Across Drug Delivery Presentations

Presentation type: In-Person
Track: Science - Novel Modalities and Manufacturing Innovations

This workshop will provide a forum to learn about transitioning across product presentations—vials, prefilled syringes, and autoinjectors— resulting in an engaging conversation on requirements, comparability, and clinical impact. Through interactive case studies covering both drug and biologic products (including vaccines and therapeutic biologics), participants will explore the considerations and decision-making frameworks that guide successful presentation transitions, fostering collaborative discussion on best practices and regulatory expectations.

11:00-11:30 East/State Rooms

Networking Break

Presentation type: In-Person

11:30-12:30 Palm Court Ballroom

Roundtable Session 1: Topics 1 - 6

Presentation type: In-Person

Table 1 - Recent Trends in Questions from Health Authorities

Table 2 - Vaccine Potency - Compare and Contrast Potency Tests for Different Vaccine Modalities

Table 3 - Novel Applications of Molecular and Structural Biology in Characterization of Well Characterized Biologics

Table 4 - Speed to Clinic - Phase Appropriate Strategies to Accelerate CMC Development Timelines

Table 5 - Expectations for the Development and Application of Extended Characterization Methods

Table 6 - Use of Prior Knowledge to Successfully Execute Manufacturing Process Changes

11:30-12:30 Chinese Room

Roundtable Session 1: Topics 7 - 12

Presentation type: In-Person

Table 7 - ICHQ6- Challenges and Opportunities for Using an Enhanced Approach to Lifecycle Management of Specifications

Table 8 - Best Practices for Execution of Low Endotoxin Recovery (LER) Studies

Table 9 - Vaccine Specific Regulatory Considerations

Table 10 - Best Practices in Peptide Map/MS/MS Analysis of

Table 11 - Degradation Products and Disulfide Linkage Analysis
Use of Chromatography Resins Across Products

Table 12 - Potency Assays for Different Modalities of Biological Products

11:30-12:30 Cabinet Room

Roundtable Session 1: Topics 13 - 18

Presentation type: In-Person

Table 13 - Host Cell Protein Assays - Are We Still Relying on Conventional Quantification by Enzyme-Linked Immunosorbent Assays (ELISAs)?

Table 14 - Challenges and Best Practices for Global Implementation of Analytical Procedures - Use of the Analytical Target Profile as Described in ICH Q14

Table 15 - Strategies for Leveraging Clinical Stability Data for Commercial Shelf Life

Table 16 - Use of Machine Learning (ML) and Artificial Intelligence (AI) in Content Creation of Early Phase Development and Managing Submissions and Information Requests with Health Authorities

Table 17 - Host Cell Proteins and Host Cell DNA Risk Assessment for Gene Therapies

Table 18 - Belonging in the Biopharma Scientific Community: How to Create and Sustain Cross-Company Scientific Connections

11:30-12:30 Rhode Island Room

Mini Case Session 1 - Case Studies of Characterization of Minor Degradation Products from High Performance Liquid Chromatography (HPLC) or Capillary Electrophoresis (CE) Methods

Presentation type: In-Person
Track: Science - Novel Modalities and Manufacturing Innovations

11:30-12:30 South Carolina Room

Mini Case Session 1 - Applying Prior Knowledge and Platform Knowledge to Accelerate CMC Development

Presentation type: In-Person
Track: Science - Novel Modalities and Manufacturing Innovations

11:30-12:30 Virginia Room

Mini Case Session 1 - Advances in Process Analytics and Real Time Release Testing (RTRT)

Presentation type: In-Person
Track: Digitalization - AI, Predictive Modeling, Automation, Data Management

11:30-12:30 Grand Ballroom

30th Anniversary Workshop: Pet Peeves and Roadblocks in CMC: Improving your Quality Submissions through the Product Lifecycle Redux – The 2026 Version

Chana Fuchs, Marjorie Shapiro
Presentation type: Live Streamed

Marjie Shapiro and Chana Fuchs retired from the FDA with a combined experience of over 60 years regulating monoclonal antibodies and other therapeutic proteins. This talk, first presented in 2010, describes FDA CMC reviewer frustrations with poor quality submissions and unclear communications with sponsors, and provides examples of specific roadblocks in CMC development throughout the product lifecycle. The 2026 version has been updated but still aims to help sponsors prepare better quality documents, whether they are submitting their first pre-IND meeting package or their 10th BLA.

