



International Alliance for
Biological Standardization

Europe



Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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Title: The Journey of Compendial General Analytical Procedures: From Establishment to Lifecycle Management

European Pharmacopoeia (Ph. Eur.) standards are a key component of the regulatory framework. They rely on specifications for products approved in the Ph. Eur. member states, and are established and maintained through a rigorous process, based on robust data and sound scientific principles. Compendial general analytical procedures are designed for broad applicability across multiple (types of) products, with specific steps required to demonstrate suitability for a specific product. This presentation will highlight key concepts underlying these analytical procedures and their lifecycle, from establishment to implementation, including also elements such validation, revalidation of technical modifications to existing procedures, and comparability of alternative analytical procedures. Drawing on recent examples from the standardisation of methodologies for monoclonal antibodies' analysis, the presentation will illustrate how the Ph. Eur. ensures that these procedures remain scientifically robust, offering insights to broader analytical procedure lifecycle strategies to enable flexibility and innovation.

