



Global regulators and biopharmaceutical and vaccine industry to share experiences with managing pharmaceutical quality systems

On 20 July 2023, the International Coalition of Medicines Regulatory Authorities (ICMRA) [is hosting](#) a virtual workshop on the development of a global Pharmaceutical Quality Knowledge Management System (PQ KMS), which aims to facilitate the exchange of knowledge related to pharmaceutical quality amongst national regulatory authorities worldwide.

The workshop will be attended by representatives from the leading trade associations representing biotech companies, vaccine manufacturers from across the globe, and innovative biopharmaceutical, generic and biosimilar companies. This represents an important opportunity for the associations to share industry's experience with the two ongoing pilot programmes initiated within the PQ KMS, on post-approval change management and hybrid inspections.

The operational agility that enables companies to respond to changes and improvements in their manufacturing processes, adapt to new technological advancements, and reflect evolving supply chains is critical for the biopharmaceutical and vaccine industry. Companies manage these changes within their pharmaceutical quality systems and seek regulatory review when changes require prior approval. Given the highly regulated nature of the industry, as well as its global presence, companies must often obtain approvals from multiple national regulatory authorities with different timeframes. However, this can potentially lead to delays to the implementation of any changes.

By aligning on data submissions and expectations for applications, the aim of the PQ KMS is to efficiently manage post-approval changes and streamline CMC assessments and facilities inspections to enable greater regulatory reliance among national regulatory authorities.

During the workshop, the biopharmaceutical and vaccines industry will present case studies providing an overview of experiences to date with the pilot programmes, along with recommendations for additional approaches that can allow for more efficiencies.

The trade associations acknowledge and appreciate ICMRA's global leadership and commitment to fostering collaboration and information sharing among national regulatory authorities. Such open exchange and collaborative efforts between industry and regulatory bodies can help advance regulatory systems, expedite the availability of quality medicinal products to patients while maintaining robust regulatory oversight and ensuring patient safety. The recognition of the need for operational agility within pharmaceutical manufacturing processes is strongly welcome.

This workshop is organized with the following industry associations:

- Association of the British Pharmaceutical Industry [ABPI](#)
- Biotechnology Innovation Organization [BIO](#)
- Developing Countries Vaccine Manufacturers' Network [DCVMN](#)
- European Federation of Pharmaceutical Industries and Associations [EFPIA](#)
- International Federation of Pharmaceutical Manufacturers and Associations [IFPMA](#)
- International Generic and Biosimilar Medicines Association [IGBA](#)
- Japan Pharmaceutical Manufacturers Association [JPMA](#)
- [Medicines Australia](#)
- Pharmaceutical Research and Manufacturers of America [PhRMA](#)
- [Vaccines Europe](#)