



International Alliance for  
Biological Standardization

Europe



## Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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### Platforms in Biotechnology Development and Manufacturing: Laying the framework

#### Background

The application of platforms in biotechnology encompasses various processes, procedures, and technologies. However, the concept is greatly matured since its introduction, and there are many more real-world applications to illustrate the concept.

#### Challenges

The establishment and justification of these platforms may vary depending on their specific application or stage of development. The appearance and functionality of a platform will differ significantly based on its intended use or the entity responsible for its development.

#### Relevant Guidance

This presentation will focus on the utilization of platforms from an industry perspective, emphasizing the benefits and opportunities they provide. Key elements fundamental to platform use, including how they can streamline and enhance process and product understanding, will be addressed. Potential lifecycle considerations that aid in framing decisions for late-stage development and the internal management of platforms within companies will also be discussed. Additionally, the capability to transfer and sustain platforms across a global manufacturing network will be examined. Finally, as new modalities emerge and existing platforms are extended to meet evolving needs, considerations for future applicability will be explored.

#### Conclusions

As we advance in integrating platforms across various technologies, processes, and procedures, this approach has great potential to significantly enhance the pace of development and expedite the delivery of new medicines to patients.

