CMC Strategy Forum North America Summer 2026

Schedule

Tuesday, 28 July, 2026

07:30-08:30 Confederation Foyer

Registration for CMC Strategy Forum North America

Registration will be open until 17:00.

07:30-08:30 Confederation II

Rise and Dine: Breakfast

Breakfast will be available until 9:00 AM

08:30-08:40 Confederation III

CASSS Welcome and Introductory Comments

08:40-08:45 Confederation III

CMC Strategy Forum Welcome and Session Introduction

08:45-10:00 Confederation III

Workshop I: Regulatory Modernization and Global Harmonization

Paula Russell, Helen Thomas
Topic: Modernization of CMC Review

Modernization of CMC review is rooted in new ways of working; facilitated by responsive regulatory infrastructure and in collective and collaborative approaches. Policy innovations, a willingness to harmonize, and international frameworks are key features that support the modernization of CMC review in a global landscape.
This session will bring together regulators and industry to discuss efforts to modernize CMC review with a focus on evolving regulatory policies and optimizing collaborative practices.

Ideas for Discussion:

- Implementation experiences with ICH Q12 (Lifecycle Management), Q13 (Continuous Manufacturing), Q2(R2)/Q14 (Analytical Procedure Development and Validation); a forward look into the ongoing revision of ICH M4Q (Common Technical Document)

- Agile regulations – e.g., Health Canada Food and Drug regulations, Division 4 update or an update from ICH on the work plan going forward - what key topics do they foreshadow that will help enable modernization

- Implications of the new global biosimilars guidance / ICH M18 (Framework for Determining the Utility of Comparative Efficacy Studies in Biosimilar Development Programs) and its interface with CMC considerations

- The use of foreign information (e.g., Q&As, assessment reports, decisions) and reliance pathways

- The evolution of our understanding of risk and risk-mitigation tools (e.g., PQS, QRM)

- Use and expectations for model-informed decision-making (empirical and statistical analyses to multivariate and AI/ML-based approaches).

Outcomes:
Participants will gain insight into regulatory modernization efforts that enhance flexibility, promote reliance, and streamline global product development and post-approval lifecycle management.

Session Speakers:

From Policies to Practices: Health Canada's Approach to Modernization of CMC Review
Elana Cherry, *Health Canada*

Operationalizing Modern CMC Lifecycle Management: The Digital Infrastructure Behind Collaborative Regulatory Execution
Francisco Nogueira, *Accumulus Technologies*

Near-Concurrent Collaborative Reliance with Accumulus Technologies to Streamline Post-Approval Variations
J. Paul Kirwan, *Amgen Inc.*

10:00-10:30 Confederation Foyer

Coffee and Conversation Networking Break

Please feel free to stretch, grab coffee, water, and return to the general session room for the panel discussion!

10:30-11:50 Confederation III

Workshop I: Panel Discussion

Cassandra Overking, Paula Russell
Topic: Modernization of CMC Review

Additional Panelists:

Kavita Aiyer, *Teva Pharmaceuticals USA, Inc.*
Magda Joseph, *Health Canada*

11:50-13:05 Confederation II

Networking Lunch: Refuel & Reflect

13:05-14:25 Confederation III

Workshop II: From Pilot to Practice: Are Work-Sharing and Reliance Ready for Prime Time?

Kavita Aiyer, John Armando, Cynthia Ban
Topic: Global Harmonization

Despite years of pilots and proof-of-concept efforts, global work-sharing for medicines remains the exception rather than the norm. At a time when medicines are transforming care—and stretching regulatory capacity—can the global community afford continued duplication?

This session brings together regulators and industry leaders to confront a central question: what is holding collaborative models back from becoming business-as-usual? Drawing on real-world experience with joint assessments, parallel reviews, and reliance-based pathways, speakers will move beyond success stories to unpack persistent barriers, including misaligned requirements, limited trust frameworks, inspection challenges, and uneven digital maturity.

A defining feature of this session is the integration of key insights from a closed-door, pre-conference dialogue among senior leaders of global regulatory agencies. Selected perspectives from these candid discussions—exploring both the promise and limitations of current approaches—will be shared to inform and challenge the broader conversation.

The discussion will also push boundaries by questioning assumptions about regulatory sovereignty and exploring what must change—legally, operationally, and culturally—to move from pilots to sustained practice.

Attendees will gain rare visibility into evolving regulatory thinking and leave with actionable strategies to scale reliance, strengthen collaboration, and accelerate global access to high-quality biologics.

