CMC Strategy Forum North America Summer 2025

Schedule

Monday, 14 July, 2025

07:30-08:30 Washingtonian Foyer

Registration for CMC Strategy Forum North America

Registration will be open until 17:00.

07:30-08:30 Salon C

Rise and Dine: Breakfast

Breakfast will be available until 9:00 AM

08:30-08:40 Salons D - G

CASSS Welcome and Introductory Comments

08:40-08:55 Salons D - G

CMC Strategy Forum Welcome and Session Introduction

08:55-10:10 Salons D - G

Workshop Session I - Novel Bioconjugates and Multispecifics

Tura Camilli, Dawn Spiller

Antibody drug conjugates and bispecifics are just the tip of the iceberg of an emerging landscape of novel and complex antibody-based conjugates and multispecifics . Targeted therapies of radio, peptide and oligonucleotide bioconjugates demonstrate potential in expanding the scope of precision medicine. The next generation of antibody engineering has led to diverse formats such as single-domain antibodies, T-cell receptor mimetics, and non-immunoglobulin domain or scaffold products. Designing scalable manufacturing processes that can efficiently meet demand without compromising product quality, expanding the analytical toolbox, and increasing flexibility in the regulatory framework are essential to support innovation.

This session aims to explore the development considerations for these new product types and learnings that can be leveraged from existing monoclonal antibody and ADC experience.

Potential Questions:

Which established expectations for oncology ADCs apply to conjugates with novel payloads such as radionuclides, peptides or oligonucleotides?

Which established expectations for monoclonal antibodies apply to multispecifics?

Is the regulatory framework well understood and flexible enough for these new product types?

What has been the industry's experience with agency recommendations regarding the application of existing ICH guidance and GMP regulations?

What are the technical considerations (manufacturing footprint, CMDO, robust QC methods) for commercial scale and complex supply chain strategies?

What are the considerations for bioassay, including their relationship to the Mechanism of Action?

Session Speaker:

Robust Developability Assessment for Multi-specific Biologics: Phase-appropriate Strategies for Accelerating Drug Product Development
Francis Kinderman, *Amgen Inc.*

CMC Development Considerations for Radioconjugates
Dawn Spiller, *AstraZeneca*

Navigating the Regulatory Landscape for Multispecific Bioconjugates
Angela Yeung, *Health Canada*

10:10-10:40 Washingtonian Foyer

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 Salons D - G

Workshop Session I: Panel Discussion

Tura Camilli, Dawn Spiller

Additional Panelist:

David Barnes, *RLS Radiopharmacies*
Alan Hunter, *AstraZeneca*
Félix Jules, *Health Canada*

11:55-13:15 Salon C

Networking Lunch: Refuel & Reflect

13:15-14:35 Salons D - G

Workshop Session II - New Technologies and Approaches to Analytics

Jason Starkey, Angela Yeung

Multispecific and bioconjugated molecules provide treatment mechanisms that can potentially improve the current standards of care in various therapeutic categories. By combining and enhancing the mechanistic actions of drugs to operate on multiple or difficult-to-target pathways, these molecules have attracted attention from numerous innovators. However, these features also present significant challenges in terms of characterization, purity and impurity measurements, and potency determinations. This session will address analytical assay development and characterization tools used to facilitate process and formulation development, culminating in CMC analytical control strategies for multispecific and bioconjugated molecules. The focus will be on overcoming new challenges and identifying opportunities for further technological or knowledge development for these modalities.

Session Speaker:

The "5C" Network of Linker-Payloads: Chemistry, Conjugation, Characterization, and Control of the Cytotoxic Intermediate
Ernest Kovacs, *Immunome Inc.*

Advanced Analytical Approaches and Case Studies to Support Process Development and Characterization
Xiaoqing Hua, *Merck & Co., Inc.*

"Catch Me if You Can" Analytical Considerations for the Control of Multi-Specific Antibody (MsAb) Homodimer Impurities
Fang Zhang, *Pfizer, Inc.*

A QbD Approach for Analytical Comparability of ADC Molecule
Ally Liu, *Gilead Sciences, Inc.*

14:35-15:05 Salon C

Networking Break

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

15:05-16:20 Salons D - G

Workshop Session II: Panel Discussion

Jason Starkey, Angela Yeung

Additional Panelist:

Xiaoyu Chen, *AstraZeneca*

16:20-16:30 Salons D - G

Day 1 Wrap Up & Closing

16:30-17:30 Washingtonian 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!

Tuesday, 15 July, 2025

07:30-08:30 Washingtonian Foyer

Registration for CMC Strategy Forum North America

Registration will be open until 15:30.