12:30-14:00

Lunch Break

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

12:50-13:50 Grand Ballroom

Advancing Biotherapeutic Analysis Through Capillary Electrophoresis | Presented by Bio-Techne

Presentation type: Live Streamed
Session Speakers:

Advancing Biotherapeutic Analysis Through Capillary Electrophoresis
Aakash Patel, *AstraZeneca*
Xiaochan Zhang, *MilliporeSigma*
Caroline Daniels, *Shattuck Labs*

12:50-13:50 District Ballroom

Investigating the Root Cause of Biotherapeutic Coloration and Charge Heterogeneity During Cell Culture Processes | Presented by SCIEX

Presentation type: Live Streamed
Session Speakers:

Investigating the Root Cause of Biotherapeutic Coloration and Charge Heterogeneity During Cell Culture Processes
Kristen Nields, *Johnson and Johnson Innovative Medicine*
Andrew Mahan, *Johnson and Johnson Innovative Medicine*

12:50-13:50 Palm Court Ballroom

Evolving USP Standards to Enhance Quality Assessment of mAbs and AAV | Presented by USP-US Pharmacopeia

Presentation type: In-Person
Session Speaker:

Evolving USP Standards to Enhance Quality Assessment of mAbs and AAV
Anthony Blaszczyk, *US Pharmacopeia (USP)*

14:00-15:30 Grand Ballroom

Parallel Session 4A - Emerging Regulatory and Quality Expectations on Control and Characterization of Particulate Matter for Biotherapeutics

Judy Lin, Zahra Shahrokh, Karen Sitney, Hailin Wang
Presentation type: Live Streamed
Track: Science - Novel Modalities and Manufacturing Innovations

Particulate matter is a critical quality aspect of biotherapeutics. Control of both visible and subvisible particulate matter remains one of the most persistent and complex challenges in the development and lifecycle management of biologics despite significant advances in analytical and manufacturing controls. This is due to the highly variable properties, the limitations of current analytical tools, and the complexity of distinguishing inherent particulates from particulate contaminants. In this session, the speakers will present emerging knowledge and analytical technologies around different types of visible and subvisible particles. Case studies will be provided on characterization and control of polysorbate hydrolytic degradants, silicon oil, and proteinaceous particles in parenteral drug products. Unique challenges for identification and enumeration of subvisible particulate matter within ophthalmic indication and cell and gene therapy products will also be presented. The insights from presented studies should provide better understanding of respective safety profiles and inform robust risk-based control strategies for particulate matter in biologics.

Session Speakers:

Evaluating Clinical Safety and Analytical Impact of Subvisible Silicone Oil Particles in Biopharmaceutical Products
Miguel Saggu, *Genentech, a Member of the Roche Group*

Controlling Particulate Matter in Ophthalmic Biologics; Establishing a Risk-Based Analytical Approach to Sub-Visible Particulates
Lauren Jones, *Regeneron Pharmaceuticals*

Visible Particle Control in Biologics and Advanced Therapy Products: Challenges, Case Studies, and Evolving Expectations
Atanas Koulov, *Clear Solutions Laboratories AG*

Additional Panelists:
Desmond Hunt, *USP-US Pharmacopeia*
Stanley Kwok, *AstraZeneca*
Ewa Marszal, *CBER, FDA*
Sheena Wang, *CDER, FDA*

14:00-15:30 District Ballroom

Parallel Session 4B - Unblocking Regulatory Barriers to CMC and Quality Innovation for Biotechnology Products—Escaping Inertia, Embracing Change

Simon Hotchin, Demetra Macheras, Anjali Shukla, Kim Wolfram
Presentation type: Live Streamed
Track: Science - Novel Modalities and Manufacturing Innovations

As biotechnology products evolve the regulatory frameworks governing Chemistry, Manufacturing, and Controls (CMC) and Quality must keep pace. Yet, innovators face persistent barriers that delay development, complicate global alignment, and stifle the adoption of transformative technologies.

This session will explore how industry and regulatory agencies are responding to these challenges through convergence initiatives, reliance frameworks, and digital modernization. Drawing on insights from the National Academies' workshop Barriers to Innovations in Pharmaceutical Manufacturing, we will examine the interplay between regulatory expectations, industry capabilities, and emerging technologies. The session will also rethink traditional boundaries by exploring cross-industry approaches and how they apply to biologics development.

Key themes include:

- Innovation: Broaden perspectives by engaging external experts and industries to foster collaboration and apply cross-sector insights.