Session Speakers:

ACCESS Worksharing Operational Insights and Process Optimization
Sharlene Henry, *Sanofi Canada*

Beyond Borders: Scaling Biologics Post-Approval Changes Through Regulatory Reliance and Cloud-Based Digital Review
Kavita Aiyer, *Teva Pharmaceuticals USA, Inc.*

Introducing Health Canada's Approach to Reliance on Foreign Regulatory Decisions
Christine Lefebvre, *Health Canada*

Closed Door Pre-Session Report Out
Paula Russell, *Health Canada*

14:25-14:55 Confederation II

Coffee and Conversation Networking Break

Please feel free to stretch, grab coffee, water, and return to the general session room for the panel discussion!

14:55-16:10 Confederation III

Workshop II: Panel Discussion

Kavita Aiyer, John Armando, Cynthia Ban

Additional panelists:

Jorge Canales, *Instituto de Salud Publica de Chile*
Patrick McGeehan, *AstraZeneca*
Mphako Brighton Ratlabyana, *SAHPRA*

16:10-16:20 Confederation III

Day 1 Takeaways

Session Speaker:

Sonia Corrent, *Health Canada*

16:20-16:35 Confederation III

Regulator Roll Call: Who's in the Room?

16:35-18:00 Confederation Foyer

The Wine Down – Beer and Wine Reception

Wrap up your first day by joining us for the Beer & Wine Reception! Enjoy drinks, connect with fellow attendees, and unwind after a day of engaging sessions. We look forward to seeing you there!

Wednesday, 29 July, 2026

07:30-08:30 Confederation Foyer

Registration for CMC Strategy Forum North America

Registration will be open until 16:30.

07:30-08:30 Confederation II

Rise and Dine: Breakfast

Breakfast will be available until 9:00 AM

08:30-08:50 Confederation III

Morning Welcome and Presentation of Hancock Award

08:50-08:55 Confederation III

Introduction

08:55-10:10 Confederation III

Workshop III: From Development to Global Implementation

JR Dobbins, Jason Starkey, Helen Thomas
Topic: Product Development and Commercial Readiness

This session will focus on strategies to accelerate development and ensure smooth transition to commercial readiness, while maintaining quality and regulatory compliance. Emphasis will be placed on phase-appropriate CMC expectations, and emerging technologies and approaches.

Outcomes:
Participants will explore how modernization of early development pathways and the use of innovative technologies can accelerate timelines and enhance readiness for commercialization.

Session Speakers:

Submission Considerations for Platform Analytical Procedures Used to Support Commercial Filings
Karen Rule, *Pfizer, Inc.*

Advancing Biomanufacturing and Regulatory Modernization: Innovation, Implementation, Operationalization
Richard Siggers, *Health Canada*

Digital Innovation for Sustainable, Accelerated Development in an Era of Uncertainty
Maria Papathanasiou, *Imperial College London*

10:10-10:40 Confederation Foyer

Coffee and Conversation Networking Break

Please feel free to stretch, grab coffee, water, and return to the general session room for the panel discussion.

10:40-11:55 Confederation III

Workshop III: Panel Discussion

JR Dobbins, Jason Starkey, Helen Thomas
Topic: Product Development and Commercial Readiness

Additional panelist:

Helen Thomas, *Swissmedic*

11:55-13:15 Confederation II

Networking Lunch: Refuel and Reflect

13:15-14:55 Confederation III

Workshop IV: From Development to Global Implementation

Mary Beth Pelletier, Jason Starkey
Topic: Product Quality – Enhanced Approaches

ICH Q1 (Stability) and Q6 (Specifications) have long underpinned product quality assurance. In a modern, science- and risk-based framework, their application is evolving from fixed regulatory endpoints to dynamic, evidence-based elements of an integrated control strategy. This session will discuss how stability data and specification setting can enable continuous improvement, regulatory flexibility, and lifecycle management.

Session Speakers:

Predictive Stability for Biopharmaceuticals & Vaccines: Accelerating Patient Access through Industry Recommendations and Stakeholder Alignment
Daniel Skomski, *Merck & Co., Inc.*

The Need for Science and Risk-Based Approaches to Setting Specifications: A Regulatory Perspective
Dean Smith, *Health Canada*

ICH Q14 Enhanced Approaches: From ATP t Analytical Procedure Validation Using Prior Knowledge and Development Data
Mark Milford, *Eli Lilly and Company*

14:55-15:15 Confederation Foyer

Coffee and Conversation Networking Break

Please feel free to stretch, grab coffee, water, and return to the general session room for the panel discussion!

15:15-16:30 Confederation III

Workshop IV: Panel Discussion

Mary Beth Pelletier, Jason Starkey
Topic: Product Quality – Enhanced Approaches
Additional panelists:

Timothy Graul, *Pfizer, Inc.*
Karen Rowlandson, *Health Canada*
Paula Russell, *Health Canada*
Cecilia Tami, Genentech, a *Member of the Roche Group*

16:30-16:45 Confederation III

Closing Remarks and Invitation to CMC Strategy Forum North America 2027