



International Alliance for
Biological Standardization

Europe



Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

May 14-15, 2025
Brussels, Belgium

Leveraging Prior Knowledge and Platform Technologies to Streamline Biologics Drug Product Development

Background OR Introduction:

Biologic therapeutics have been transformational in the treatment of diseases and will continue to grow in importance over the next decade. The promise of these therapeutics has necessitated the need to accelerate their development and commercialization.

Challenges

However, due to the inherent complexity of Biologics, acceleration can be challenging. Additionally, the amount of material available for development is frequently limited. Therefore, it is critical to employ efficient development strategies and processes that enable successful development.

Proposed Approach, Approach Being Taken, Proposed Solutions, OR Relevant Guidance

Maximizing value during development can be achieved through leveraging prior Knowledge and Platform Technologies to streamline Biologics Drug Product Development. In silico derived physicochemical properties can be compared to properties of previously developed assets to guide the prioritization of laboratory experimentation. This experimentation can be further streamlined through the use of High-Throughput Screening platforms.

In silico modeling platforms can also be employed towards development of fill/finish manufacturing processes. Advanced tools such as computational fluid dynamic modeling, in combination with prior knowledge, can be used to develop platform processes, which in turn reduces the large consumption of materials and development time associated with at-scale experimentation.

Furthermore, standardized Control Strategy platforms can further accelerate development.

Conclusions:





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Implementation of standardized processes and platform technologies enable the acceleration and streamlining the development and commercialization of Biologic Drug Products