- Policy and partnership opportunities: Public–private collaborations like FDA's Emerging Technology Program and NIIMBL to de-risk innovation, promote regulatory convergence, and foster informal engagement between regulators and industry.

- Regulatory inertia and divergence: Existing frameworks often struggle to accommodate novel technologies, leading to inconsistent global standards, lifecycle maintenance burdens, and risk-averse review practices.

- Technical and operational hurdles: Legacy systems, inflexible processes, and limited analytical capabilities hinder real-time quality assurance and process intensification.

- Control strategy transformation: Industry leaders advocate for science- and risk-based approaches, including mechanistic modeling and attribute-based control strategies to ensure product quality and accelerate development.

Panelists will share real-world experiences and strategic recommendations, including:

- Promoting global regulatory convergence and collaborative reviews.

- Leveraging prior knowledge and modeling to streamline development.

- Refocusing regulatory submissions on scientific justification rather than volume.

- Creating incentives for adopting advanced manufacturing and analytics.

- Aligning post-approval change management with existing and future ICH guidelines.

Attendees will gain actionable insights to navigate global regulatory landscapes, advocate for policy changes, and implement transformative technologies across the product lifecycle.

Session Speakers:

Enabling Global Pharmaceutical Innovation
Roger Nosal, *Vaxcyte, Inc.*

Unlocking CMC Innovation: Science and Risk Based Paths to Global Progress
Ingrid Markovic, *Novartis Pharmaceuticals Corporation*

Enabling the Future of Biopharmaceutical Manufacturing Through Collaborative Innovation
Riley Myers, *National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)*

Additional Panelist:

Elana Cherry, *Health Canada*

Anjali Shukla, *CDER, FDA*

15:30-16:00 East/State Rooms

Networking Break

Presentation type: In-Person

16:00-17:30 Grand Ballroom

Parallel Session 5A - Emerging Therapeutic Modalities

Marla Abodeely, Tyler Goodwin, Charles Morgan, John Schiel, Nailing Zhang
Presentation type: Live Streamed
Track: Science - Novel Modalities and Manufacturing Innovations

The landscape of therapeutic innovation continues to expand with groundbreaking modalities that redefine the boundaries of modern medicine. This session will explore the evolution of emerging therapeutic technologies and the enabling role of CMC and regulatory science as critical partners to advance innovation. A case study on the development and clinical application of customized CRISPR-based gene editing for the KJ Baby, treated at Children's Hospital of Philadelphia, will be featured, followed by a panel discussion with leaders from industry, academia, and regulatory agencies to foster dialogue on accelerating the safe and efficient translation of emerging modalities from bench to bedside. Attendees will examine how novel regulatory review processes and collaborative approaches can overcome manufacturing, characterization, and safety challenges. These innovative frameworks not only enable current therapeutic breakthroughs but also serve as models for accelerated development pathways, setting the stage for the next wave of transformative treatments.

Session Speakers:

Risk-Benefit Appropriate Platform Manufacturing for Personalized Gene Editing
Sadik Kassim, *DH Life Sciences, LLC*

Developing and Deploying Personalized Gene-Editing Therapies
Kiran Musunuru, *University of Pennsylvania*

Additional Panelists:

Paula Russell, *Health Canada*

Brian Stultz, *CBER, FDA*

Heidi Zhang, *Tune Therapeutics*

16:00-17:30 District Ballroom

Parallel Session 5B - Parallel Session 5B: Use of Reliance Pathways, Collaboration and Cloud Platforms to Enhance Submissions

Cynthia Ban, Varnika Roy, Dulce Aldana Sanchez
Presentation type: Live Streamed
Track: Regulations - International Harmonization and Collaboration

The healthcare industry is continually transformed by the rapid evolution of science and medicine. Technology has been a key driver, enabling advancements like real-world evidence, personalized medicine, and data analytics that can accelerate the development of life-saving therapies. However, bringing new medicines to patients around the world and ensuring a consistent global supply can be a complex and lengthy process. Timely approval of marketing authorization applications and post approval variations is critical for patient access, and for maintaining supply continuity. Both the pharmaceutical industry and regulatory authorities can work together to streamline these processes, promoting more timely access to new and improved medicines for patients.

