

# CMC North America Winter 2026

Schedule

Monday, 26 January, 2026

07:00-08:30 Promenade Foyer / Senate Room

## Registration for CMC Strategy Forum North America Winter 2026

Presentation type: IP - In Person

*Registration is open from 07:00 to 16:00*

07:00-08:30 Palm Court Ballroom

## Rise and Dine: Breakfast

Presentation type: IP - In Person

*Breakfast will be served until 09:00.*

08:30-08:50 Grand Ballroom

## CASSS Welcome and CMC Strategy Forum 2026 Introductory Comments

Kavita Aiyer, Jennifer Eck, Shawn Novick, Hirendrasinh Parmar

Presentation type: LS - Live Streamed

Track: Making Creative Protein Therapies a Reality for Patients

In biotechnology, we have advanced to create proteins that, while structurally similar to their human counterparts, exhibit purposeful variations. With our growing understanding of disease biology, we are now able to design proteins with enhanced specificity and anticipated efficacy for targeting diseases. Frequently, the IgG1 scaffold serves as the foundational structure upon which modifications—additions, deletions, or alterations—are implemented to optimize therapeutic potential against specific targets.

The development of bi-, tri-, and higher-order specific molecules based on monoclonal antibody (mAb) scaffolds, constitutes the central theme of the Winter CMC Strategy Forum. Building on discussions initiated during the Summer CMC Strategy Forum, this event will delve into complex topics such as manufacturing challenges, potency assay development, and comprehensive control strategies for final products spanning the life cycle of the product. The program will begin with a focus on early to late stages of product development and progress in the afternoon to initial market authorization to post approval phases.

We invite you to join us as we examine and advance the frontiers of this rapidly evolving field.

08:30-08:50 District Ballroom

## CASSS Welcome and CMC Strategy Forum 2026 Introductory Comments

Jennifer Ferrence Sexton, Andrea Redd, Jason Starkey, Chandra Webb

Presentation type: LS - Live Streamed

Track: Right Dose, Real Impact: Strategies to Ensure Consistent Dose for Every Patient

Control of drug product content and uniformity is critical to ensuring patients reliably receive the intended dose per the drug product label claim. Drug product design, manufacturing process control and release testing work together to ensure the drug product delivered is as described in labeling. This forum will take a deep dive into the challenge of developing control strategies for drug product content in and across vials, single-dose and multi-dose devices. An acceptable level of variability during manufacturing and analytical testing is maintained through a comprehensive strategy that includes in-process controls and release testing with adequate acceptance criteria. Control strategy for drug product content is subject to regulation (law), to regulatory guidelines and to compendial requirements.

08:50-10:10 Grand Ballroom

### Workshop I - Making Creative Protein Therapies a Reality for Patients: Early-Stage Development

Kavita Aiyer, Shawn Novick, Sarah Owen, Mary Beth Pelletier

Presentation type: LS - Live Streamed

Track: Making Creative Protein Therapies a Reality for Patients

#### Session Speakers:

Strategies for Analytical Characterization of Multi-Specific Proteins

Jared Auclair, *Northeastern University (Virtual Presentation)*

B7-H7 Bispecific Antibody Development: Protein Engineering and Product Quality-focused Cell-line Development to Minimize Mispairing and Homodimer Formation

Jamie Strand, *NextPoint Therapeutics*

Regulatory Considerations for Early-Stage Development of Bi-, Tri-, and Multispecific Therapeutics

Hirendrasinh Parmar, *Health Canada*

Strategies for Successful Development and Manufacturing of Multispecific Antibodies and Proteins

Yuan Chang, *WuXi Biologics (Virtual Presentation)*

08:50-10:10 District Ballroom

### Workshop II - Right Dose, Real Impact: Strategies to Ensure Consistent Dose for Every Patient

Jennifer Ferrence Sexton, Joanne McBane, Andrea Redd

Presentation type: LS - Live Streamed

Track: Right Dose, Real Impact: Strategies to Ensure Consistent Dose for Every Patient

The morning session will bring together industry professionals, consultants, and global regulatory authorities to discuss the complexities inherent in verifying that injectable drug products conform to label claims. The session will define critical terms including gross content, net content, excess volume, overfill, label claim, and intended dose. Established industry strategies for control of drug product content and uniformity across injectable dosage forms will be presented. The session will also delve into the regulatory expectations for both liquid and lyophilized drug products, referencing key reference documents including relevant compendial chapters, regulations and related guidelines on content. The panel discussion that follows will foster dialogue between industry and regulators on challenges and potential solutions to ensure patients reliably receive the intended dose per drug product label claim.

#### Speakers:

Ensuring Drug Product Content Meets Label Claim - Are You Getting What You Paid For?

Leslie Ann Rivera Rosado, *OPQ CDER, FDA (Virtual Presentation)*

Compendial Expectations for Dose Content and Uniformity for Biologics

Diane McCarthy, *US Pharmacopeia*

Strategies to Support Right Dose, Every Time: How to Meet Label Claim

Katie Kim, *Eli Lilly and Company (Virtual Presentation)*

IQ Survey Results: Industry Approaches to Allowable Content in Vials

Shashi Sivakumar, *AstraZeneca (Virtual Presentation)*

10:10-10:40 Palm Court Ballroom

### Coffee Connection: Networking Break

Presentation type: IP - In Person

Enjoy some coffee, a snack, and network with your peers!

