



International Alliance for
Biological Standardization

Europe



Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

May 14-15, 2025
Brussels, Belgium

EMA QIG Listen & Learn Focus Group on Platform technologies; What have we learned?

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The EMA Quality Innovation Group (QIG) organised a Listen & Learn Focus Group (LLFG) on Platform technologies in November 2024¹. In this open dialogue stakeholders were invited to share their thinking on platform technologies in pharmaceutical manufacturing and present case studies that use prior knowledge to support manufacturing platforms. The meeting aimed to also identify general scientific challenges with the use of platforms and possible solutions.

Three scenarios were discussed: 1) Platforms for medicinal products manufactured using prior knowledge, such as common manufacturing platform approaches (multiple MAs). 2) Platforms for medicinal products against agents which are or have a potential to cause serious cross-border threats to health e.g. pandemic/pandemic preparedness (one MA). 3) Platforms for the manufacture of personalised or individualised medicines (one patient/group of patients-one product', one MA) e.g. covering different ultra-rare orphan indications.

Ten case studies were presented including: Platforms technologies for accelerating vaccine development, *Ex vivo* gene therapies for rare genetic diseases, mRNA-lipid nanoparticle and synthetic oligonucleotides. Topics discussed included: platform definition, minimum data required to show that a platform is established, applicability of a platform to different products and lifecycle management considerations. Although End-to-End approaches are feasible for some processes, some stakeholders proposed modular approaches. The possibility for CDMO to use data from different sponsors for efficient & accelerated development and process characterisation was discussed.

¹ https://www.ema.europa.eu/en/documents/report/report-fourth-listen-learn-focus-group-meeting-quality-innovation-group_en.pdf¹

