How does Viatris guided in

compassing all our operations and
rised of the extensive experience and
y Policies that establish uniform
ith our Global Quality Management
lemented and designed to
lity assurance throughout our

ignment with our business
ndards. Establishing global quality
o align closely with business units and

We apply relevant external quality guidelines into our Global Quality Policies and Management Systems, including Eudralex, Harmonised Policies Directive, EU Quality Guidelines, WHO Good and Drug Administration Safety and Innovation Act and the Excipient Risk Assessment for ascertaining the GMP 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.

Aim in addition to continuously monitoring and evolving our approach to quality, colleagues

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