How does Viatris work to promote product quality?

Protecting patients and consumer health by ensuring the quality and safety of our products is at the heart of how we operate across our network. Every step of our development, manufacturing and monitoring processes – from developing products to sourcing of raw materials to producing and distributing finished dosage forms – is grounded in this commitment.

> All Viatris operations are covered by and expected to comply with statutory and regulatory requirements, such as current Good Manufacturing Practices (cGMP), Good Pharmacovigilance Practices (GPvP), Good Distribution Practices (GDP) and Good Clinical Practices (GCP) for all markets that they serve.

We maintain a robust quality infrastructure and strategy, encompassing all our operations and manufacturing sites globally. This infrastructure is comprised of the extensive experience and expertise of our personnel, our comprehensive Global Quality Policies that establish uniform requirements for fundamental processes and controls within our Global Quality Management System (QMS), as well as Global Quality IT systems, which are implemented and designed to establish industry best practices, consistency and global quality assurance throughout our network.

We continuously evolve our quality organization to ensure alignment with our business operations and to enhance compliance with applicable standards. Existing global quality resources are embedded within operational verticals to align closely with business units and drive consistency across sites.

We apply relevant external quality guidelines into our Global Quality Policies and Management Systems, including: EudraLex, Falsified Medicines Directive, ICH Quality Guidelines, WHO GMP, U.S. Food and Drug Administration Safety and Innovation Act and the EU Excipient Risk Assessment for ascertaining the GMPs for all the excipients of medicinal products for human use. We have developed and maintain a Regulatory Intelligence, Quality Action System and Knowledge Management Dissemination Program to inform, evaluate and implement regulatory updates, industry trends and internal knowledge across the Viatris network.

And in addition to continuously monitoring and evolving our approach to quality, colleagues around the world are provided training on quality culture to ensure personnel have a clear understanding of our commitment to quality.

- Procedural and cGMP training is required for all personnel whose duties are in any way associated with the manufacturing, packaging, processing, holding or testing of products

or whose duties require them to enter manufacturing areas or laboratories, as well as any other personnel whose activities could affect the quality of the product. Personnel working in areas where contamination is a hazard, such as clean areas, sterile areas or areas where highly active, toxic, infectious or sensitizing materials are handled, are given additional specific training. Training in cGMP is conducted by qualified individuals to ensure that employees remain familiar with the specific cGMP requirements applicable to them.

Quality Risk Assessment

Proactive risk assessment is central to our approach to ensuring quality. We apply the principles outlined in the International Conference of Harmonization (ICH) Q9 Quality Risk Management as well as those in ICH Q10 Pharmaceutical Quality System.

Ensuring a High-Quality Supply Chain

To help ensure the integrity of our supply chain, a highly experienced Viatris cross-departmental committee including Sourcing and Quality undertakes a rigorous review of suppliers and third parties prior to their selection for the supply of active pharmaceutical ingredients and drug products.

Working with Health Authorities

We constantly review our products, processes and facilities throughout our network and work closely with external health authorities to ensure transparency regarding emerging information, including shortages, the development of new scientific and testing criteria and evolving regulatory and manufacturing expectations everywhere we operate. We continuously learn from these interactions as scientific, technological and regulatory expectations continue to evolve. In 2023, more than 95 health authority inspections were conducted across our facilities.

External Engagement on Quality

Viatris actively engages and collaborates with external stakeholders to advance quality management in the pharmaceutical sector. We are members of and have representatives on key recognized industrywide partnerships and groups such as the International Society for Pharmaceutical Engineering (ISPE) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

A few examples of our active participation include:

- ISPE's Core Team on Advancing Pharmaceutical Quality (APQ) program, an industry-led quality management maturity assessment and benchmarking program
- ICH Quality Risk Management Implementation Working Group
- ISPE GAMP India Steering Committee

6/26/24