The World Health Organization (WHO) actively promotes the use of informed reliance as a twenty-first-century regulatory solution. This method leverages the work of trusted partners, such as advanced regulatory authorities or the WHO Prequalification program, to expedite product approval, particularly in low- and middle-income countries (LMICs). National Regulatory Agencies (NRAs) can rely on assessments performed by a reference regulatory authority (e.g., a WHO Listed Authority) to streamline their review and authorization processes while retaining the autonomy to make their own regulatory decisions. Encouraging the practice of evidence-based reliance builds efficiencies for both health agencies and the pharmaceutical industry.

Submitting a single application facilitates collaborative reviews among NRAs, creating opportunities for collaborative assessments, full or partial reliance that can increase efficiency. By implementing risk-based approaches while ensuring scientific rigor, we can accelerate product development and maintain patient access to essential medicines. The use of cloud-based platforms could enable the streamlined preparation, management, and sharing of standardized regulatory documentation to NRAs.

Several existing programs and pilot projects that use work-sharing models or unilateral reliance based on reference agency assessment are ongoing. A successful work-sharing program can promote global alignment and improve regulatory efficiency by eliminating redundancies, allowing both regulators and industry to use their resources more effectively. The results so far demonstrate that these reliance pathways have great potential to increase efficiency and could be integrated into standard operations where appropriate.

This plenary session will explore how different reliance and collaborative pathways can expedite patient access to medicines. We will delve into how industry and regulators can work together to make this a common global practice, leveraging cloud-based platforms to enhance collaboration and build trust.

Session Speakers:

Insights to Industry Led CMC PAC Reliance Pilots on behalf of EFPIA
Cynthia Ban, *Sanofi Pasteur Limited Canada*

International Collaboration and Reliance
Brian Dooley, *EMA-European Medicines Agency*

Pivoting to Platform: A Case Study in Leveraging Reliance to Enable Fast Implementation of Platform Method for Commercial Products
Christine Wu, *Genentech, a Member of the Roche Group*

Leveraging Reliance for Accelerating Global Access to Vaccines: A GSK Case Study
Katharine Duncan*, GlaxoSmithKline*

Additional Panelists:

Robin Levis, *CBER, FDA*
Claudia Müller, *Swissmedic*
Dean Smith, *Health Canada*

17:30-18:45 East/State Rooms

Exhibitor Reception

Thursday, 29 January, 2026

06:00-07:00

Visit the WCBP 2026 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.

View the poster abstracts below.

Virtual posters will be available to view on Tuesday, January 20.

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

Registration

Registration is open until 16:00

Pre-registered attendees should go to the Foyer.

07:00-08:15 Pennsylvania Room

CASSS Consultants' Network

Presentation type: In-Person

Meet in the Pennsylvania Room from 7:00-8:25am to meet and network with other consultants. Open discussion will include hot topics for the coming year of quarterly programming. Breakfast will be provided!

07:00-08:15 East/State Rooms

Continental Breakfast

Presentation type: In-Person

Breakfast is available until 09:00

08:15-08:30 Grand Ballroom

Welcome Day 3 & CASSS Distinguished Fellow Presentation

Presentation type: Live Streamed

The designation of CASSS Distinguished Fellow is designed to recognize individuals 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 a deserving individual as the new CASSS Distinguished Fellow.

08:30-09:00 Grand Ballroom

Keynote Session III - The Heart of Innovation: Patients Shaping the Future of Biologics

Presentation type: Live Streamed

This session will highlight three patients who will tell their own stories. It will celebrate patients as co-creators in the healthcare journey, who are at the heart of everything we do as innovators and regulators. It will tie their personal impact to the conference's global access theme and discuss how patient-centered approaches can inform development, access, and delivery strategies that truly reflect patient needs across diverse healthcare settings. The featured speakers will share their personal experiences and perspectives on navigating access to therapies, highlighting opportunities to strengthen collaboration between patients and the biopharmaceutical community.

Session Speakers:

Mike Abernathy, *Amgen Inc.*

Kathy Lee, *Acumen Pharmaceuticals*

Michael Sheahan, *Danforth, Health, Inc.*

09:00-09:15

Transition Time

09:15-10:45 Grand Ballroom

Parallel Session 6A - Navigating the Comparability Maze: Case Studies, Challenges, and Best Practices

Markus Blümel, Nomalie Jaya, Babu Kunnel, Joanna Zhou
Presentation type: Live Streamed
Track: Science - Novel Modalities and Manufacturing Innovations

As biologics development accelerates and therapeutic modalities diversify, demonstrating comparability after implementing manufacturing process changes remains a critical challenge. Advances in process intensification, analytical technologies, and digital tools are reshaping how comparability may be assessed and executed across the product lifecycle. This session will explore the multifaceted nature of comparability strategies with case studies for antibody-drug-conjugates, vaccines, and gene therapy products. In close collaboration, process developers and analytical scientists address the scientific and regulatory challenges, but also the opportunities to reimagine comparability frameworks that enable speed, flexibility, and innovation - without compromising patient safety, product quality, or efficacy.

