CMC Strategy Forum Europe 2025

Schedule

Monday, 20 October, 2025

07:30-08:30 The Ballroom Foyer Level B2

Registration

Presentation type: IP - In Person

Registration will be open until 17:00.

08:30-09:50 The Ballroom Level B2

EFPIA Biomanufacturing Group Satellite Session I: Working Subteams and Concept Paper Updates

Karoline Bechtold-Peters, Stu Finnie, Helen Newton

Presentation type: IP - In Person

The EFPIA Biomanufacturing Working Group is a cross-company industry team working to aid the development of biological products for patients. Through areas of special interests, the group supports and develops cutting edge science and technology strategies. In the first half of the session, the working group will showcase some of the current concept papers under development.

The second session will focus on Unlocking the Potential of Multispecific Antibodies: Design, Development, and Future Opportunities.

Session Speakers:

Welcome and Introduction to the EFPIA Biomanufacturing Working Group Satellite Session
Markus Goese, *F. Hoffmann-La Roche Ltd*

ADCs and AxCs: Summary of a Recent EFPIA Member Survey on Antibody Conjugates
Karoline Bechtold-Peters, *Novartis Pharma AG*

Prior and Platform Knowledge Use (Specifically Through a PTMF) in EU/EEA
Mihai Bilanin, *GlaxoSmithKline*

Do We Worry Too Much About Polysorbate Degradation? - An Industry-Wide Perspective with Real Life Case Studies
Cyrille C. Chéry, *UCB Pharma SA*

A Streamlined Approach for Low-Risk, Multi-Site Regulatory Submissions: The 'Sister Site' Concept
Andrew Lennard, *Amgen Limited (UK)*

Subcutaneous Biologics: Advancing High-Concentration Technologies and Justifying CQA Specification Limits Through Translational Immunogenicity Models – Status Update
Karoline Bechtold-Peters, *Novartis Pharma AG*

09:50-10:20 The Ballroom Foyer Level B2

Networking Break

Presentation type: IP - In Person

10:20-12:25 The Ballroom Level B2

EFPIA Satellite Biomanufacturing Group Satellite Session II: Unlocking the Potential of Multispecific Antibodies: Design, Development, and Future Opportunities

Karoline Bechtold-Peters, Stu Finnie, Helen Newton
Presentation type: IP - In Person

Multispecific antibodies represent a transformative advancement over traditional monospecific formats, offering enhanced specificity, efficacy, and reduced drug resistance. These attributes translate into significant clinical benefits, particularly in the treatment of complex diseases.

These sophisticated molecules present unique challenges for CMC, such as managing product- and process-related impurities, quality control and analytical methods, and formulation strategies. This session explores the diverse design architectures of multispecifics—including case studies—and the engineering strategies behind them.

Session Speakers:

Challenges of Multispecific Antibodies From the Reviewers Perspective
Steffen Gross, *Paul-Ehrlich-Institut*

MAIT Engagers: Safer T-Cell Engagers With a Large Therapeutic Window for the Treatment of Cancer
Simon Plyte and Pierre-Emmanuel Gerard, *Biomunex Pharmaceuticals*

Design and CMC Considerations for Oligo-Functionalized Antibodies: The Case of Brainshuttle™-ASO Conjugates
Felix Schumacher, *F. Hoffmann-La Roche Ltd.*

Additional Panelists:

Marie Valentin, *WHO – World Health Organization*

Christian Ostermeier, *Novartis Pharma AG*

12:25-13:30 Topaz 1 Level 2

Networking Lunch

Presentation type: IP - In Person

13:30-13:45 The Ballroom Level B2

CASSS Welcome to the 19th European CMC Strategy Forum

Presentation type: IP - In Person

13:45-15:10 The Ballroom Level B2

Session I - Global Reliance

Sandra Auguste-Bowler, Ulla Grauschopf, Richard Keane, Helen Newton
Presentation type: IP - In Person

Global reliance, be it during initial registration or life-cycle management through work sharing programmes such as ACCESS, the Orbis Type C reliance pathway, the ICMRA pilots, or through other country-specific reliance pathways is a common goal across Health Authorities and Industry partners to foster effective use of resources, to accelerate regulatory decision making, and to strengthen global regulatory convergence.

This session will focus on the need to foster better global reliance from initial submissions through the product lifecycle, and you will hear from both global regulators and companies who will share real world practical examples, lessons learned and considerations for building effective global reliance regulatory strategies. We look to answer the questions of are these reliance approaches delivering on global health expectations and where are there opportunities for improvements?

