



International Alliance for
Biological Standardization

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Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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
- **Christopher Carl Frye**
Eli Lilly & Company
- **Jean-François Dierick** - GSK
- **Marcel Hoefnagel** - MEB
- **Caroline Leveder** - Sanofi
- **Mourad Mellal** - Catalent
- **Nadine Ritter** - Global Biotech Experts
- **Marc Verhagen** - Sanofi

More information



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Venue:

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