Speakers will share comparability challenges, experiences, and best practices for a successful regulatory outcome. A moderated panel discussion will engage participants in a critical dialogue on how industry and regulators can evolve expectations, foster global harmonization, and harness innovation to transform comparability from a regulatory hurdle into a catalyst for progress.

Session Speakers:

Side-by-Side Stress Studies Designed to Support Post-Change Shelf Life
Tawnya Flick, *Gilead Sciences, Inc.*

From Lyo to Liquid: Smart Post-Approval Comparability Strategies for Patient-Friendly Vaccine Reformulation Across Regions
Varnika Roy, *GlaxoSmithKline*

Comparability for Cell and Gene Therapeutics
Fan Zhang, *Novartis Institutes for BioMedical Research (NIBR)*

Building a Resilient Commercial Supply Chain for Antibody-Drug Conjugate Products: A Risk-Based Comparability Approach
Dipkumar Jagani, *Astellas Pharma US, Inc.*

Additional Panelists:

Patrick Lynch, *CDER, FDA*
Holly McCaleb, *Pfizer, Inc.*

09:15-10:45 District Ballroom

Parallel Session 6B - Overcoming Barriers to Local GMP Manufacturing and Testing in LMICs: Doing the Things We Never Had

Lakshmi Khandke, Frances Namuswe, Shawn Novick, Dean Smith
Presentation type: Live Streamed
Track: Patient-Centered Care - Ensuring Equitable Access to Life-saving Medicines Globally

Building local GMP manufacturing and quality testing capacity in low- and middle-income countries (LMICs) is critical to achieving global health equity. This session will focus on Africa's evolving biomanufacturing landscape, highlighting progress in regulatory convergence, regional manufacturing hubs, and local biotech innovation. It will explore the role of non-profit and NGO workstreams in enabling sustainable capacity, and examine persistent CMC challenges such as raw material sourcing, comparability, and quality systems development. With perspectives from regulators, manufacturers, and global health stakeholders, the discussion will explore what it takes to move from aspiration to implementation—and ensure that LMICs can produce and test vaccines and biologics locally.

Session Speakers:

Building End-End Vaccine Development and Manufacturing Capability in Africa- The South African Experience
Morena Makhoana, *Biovac*

SAHPRA Support for Local GMP Manufacturing and Quality Testing
Mphako Brighton Ratlabyana, *South African Health Products Regulatory Authority*

From Construction to End-to-End Drug Substance and Drug Product GMP Manufacturing of mRNA Vaccines in Africa: A Cross-Country Race to Epidemic/Pandemic Preparedness and Public Health Impact
Petro Terblanche, *Afrigen Biologics (Virtual Presentation)*

10:45-11:15 East/State Rooms

Networking Break

Presentation type: In-Person

11:15-12:15 Palm Court Ballroom

Roundtable Session 2: Topics 1 - 6

Presentation type: In-Person

Table 1 - Recent Trends in Questions from Health Authorities

Table 2 - Vaccine Potency - Compare and Contrast Potency Tests for Different Vaccine Modalities

Table 3 - Novel Applications of Molecular and Structural Biology in Characterization of Well Characterized Biologics

Table 4 - Speed to Clinic - Phase Appropriate Strategies to Accelerate CMC Development Timelines

Table 5 - Expectations for the Development and Application of Extended Characterization Methods

Table 6 - Use of Prior Knowledge to Successfully Execute Manufacturing Process Changes

11:15-12:15 Chinese Room

Roundtable Session 2: Topics 7 - 12

Presentation type: In-Person

Table 7 - ICH Q6 - Challenges and Opportunities for Using an Enhanced Approach to Lifecycle Management of Specifications

Table 8 - Best Practices for Execution of Low Endotoxin Recovery (LER) Studies

Table 9 - Vaccine Specific Regulatory Considerations

Table 10 - How to Move From Pilot Initiatives to Sustainable Programs

Table 11 - Interpreting Confidence Intervals in Analytical Validation under ICH Q2(R2): From Statistical Reporting to Decision-Making