Session Speakers:

Reliance as an Essential Tool to Promote Efficient and Robust Global Regulatory Oversight
Marie Valentin, *WHO – World Health Organization*

Marketing Authorization Assessment and GMP Inspection by the African Medicinces Agency (AMA) - CMC Experience From the Pilot Programme
Oliver Gram, *Merck Sharpe & Dohme*

Trends for CMC Post-Approval Change Review Time: 2018-2024
Karim Kacimi, *Novo Nordisk A/S*

Better Together: Reliance Practices at Swissmedic
Simon Dalla Torre, *Swissmedic*

15:10-15:40 The Ballroom Foyer Level B2

Networking Break

Presentation type: IP - In Person

15:40-16:55 The Ballroom Level B2

Session I Panel Discussion Q&A

Sandra Auguste-Bowler, Ulla Grauschopf, Richard Keane, Helen Newton
Presentation type: IP - In Person

Additional Panelists:

Mphako Brighton Ratlabyana, *SAPHRA – South African Health Products Regulatory Authority*

Veronika Jekerle, *EMA - European Medicines Agency*

18:00-22:30 Sandoase Basel

Welcome Reception and Networking Dinner

Presentation type: IP - In Person

Join us for the welcome reception at Sandoase Basel, a beautiful waterfront venue overlooking the Rhine. Sandoase offers a cozy lounge and spacious terrace making it the perfect place to connect with fellow attendees and kick off the event. Dinner, drinks, and great views await!

Tuesday, 21 October, 2025

07:30-08:30 The Ballroom Foyer Level B2

Registration

Presentation type: IP - In Person

Registration will be open until 17:00

08:30-09:55 The Ballroom Level B2

Session II: Analytical Procedures & Platform Methods: A Deep Dive into the Guidance and Challenges Associated with Method Development, Validation, and Method Replacement

Kristina Martinell, Lionel Randon, Tara Sanderson, Heli Suila
Presentation type: IP - In Person

Over the last year, we have seen updates in the regulatory guidance that support analytical procedure development and validation as well as the utilisation of platform analytical procedures. In 2024, ICH Q14 became effective providing greater clarity on lifecycle management of analytical procedures using risk management and enhanced analytical approaches to complement ICH Q2. In light of these new approaches, we have recently seen a publication from PDA (1) that builds upon these principles and provides a dedicated chapter to method replacement, and includes the concepts of risk and prior knowledge. It also provides a compromise between the very statistical approach (statistical equivalency between 2 methods) and a more pragmatic approach when the new method (or method package) is superior to the current method. In addition, the EDQM has embarked on the development of compendial general analytical procedures that align with these new approaches, thus promoting flexibility and analytical innovation (2).

However, while these guidelines provide more support for industry, there is still a need to build a common understanding between regulatory and industry expectations. Furthermore, there is still some ambiguity with how ICH Q14 can be used for analytical procedure replacement during lifecycle management. In this session, we will look in more detail at these guidance updates and regulatory expectations with presentations from EU regulators and EDQM. We will also look at the challenges industry are facing and how to solve them, with case studies from industry analytical experts and EFPIA.

(1) PDA Technical Report for Analytical Method Validation and Transfer for Biotechnology Products
(2) 2.5.43 SEC for recombinant Therapeutic monoclonal antibodies

Session Speakers:

Key Principles and Lifecycle Considerations for Pharmacopoeial Analytical Procedures
Mihaela Buda, *EDQM-European Directorate for the Quality of Medicines and Healthcare*

Establishment of Robust Compendial Methods for Analysis of Monoclonal Antibody Products
Jaana Vesterinen, *FIMEA-Finnish Medicines Agency*

Method Replacement: I Have a Bridge(ing) to Sell You
Cyrille C. Chéry, *UCB Pharma SA*

Platform Method Applications – Leveraging Knowledge and Addressing Challenges
Karina Bora, *Lonza Group AG*

09:55-10:45 Topaz 1 Level 2

Networking Break

Presentation type: IP - In Person

10:45-12:00 The Ballroom Level B2

Session II: Panel Discussion - Q&A

Kristina Martinell, Lionel Randon, Tara Sanderson, Heli Suila
Presentation type: IP - In Person

Additional Panelists:

Mihai Bilanin, *GlaxoSmithKline*
Kowid Ho, *F. Hoffmann-La Roche Ltd.*
Claudia Mueller, *Swissmedic*

12:00-13:20 The Ballroom Foyer Level B2

Networking Lunch

Presentation type: IP - In Person

13:20-14:45 The Ballroom Level B2

Session III: Reference Materials: Navigating Regulatory and Scientific Best Practices

Mihaela Buda, Katrin Buss, Teresa Pepper
Presentation type: IP - In Person

Reference materials are fundamental to the execution of analytical testing across all stages of product development and commercialization. From characterization and comparability studies to lot release and stability monitoring, these materials provide the foundation for generating trustworthy data and ensuring product quality. However, the selection, characterization, qualification, and lifecycle management of reference materials continue to present scientific and practical challenges.