07:30-08:30 Salon C

Rise and Dine: Breakfast

Breakfast will be available until 9:00 AM

08:30-08:40 Salons D - G

CASSS Welcome and Session Introduction

08:40-10:05 Salons D - G

Workshop Session III - Global Regulatory Considerations for CMC Regulatory Strategies

Kavita Aiyer, Kathy Lee

Bioconjugates and multi-specifics have ushered in a new era of precision medicine, with the potential to revolutionize the treatment of various diseases through their unique ability to engage multiple targets simultaneously. Despite their potential, often their design, development, production complexity and stability of such multivalent and multi-specific therapeutics pose significant challenges. Regardless of the diversity in format and structures, there are some common quality attributes which present the opportunity for leveraging platform knowledge during development. In parallel, manufacturers encounter new challenges ranging from development of bioassays, characterization, analytical methods, stability, understanding CQAs and development of an appropriate control strategy given the complexity of the engineered structures.

It is acknowledged that albeit commercially approved bioconjugates and multi-specifics, it continues to be a growing field of gaining knowledge for both manufacturers and regulators. This session will focus on regulatory barriers and lessons relevant to accelerated development, health authority interactions, process validation, stability and comparability approaches and how to enable acceleration of global market submissions.

Session Speakers:

Regulatory Considerations in the Design, Development and Quality of Monoclonal Antibodies and Related Novel Antibody-Based Products
Marjorie Shapiro, *CDER, FDA (Retired)*

CMC Considerations For Bioconjugates and Multispecifics: A Regulator's Perspective
Kanoko Goto, *Pharmaceuticals and Medical Devices Agency (PMDA)*

From Complexity to Clarity: Chile's Regulatory Vision for Bioconjugates & Multispecifics
Jorge Canales Pacheco, *Public Health Institute of Chile (Instituto de Salud Pública de Chile)*

Antibody-Drug Conjugates: Regulatory Insights and Lessons Learned
Katharine Duncan, *GlaxoSmithKline*

10:05-10:35 Washingtonian Foyer

Networking Break

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

10:35-11:50 Salons D - G

Workshop Session III: Panel Discussion

Kavita Aiyer, Kathy Lee

Additional Panelists:

Kathleen Bassett, *AstraZeneca*

Allison Wolf, *Eli Lilly and Company*

11:50-13:00 Salon C

Networking Lunch: Refuel and Refect

13:00-14:20 Salons D - G

Workshop Session IV - Integrated Control Strategies, CQAs, and Risk Management for Bioconjugate Therapeutics

Patrick McGeehan, Allison Wolf

Antibody drug conjugates are well established as oncology therapeutics and this success has led to a burgeoning field of diverse bioconjugates that extend far beyond oncology. Control strategy development for bioconjugates needs to take into consideration the best point of control in addition to understanding CQAs. Merging synthetic molecule considerations with biologic molecule considerations complicates the control strategy and requires strong cross functional collaboration throughout the product lifecycle.

Recent progress includes:

Advancements in protein engineering that have allowed for very specific conjugation, enabling improved control and less heterogeneity compared to some of the earliest ADC therapeutics.

A growing body of knowledge and experience with monoclonal antibodies and ADCs that can aid in the identification of CQAs, which better informs risk assessments.

Commercialization of oligopeptide and oligonucleotide-based therapeutics that have opened the door for use of these modalities as payloads in ADCs.

Given this evolving landscape, there may be opportunities for more facile implementation of process improvements during development and post launch. This session will highlight some industry case studies to illustrate where traditional ADC control strategy approaches have been considered for relevancy to a different type of bioconjugate. Some of the specific challenges to be discussed include control of DAR, approaches to potency testing, impurity clearance/control, and assessing charge heterogeneity of the protein after conjugation. Commercial control strategy implementation and maintenance will also be discussed with the hopes of identifying some lessons learned from commercial ADCs that can help the emerging class of bioconjugates as they look to accelerate development while also trying to avoid extensive post approval change agendas.

Session Speaker:

Putting the Pieces Together: Analytical Control Strategy Challenges for Bioconjugates
Juliana Kretsinger, *Eli Lilly and Company*

Control Strategies for Radiobioconjugates
Gowri Raghunandan, *Fusion Pharma*

Strategies to Streamline ADC Potency Testing
Joe Callahan, Genentech, a Member of the Roche Group

14:20-14:50 Washingtonian Foyer

Networking Break

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14:50-16:05 Salons D - G

Workshop Session IV: Panel Discussion

Patrick McGeehan, Allison Wolf

Additional Panelists:

Chana Fuchs, *CDER, FDA (Retired)*
Bharat Jagannathan, *Amgen Inc.*
David Robbins, *AstraZeneca*

16:05-16:15

Closing Remarks and Invitation to CMC Strategy Forum North America 2026