Table 12 - Use of Artificial Intelligence for Process and Analytical Method Development

11:15-12:15 Cabinet Room

Roundtable Session 2: Topics 13 - 18

Presentation type: In-Person

Table 13 - Using Accelerated Degradation Studies to Support Comparability Assessments, e.g. to Use Pre-change Shelf Life for Post-Change Material

Table 14 - Best Practices in HIAC Testing of Subvisible Particles

Table 15 - Host Cell Proteins (HCP) and Host Cell DNA Risk Assessment for Gene Therapies

Table 16 - Challenges When Working With Contract Development Manufacturing Organizations (CDMOs)

Table 17 - In-use Studies - Compatibility Studies and Defining Label Claim

Table 18 - Wellness in the Workplace

11:15-12:15 Rhode Island Room

Mini Case Studies Session 2 - Use of Predictive Stability for Shelf-Life Extension, ICH Q1 Annex 2

Presentation type: In-Person
Track: Regulations - International Harmonization and Collaboration

11:15-12:15 South Carolina Room

Mini Case Studies Session 2 - Replacement of in Vivo Testing With in Vitro Approaches: Implementation of High-Throughput or Next-Generation Sequencing for Adventitious Agent Testing

Presentation type: In-Person
Track: Science - Novel Modalities and Manufacturing Innovations

11:15-12:15 Virginia Room

Mini Case Studies Session 2 - Cloud-Based Platforms for Regulatory Submissions: Project PRISM and Accumulus CMC Use Cases

Presentation type: In-Person
Track: Digitalization - AI, Predictive Modeling, Automation, Data Management

12:15-13:45

Lunch Break

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

12:35-13:35 Grand Ballroom

Tackling the Polysorbate Degradation Challenge: Control Strategies and Case Studies | Presented by Clear Solutions Laboratories AG

Presentation type: Live Streamed

Session Speaker:

Tackling the Polysorbate Degradation Challenge: Control Strategies and Case Studies
Andreas Zerr, *Clear Solutions Laboratories AG*

12:35-13:35 District Ballroom

From Developability to Commercial Readiness: The New Reality of ICH Q1 Stability | Presented by Catalent, Inc.

Presentation type: Live Streamed

Session Speaker:

From Developability to Commercial Readiness: The New Reality of ICH Q1 Stability
Elizabeth Grotemeyer, *Catalent, Inc.*

13:45-15:00 Grand Ballroom

Workshop Session 3 - Qualification of Potency Reference Standards, Considerations for Reference Standards for Multispecifics, Multiple Antigens, or Multiple Mechanisms of Action

Presentation type: In-Person
Track: Science - Novel Modalities and Manufacturing Innovations

This workshop will discuss reference standard qualification focused on potency methods. They include therapeutic antibodies (monoclonal and multi-specific antibodies), therapeutic proteins, vaccines, as well as cell & gene therapies. For products with multiple modes of actions, additive vs. synergistic effects will be evaluated. Single vs. multiple reference standard for the same products will also be explored.

13:45-15:00 District Ballroom

Workshop Session 3 - Comprehensive Approach for Technology Transfers: To PACMP or Not to PACMP?

Presentation type: In-Person
Track: Regulations - International Harmonization and Collaboration

Workshop will explore critical aspects of site tech transfers, including addressing capacity needs, ensuring regulatory compliance, mitigating supply chain risks, optimizing costs, and gaining strategic benefits. Attendees will share insights into risk-based analytical comparability study design, derivation of appropriate acceptance criteria, risk assessment on facility readiness to support reduced reporting category, and regulatory strategies for successful implementation.

Some questions to pose: Biggest challenges faced? Strategy for engagement across multiple jurisdictions? What's one thing you could tell your younger self when starting this activity?

13:45-15:00 Palm Court Ballroom

Workshop Session 3 - Troubleshooting Technology Transfers Together – aka Two Heads are Better than One

Presentation type: In-Person
Track: Science - Novel Modalities and Manufacturing Innovations

For the first time at WCBP, we are introducing an interactive Tech Transfer Troubleshooting session designed for practitioners facing near term site moves, scale ups, and process transfers. The aim of this workshop is to create a practical forum for manufacturing, analytical, supply chain, and regulatory stakeholders to surface current challenges in making tech transfers faster—from regulatory pathways to validation strategy to method transfer—and to pressure test solutions with peers.

