



Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

May 14-15, 2025
Brussels, Belgium

ABSTRACT

Platforming technologies are now widespread in biotechnology for both human and veterinary products. They have demonstrated their effectiveness and serve as powerful tools throughout cell line development, upstream and downstream operations, formulation development, and analytical testing. Platforms utilize prior knowledge and shared industry experiences to speed up the development of innovative medicines. Additionally, contract development and manufacturing companies (CDMOs) heavily utilize platforms to work across products to help clients bring innovative new medicines to the clinic.

However, there are no universal standards on how to create, justify and support platforms across the pharmaceutical industry and disciplines. Including platform information and the specific non-product level of detail in dossiers is key for regulatory agencies to evaluate a platform's robustness and applicability using tools such as a risk-based assessments. Rationale and justification on how prior knowledge and platform data is suitable for the intended product is essential in a review.

This Workshop will explore the use of platform approaches and technologies in development and registration. It will include case studies demonstrating how prior knowledge for a platform is applied across products. The objective is to help developers and manufacturers work with health authorities to align expectations from Phase 1 development through commercialization. Additional topics covered will include creating, verifying, and maintaining platforms, their lifecycle, using them in regulatory submissions, and transitioning from first-in-clinic trials to commercial approval.

Scientific Committee:

Shawn **Novick**, IABS Chair
Tura **Camilli**, Amgen
Jean-François **Dierick**, GSK
Marcel **Hoefnagel**, MEB
Christopher Carl **Frye**, Eli Lilly & Co
Caroline **Leveder**, Sanofi
Mourad **Mellal**, Catalent
Nadine **Ritter**, Global Biotech Experts
Marc **Verhagen**, Sanofi

Organizing Committee:

Shawn **Novick**, IABS Chair
Madinina **Cox**, Events Manager, IABS/MC'Com, France

PROVISIONAL AGENDA

Day 1: Wednesday, May 14, 2025

8.30am Official Welcome from IABS
Shawn Novick, IABS Vice-President

Session I - Laying the Foundation: Platform Definition, Creation and Lifecycle (or Challenges and Opportunities with Platforms for Biologics?)

Moderators: Mourad Mellal, Catalent & Jean-François Dierick, GSK

8.45am Platforms in Biotechnology Development and Manufacturing: Laying the framework
Jason **Starkey**, Pfizer

9.15am Summary of the Quality Innovation Group Listen and Learn Focus Group (LLFG)
meeting on Platforms (November 2024)
Marcel **Hoefnagel**, MEB

9.45am Platform analytical procedures and opportunities from ICH Q2 Q14
Jean-François **Dierick**, GSK

10.15-11.00am *Coffee & Tea Break*

11.00 am Standardized Platform Process With In-Line Cell Lysis Purifies Plasmid DNA Using A
Single Chromatographic Step For Cell And Gene Therapy
Sebastien **Gillet**, Catalent

11.30 am Panel Discussion with Veronika Jekerle, EMA

12.30-1.45pm *Lunch Break*
POSTER SESSION

Session II – The Use of Platform Capabilities in Late-Stage Development and Commercial Applications

Moderator: Christopher Carl Frye, Eli Lilly & Co

- 1.45pm** Analytical Platform Case Study: Is The Charge Assay Suitable As Platform Procedure
Nermin **Buza**, Novartis
- 2.15pm** The Role of Platform Host Cell Protein ELISAs in Biopharmaceutical Quality Control
Florian **Semmelmann**, Roche
- 2.45pm** Leveraging Prior Knowledge for Process Parameter Classification in mAb Protein A Chromatography
Yinying **Tao**, Lilly
- 3.15-3.45pm** *Coffee & Tea Break*
- 3.45pm** Leveraging Prior Knowledge and Platform Technologies to Streamline Biologics Drug Product Development
Sy **Gebrekidan**, Johnson & Johnson
- 4.15pm** Capturing the Essence of a Purification Step: Data-Driven Simplification of a Protein Purification Platform
Yannick **Van Haelst**, Sanofi
- 4.30-4.45pm** *Mini Break*
- 4.45pm** Panel Discussion
- 5.30pm** *End of Day 1*

Day 2: Thursday, May 15, 2025

8.30am Official Welcome from IABS
Shawn Novick, IABS Vice-President

Session III – Platforms Go Commercial: Lifecycle Management of Approved Platforms - *prior knowledge vs platform filing*

Moderator: Marc Verhagen, Sanofi

8.45am The Journey of Compdial General Analytical Procedures: From Establishment to Lifecycle Management
Mihaela **Buda**, EDQM

9.15am Commercial Submission Considerations for Platform Analytical Procedures
Karen **Rule**, Pfizer

9.45am Platform Lifecycle Management of Commercial Product
Kowid **Ho**, Roche

10.15am *Coffee & Tea Break*

10.45am The Use Of Platform Technologies In Regulatory Applications For Veterinary Vaccines In The European Union – Perspective From The Pharmaceutical Industry
Frédéric **Descamps**, Zoetis

11.15am Panel Discussion

12.15pm *Lunch Break*
POSTER SESSION

Break-Out Working Sessions: Early Phase/Commercial Platforms

Moderators: Nadine **Ritter**, Global Biotech Experts, Shawn **Novick**, IABS, Jean-François **Dierick**, GSK & Caroline **Leveder**, Sanofi, Ruby **Casareno**

1.15pm 4 Break-Out Working Sessions:
Early Phase Process/Analytical
Commercial Process/Analytical

2.30 pm Feedback

3.00pm *Afternoon Break*

Session IV – Remaining Hurdles: Sponsor Master Files? CDMO Master Files? Global Acceptance of Platforms?

Moderator: Nadine **Ritter**, Global Biotech Experts

3.30pm Thoughts from a former regulator on platform technologies, platform technology designation, and the use of contract manufacturing/testing organizations for biotechnology products.
Marjorie **Shapiro**, FDA-CDER retired

4.00pm Perspective, Regulatory, or other presentation style without primary data: Industry Proposal – EFPIA/CEPI White paper platform MFs
Mihai **Bilanin**, GSK

4.30pm Leveraging Platform Approaches In Regulatory Filings
Laurent **Lefebvre**, Novartis (Virtual)

5.00pm Panel discussion

5.45pm End of meeting

Session II

The Use of Platform Capabilities in Late-Stage Development and Commercial Applications

Chairperson: Christopher Carl **Frye**, Eli Lilly & Co

This session will focus on real examples of how platforms for large molecule modalities, both process and analytical, can be developed, submitted to Health Authorities, and successfully implemented. Key enablers and challenges for a successful submission will be presented and discussed. Documentation, data analysis and use of prior knowledge in the scientific justifications along with key experimentation from development through commercial application are among the topics we hope to cover as it pertains to the updated ICH guidance.