This session will explore current best practices for establishing and maintaining reference materials, with a focus on standardization, stability, and ongoing suitability for intended use. It will also discuss considerations regarding the implementation of a two-tier reference material approach. The session will also cover regulatory expectations and showcase strategies to address practical hurdles in maintaining integrity of reference materials throughout the product lifecycle. Case studies will illustrate the use of reference materials for potency testing and monitoring potency drifts, to support robust and reliable analytical programs.

Session Speakers:

General Principles for Life-Cycle Management of Reference Standards
Yves Bobinnec, *Ipsen Pharma*

It's All About Consistency: Change of Reference Standards for Potency Assessment in Clinical Phases
Hermann Beck, *F. Hoffmann-La Roche Ltd.*

Lifecycle Management of Reference Standards: Case Studies and Best Practices
Carmilia Jiménez Ramírez, *Miliar Biopharma Solutions*

Harmonizing Product Quality of Biotherapeutics Through WHO International Standards
Meenu Wadhwa, *Medicines and Healthcare Products Agency (MRHA)*

14:45-15:15 The Ballroom Foyer Level B2

Networking Break

Presentation type: IP - In Person

15:15-16:30 The Ballroom Level B2

Session III: Panel Discussion - Q&A

Mihaela Buda, Katrin Buss, Teresa Pepper
Presentation type: IP - In Person

Additional Panelist:

Andrew Lennard, *Amgen Limited (UK)*
Helen Thomas, *Swissmedic*

16:30-17:40 The Ballroom Level B2

Rapid Fire Session with Regulatory Updates

Ulla Grauschopf, Kowid Ho, R. Martijn van der Plas
Presentation type: IP - In Person

This session will provide updates on some of the most recent highlights from different regulators including an update on the EU New Variations Guideline, efforts made in the area of regulation of Biosimilars, the handling of Notified Body Opinions during the assessment of the quality documentation for single integral drug device combinations, updates on 3R activities and rapid microbial methods, and an overview of the efforts from Sahpra supporting regional harmonization and piloted centralized procedures in Africa.

Featured Panelists:

Emmanuelle Charton, *EDQM-European Directorate for the Quality of Medicines and Healthcare*

Ulla Grauschopf, *Swissmedic*

Veronika Jekerle, *EMA-European Medicines Agency*

Mphako Brighton Ratlabyana, *SAPHRA-South African Health Products Regulatory Authority*

R. Martijn van der Plas, *MEB NL-Medicines Evaluation Board*

Wednesday, 22 October, 2025

08:00-08:30 The Ballroom Foyer Level B2

Registration

Presentation type: IP - In Person

Registration will be open until 15:30

08:30-09:45 The Ballroom Level B2

Session IV: Bridging Strategies During Clinical Development (Dosage Forms, Specifications, Devices)

Karoline Bechtold-Peters, Katrin Buss, Colm Reddington

Presentation type: IP - In Person

The development and approval of combination drug products benefit significantly from risk-based approaches, which utilize predictive models to assess the impact of changes on pharmacokinetics (PK), stability, compatibility, and real-world usability. The acceptability of these models by regulatory bodies is crucial, as it ensures that the predicted outcomes are reliable and can be used to streamline the approval process. Effective communication with regulatory bodies is essential for identifying and resolving potential issues before they become critical, while ongoing dialogue ensures that any changes or updates are promptly addressed. This collaborative approach fosters a transparent and efficient approval process, reducing the likelihood of delays and facilitating the timely introduction of new drug products to the market.

Clinical bridging strategies, whether conservative or smart, provide a structured approach to transitioning between different stages of drug development. Conservative strategies focus on maintaining safety and efficacy by adhering to established protocols and guidelines, while smart strategies leverage innovative methods and technologies to optimize the development process. It is the aim of the session to present more advanced and novel tools to support smart strategies.

