International Alliance for Biological Standardization

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.

PROVISIONAL AGENDA

Day 1: Wednesday, May 14, 2025

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

Session I - Laying the Foundation: Platform Definition, Creation and Lifecycle

*Moderators: Mourad **Mellal**, Catalent, Jean-François **Dierick**, GSK, Marcel **Hoefnagel**, MEB & Shawn **Novick**, IABS*

8.45am Laying the Foundation for Platform tech

9.15am Definitions: What is a platform (regulatory perspectives) – Marcel **Hoefnagel**, MEB

9.45am Industry Perspectives Analytical – Jean-François **Dierick**, GSK

10.15-11.00am *Coffee & Tea Break*

11.00 am Industry Perspectives Process

11.30 am Panel Discussion

12.30-1.45pm *Lunch Break*
POSTER SESSION – from 1.15-2.00 pm

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

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

1.45pm Analytical Case Studies

2.15pm Analytical: Different modalities

2.45pm	Analytical: Different CMC aspects; ADCs mRNA, DP, Analytical
3.15-3.45pm	*Coffee & Tea Break*
3.45pm	Process: Creating and maintaining a platform
4.15pm	
4.45pm	
5.15pm	Panel Discussion
6.15pm	*End of Day 1*

Day 2: Thursday, May 15, 2025

Session III – Forward Looking Opportunities – Impact to CDMOs, Impact to Sponsors

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

8.45am	
10.30am	*Coffee & Tea Break*

Session V – Break-Out

11.15am	What do we want this to look like in 5 years?
	How to get there ? (Discussion with regulators)
	Be provocative
12.15 pm	Feedback
1.00-2.00pm	*Lunch Break*

Session V – Platform Go Commercial

*Moderator: Marc **Verhagen**, Sanofi*

2.00pm	Life cycle management: commercial
2.30pm	New sites
3.00pm	Using and Filing the Master File
3.30pm	*Coffee & Tea Break*
4.00pm	Panel discussion
5.00pm	Conclusions
5.00pm	End of meeting

Session II — Case Studies – 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.