The format has earned strong feedback at other CASSS meetings, where participants consistently report gaining helpful insights and actionable feedback. Due to this overwhelmingly positive reception, we are bringing it to CASSS's flagship event.

Attendees are encouraged to bring an active issue they are facing (e.g., rapid onshoring, standing up a new site, or optimizing comparability strategy) and past lessons learned that could benefit the group. You can opt to submit details of your situation anonymously ahead of time without revealing any identifying information.

Potential topics to be brought for discussion include:

Are you having issues using innovative regulatory pathways (comparability protocol/PACMP, joint review/reliance programs)?

Are you receiving pushback when trying to leverage prior knowledge to reduce new data expectations?

Are you not being successful leveraging Mutual Recognition Agreements to reduce the inspection or review burden?

Are there bottlenecks with parts of your tech transfer package (facility fit, gap-closing data, long-lead items)?

Are there risks you are unable to mitigate to shorten tech transfer timelines?

Have digital tech transfer or structured data tools been failing you?

Is analytical method transfer on the critical path? Are previous bridging strategies or risk based criteria not helping?

Is evaluation of comparability a challenge?

Are material or sourcing constraints impacting your current timelines?

Are you having issues with cold chain logistics and shipping validation when introducing new sites?

13:45-15:00 Chinese Room

Workshop Session 3 - In-Use Compatibility and Stability Studies

Presentation type: In-Person
Track: Science - Novel Modalities and Manufacturing Innovations

In-Use Compatibility and Stability Studies will be discussed with a a major focus on biologics. The number of subvisible particles post-dilution during in-use and discussion around it will be the main topic for the workshop.

15:00-15:30 Promenade Foyer

Networking Break

Presentation type: In-Person

15:30-17:00 Grand Ballroom

Plenary Session 7 - Modernizing CMC Regulatory Submissions

Mike Abernathy, Ciby Abraham, Fadi Hakki, Susan Kirshner
Presentation type: Live Streamed
Track: Digitalization - AI, Predictive Modeling, Automation, Data Management

The Chemistry, Manufacturing, and Controls (CMC) regulatory landscape is rapidly evolving to streamline product registration and lifecycle management through digital and science risk-based approaches. A key driver of this transformation is the revision of ICH M4Q (R2), modernizing the Quality Common Technical Document. Complementing this, the forthcoming ICH Structured Product Quality Submissions (SPQS) guideline introduces harmonized, structured data formats for product quality, catalyzing the shift from document-centric files to standardized, data-driven electronic submissions and enabling more automated exchange between industry and regulators. In parallel, the emerging ICH Pharmaceutical Quality Knowledge Management (PQKM) concept promotes data-centric knowledge capture and reuse across the lifecycle, improving consistency, transparency, and the quality of CMC information.

Collectively, these initiatives advance global harmonization by aligning data structures and definitions across regions; strengthen benefit–risk evaluation through more complete, comparable datasets; and accelerate patient access by reducing redundancies and enabling parallel, reliance-based reviews. They also lay the foundation for cloud-based submissions, AI-assisted analytics, and collaborative reviews by standardizing digital CMC submissions and supporting real-time data sharing with version control. Ongoing multi-agency programs, including Project Orbis, ACCESS, and ICMRA's PAC reliance pilots, stand to benefit from digital CMC data submissions, as structured, reusable data improves cross-agency comparability, enables shared analytics, and streamlines both marketing authorization and post-approval change assessments.

This session will present current initiatives, practical examples, and actionable recommendations to help organizations prepare their data, systems, and teams for digital CMC and collaborative review at a global scale.

Session Speakers:

Connecting Industry and Regulators in the QbD Landscape
Sarah Pope Miksinski, *Gilead Sciences, Inc.*

ICH M16 - Transitioning to Structured Product Quality Submissions
Rodrigo Palacios, *F. Hoffmann-La Roche Ltd.*

Collaborative CMC Assessment of Post-Approval Change Management Protocols: A Regulatory Health Authority-Perspective
Willie Wilson III, *CDER, FDA*

No AI Without Architecture: FHIR as the Data Foundation
Kåre Hyttel, *NNIT A/S*

Additional Panelist:

Mphako Ratlabyana, *South African Health Products Regulatory Authority (SAHPRA)*

17:00-17:15 Grand Ballroom

Acknowledgements, Closing Remarks & Invitation to WCBP 2027

Presentation type: Live Streamed