Bridging between dosage forms is another critical aspect, ensuring that changes in the form of the drug (e.g., vial to 2 x PFS to 1 x PFS) do not compromise its efficacy or safety. This involves rigorous testing and validation to confirm that the new dosage form delivers the drug consistently and effectively. Similarly, bridging between specifications involves ensuring that any changes in the drug's specifications, such as its chemical composition or manufacturing process or subvisible particles content, do not affect its quality, safety, or efficacy. How can in-silico simulation and novel characterization means help here?

By implementing robust risk-based approaches, maintaining continuous communication with regulatory bodies, and employing effective clinical bridging strategies, including bridging between dosage forms, devices and specifications, developers can navigate the complexities of combination drug product development with confidence and precision. These practices collectively contribute to the successful development and approval of combination drug products, ensuring that they meet all necessary safety and efficacy standards.

Session Speaker:

Bridging Aspects in Terms of Medical Devices – a Regulator's Perspective
Katrin Buss, *BfARM, Federal Institute for Drugs and Medical Devices*

Regulatory Bridging for Drug Delivery Devices
Elle Lacey, *AstraZeneca*

In Vitro/in Vivo/in Silico Models to Support Bridging Strategies From SC to SC, From IV to SC and Vice Versa
Gerard Bruin, *Novartis AG*

Harnessing AI and Regulation to Hyper Accelerate Pharmaceutical R&D
Luca Emili, *InSilicoTrials Technologies*

09:45-10:15 The Ballroom Foyer Level B2

Networking Break

Presentation type: IP - In Person

10:15-11:30 The Ballroom Level B2

Session IV: Panel Discussion - Q&A

Karoline Bechtold-Peters, Katrin Buss, Colm Reddington
Presentation type: IP - In Person

Additional Panelists:

Beate Bittner, *F. Hoffmann-LaRoche Ltd.*

Ingrid Markovic, *Novartis Pharmaceuticals Corporation*

Martin Umhang, *Swissmedic*

11:30-12:45 Topaz 1 Level 2

Networking Lunch

Presentation type: IP - In Person

12:45-14:10 The Ballroom Level B2

Session V: ICH M4Q & SPQS in Regulatory Procedures: Where Do We Stand?

Sandra Auguste-Bowler, Vanja Cankovic, Richard Keane, Thomas Stangler
Presentation type: IP - In Person

Introduction of M4Q(R1) guideline on the CTD in 2002 harmonized the format of quality information for registration of pharmaceuticals for human use and offered great benefits to industry and regulators. M4Q(R2) is the next iteration to further improve registration and lifecycle management efficiency and leverage digital technologies. For the first time since its release for public consultation, you will have a chance to hear about the revision and openly discuss the new guideline.

Together with expanding the scope to include multicomponent and/or complex products, specifying the location of lifecycle management elements and better capturing the pharmaceutical development and the proposed overall control strategy, M4Q(R2) will improve submission and assessment efficiency.

It will do so by enriching communication between regulators and applicants and enhancing lifecycle and knowledge management, enabling efficient use of digital tools for submission and assessment and preparing for the closely linked, upcoming ICH guideline on structured pharmaceutical quality submission (SPQS).

We will explore SPQS and digitalization in CMC Regulatory Procedures and see how it perfectly ties into the MQ4(R2) and all the benefits it will bring to encouraging global convergence of science- and risk-based regulatory approaches in the preparation of dossiers.

Session Speakers:

ICH M4Q(R2) - Revision Overview and Regulatory Perspectives
Klara Tiitso, *EMA-European Medicines Agency*

Novel Aspects of the M4Q(R2) and Industry Perspectives
Henrik Kim Nielsen, *Novo Nordisk A/S*

Impact, Opportunities and Challenges Transitioning to CMC Structured Data Submissions in the Cloud
Rodrigo Palacios, *F. Hoffmann-La Roche AG*

Revolutionizing Regulatory Submissions Through Digital Innovation
Michael Abernathy, *Amgen Inc.*

14:10-14:30 The Ballroom Foyer Level B2

Mini-Break

Presentation type: IP - In Person

14:30-15:45 The Ballroom Level B2

Session V: Panel Discussion - Q&A

Sandra Auguste-Bowler, Vanja Cankovic, Richard Keane, Thomas Stangler
Presentation type: IP - In Person

Additional Panelist:

Laurent Lefebvre, *Novartis Pharma AG*

15:45-16:00 The Ballroom Level B2

Closing Remarks & Invitation to the CMC Strategy Forum 2026

Kowid Ho, Colm Reddington
Presentation type: IP - In Person