10:40-11:55 Grand Ballroom

### Workshop I Panel Discussion - Making Creative Protein Therapies a Reality for Patients: Early-Stage Development

Kavita Aiyer, Jennifer Eck, Shawn Novick, Hirendrasinh Parmar

Presentation type: LS - Live Streamed

Track: Making Creative Protein Therapies a Reality for Patients

#### Additional Panelist:

Brandon Anjuwon-Foster, *OPQ CDER, FDA (Virtual Chat Only)*

10:40-11:55 District Ballroom

Workshop II Panel Discussion

Jennifer Ferrence Sexton, Andrea Redd, Jason Starkey, Chandra Webb

Presentation type: LS - Live Streamed

Track: Right Dose, Real Impact: Strategies to Ensure Consistent Dose for Every Patient

Additional Panelist:

Katie Duncan, *GlaxoSmithKline*

11:55-13:15 Palm Court Ballroom

Meet and Eat: Hosted Lunch

Presentation type: IP - In Person

Join us for a nutritious networking lunch in the Palm Court Ballroom!

13:15-14:40 Grand Ballroom

Workshop I - Making Creative Protein Therapies a Reality for Patients: Late-Stage Clinical Development

Katie Duncan, Jennifer Eck, Hirendrasinh Parmar, Paresma Patel

Presentation type: LS - Live Streamed

Track: Making Creative Protein Therapies a Reality for Patients

Speakers:

Control Strategies Tailored for Multispecifics

Wenqin Ni, *Pfizer, Inc.*

Late-Stage CMC Analytical Speed Bumps: When 'Later' is Suddenly Now...

Nadine Ritter, *Global Biotech Experts, LLC*

Bispecifics and Beyond: Protein, Platform and Pipeline Considerations

Shawn Lawrence, *Regeneron Pharmaceuticals, Inc.*

Regulatory Considerations for Multispecific Antibody-Based Products for BLA and Beyond

Jennifer Swisher, *OBP CDER, FDA (Virtual Presentation)*

13:15-14:40 District Ballroom

Workshop II - Right Dose, Real Impact: Strategies to Ensure Consistent Dose for Every Patient

Markus Blümel, Kasia Nowinski, Leslie Ann Rivera Rosado, Chandra Webb

Presentation type: LS - Live Streamed

Track: Right Dose, Real Impact: Strategies to Ensure Consistent Dose for Every Patient

The afternoon session will build upon the foundation of the morning session with case studies that illustrate the challenges in practical application of expectations to real-world drug products. Case studies will include lyophilized drug product in a vial and bridging across drug product presentations. We will explore approaches to robust control strategy design taking into consideration variability inherent to manufacturing processes and analytical testing. We will close with a panel discussion focused on brainstorming approaches and solutions to the challenges that have been articulated.

Speakers:

From Aligned Nomenclature to Real-Time Release: A Practical Framework for Fill Weight Strategy

Shermeen Abbas, *Amgen Inc. (Virtual Presentation)*

Case Study of "Dose Delivered" vs. "Label Claim" in Different Delivery Systems

Andrea Redd, *Eli Lilly and Company (Virtual Presentation)*

Designing a Lyophilized Drug Product for Weight-Based Dosing

Karen Rutherford, *Pfizer, Inc. (Virtual Presentation)*

Batch Uniformity of Lyophilized Biologics with Modern Fill-Weight Control

John Peattie, *Denali Therapeutics*

14:40-15:00 Palm Court Ballroom

Coffee Connection: Networking Break

Presentation type: IP - In Person

Enjoy some coffee, a snack, and network with your peers!

15:00-16:15 Grand Ballroom

Workshop I Panel Discussion

Kavita Aiyer, Jennifer Eck, Shawn Novick, Hirendrasinh Parmar

Presentation type: LS - Live Streamed

Track: Making Creative Protein Therapies a Reality for Patients

Additional Panelists:

Felix Jules, *Health Canada*

Michael Capaldi, *Johnson & Johnson Innovative Medicine*

15:00-16:15 District Ballroom

Workshop II Panel Discussion

Jennifer Ferrence Sexton, Andrea Redd, Jason Starkey, Chandra Webb

Presentation type: LS - Live Streamed

Track: Right Dose, Real Impact: Strategies to Ensure Consistent Dose for Every Patient

Additional Panelists:

Joanne McBane, *Health Canada*

Claudia Müller, *Swissmedic*

16:15-16:30 Grand Ballroom

Closing Remarks: Invitation to CMC Strategy Forum Summer 2026

Kavita Aiyer, Jennifer Eck, Shawn Novick, Hirendrasinh Parmar

Presentation type: LS - Live Streamed

Track: Making Creative Protein Therapies a Reality for Patients

16:15-16:30 District Ballroom

Closing Remarks: Invitation to CMC Strategy Forum Summer 2026

Jennifer Ferrence Sexton, Andrea Redd, Jason Starkey, Chandra Webb

Presentation type: LS - Live Streamed

Track: Right Dose, Real Impact: Strategies to Ensure Consistent Dose for Every Patient

16:30-18:00 Palm Court Ballroom

Networking Reception

Presentation type: IP - In Person

Join us for a Networking Reception in the Palm Court Ballroom!