Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

May 14-15, 2025
Brussels, Belgium

Perspective, Regulatory, or other presentation style without primary data: Industry Proposal – EFPIA/CEPI White paper platform MFs

Background OR Introduction:

Enabling innovation in manufacturing, via a world leading regulatory framework, is a critical requirement for Europe to maintain its competitiveness and leading position as a supplier of medicines to the world.

Challenges OR Issues:

Many manufacturing processes and control strategies use similar or identical platforms to deliver quality medicines. As a result, during the registration of a new Marketing Authorisation Application (MAA) or submission of a Clinical Trial Application (CTA) for human medicines and their respective lifecycle (LC) submissions, applicants often reproduce the same or similar information in regulatory dossiers which are applicable equally to multiple products, even if this information has already been approved by a competent authority, leading to redundant reassessments of the same information in multiple applications. Current uses of MF (ASMF, PMF and VAMF) are limited in scope and do not support efficient authoring, submission or review of MAAs or CTAs when materials, components or platform technologies are used that can apply to multiple products.

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

EFPIA/VE has developed an industry position related to key guiding principles that can facilitate and enable the deployment of platforms and the use of prior-knowledge through the development of a world-leading regulatory tool (i.e., Platform Technology Master Files across modalities, see * Expanding Master Files for human medicinal products in the EU/EEA)

This position paper focuses on the significant need for an extended MF concept that would be widely applicable across therapeutic modalities, materials and components used in the manufacture of finished drug products. It would apply across the development and lifecycle of the materials and could also support the provision of process & analytical prior knowledge.

International Alliance for Biological Standardization

Europe

Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

May 14-15, 2025
Brussels, Belgium

Conclusions:

The significance of these "platform technology master file" concepts to patients and the modernization of manufacturing cannot be overstated for a rapid development, scale up and supply and for enabling innovation in manufacturing and development of new, complex active substances, finished products and devices.