Industry Priorities for the QIG

- Enabling the introduction of **new technologies** (e.g. for manufacturing, analysis, stability, drug delivery, new materials)

- Delivering harmonised global **frameworks that enable post-approval change** and implementation of innovation in manufacturing, to improve quality, sustainability and to address shortage prevention

- Enhancing the regulatory framework to **enable more mobile, modular manufacturing, including at point of care**, and require enhanced regulatory frameworks to support (e.g. platform technology master files or satellite GMP manufacturing)

- Supporting the **digital revolution in manufacturing** (including areas such as quality and compliance data in regulatory files and submissions, modelling and AI in manufacturing and control systems).

- Enabling **new science- and risk-based approaches to provision of Quality data** for clinical and marketing authorisation applications as well as variations

- **Supporting the implementation of new materials, new control strategy approaches and new product modalities** (e.g. mRNA vaccines, oligonucleotide therapeutics, peptides, ATMPs)

More specifically, the following "game-changing" technologies should be prioritised:

- **Analytical innovations for biological products such as multi-attribute methods (MAMs)** using LC-MS to replace in-vivo testing (e.g. potency assays) by automated in-vitro tests (e.g. cell analysis), with a focus on 3Rs principles.

- Novel, **automated sterile manufacturing technologies** to enable rapid development and supply and to allow multiple manufacturing processes in a single facility, coupled with **rapid microbiological QC technologies**.

- **Continuous manufacturing** (incl. wet granulation, direct compression, continuous biological processing and flow synthetic chemistry).

- **Autonomous & portable manufacturing** facilities & point-of-care and/or **distributed manufacturing** frameworks.

- **Digital/in-silico/AI based modelling approaches** for process development, process and product understanding (incl. stability) and control strategy.

- **Technologies & strategies to support accelerated assessment of comparability** following changes (such as in silico biopharmaceutics models, CQA-based assessment of biological products).

Updates to the regulatory framework in Europe

- Modernization of the EU variation framework
- Establishing a Platform Technology Master File process
- Greater flexibility in Directive 2001/83/EC Annex 1
- Alternative manufacturing processes for biological drug substance
- Updates to EudraLex GMP, such as
  - Test data in units not directly aligned
  - New approaches to environmental monitoring for self-contained, modular sterile manufacturing platforms.