Ensuring Quality and Patient Safety in Processes and Products

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 raw materials to producing and distributing finished dosage forms – is grounded in this commitment.

Quality Management

All of Viatris' operations, manufacturing sites and our contract manufacturing organizations (CMOs) globally are subject to robust quality infrastructure and strategy. 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.

All of our operations are also subject to robust quality systems, standards and processes which are designed to ensure product quality and patient safety. These programs are designed and implemented across our global operations and are executed in alignment 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. Each of our sites within our global network maintain the relevant licenses and GMP certifications required by their respective market and approved product authorizations.

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.

Core elements in Viatris' Quality Management System standard operating procedures include the following:

- Managerial oversight and responsibility
- Ongoing and continuous training
- Frequent internal site and external supplier, contractor and service provider audits
- Testing practices and compendial compliance
- Product risk assessment
- Regular compliance monitoring and communication
- Incident investigation and corrective and preventive action
- Standardized document control and change management
- Compilation, trending and review of key quality metrics

Key programs within our Quality Management organization driven by senior leadership currently include, but are not limited to, the following:

- Governance over our global data integrity program, including a broad scope: computerized systems, record management, documentation governance, training, policy, auditing, etc. to ensure data reliability throughout the data lifecycle.
- A comprehensive cleaning program which to ensure we produce quality products that are free from contamination, and a robust cleaning validation program established to support the implementation of robust cleaning methodology.
- Each manufacturing site has a comprehensive automation/ digitalization roadmap outlining future enhancements to support quality best practices and ensure our sites stay current in the use of technology. These roadmaps include elements such cludea enTjd(.063 ns iT beQ Tdtice36 36 26ext8 s i.757ifefBT1 1 1 dtice/TT2 1

- Our Product Health Evaluation program proactively facilitates life-cycle management of the manufacturing and testing processes through a structured problem solving approach. Product Health is defined as an indication of a pharmaceutical product's ability to be consistently produced to optimal performance within the registered specifications, with minimal deviations or customer complaints, which ensures supply continuity.

Quality Governance and Organization

The Chief Quality Officer reports to the CEO, and the following functions are within the overall Global Quality structure:

- Global Operations Audit
- Global Learning and Development and Regulatory Intelligence
- Global Quality Compliance
- Global OSD and API Quality
- Global Injectables Quality
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regulatory inspection performance, and potential risk for each production/API site, packaging site, distribution site and laboratory site.

- Internal sites are required to formally respond to all observations within 15 business days to the Global Operations Audit team and take appropriate corrective and preventative actions in response to any observations, with set timelines for implementation.
- Quality councils at each site oversee and monitor key performance indicators, track quality incidents, identify trends and have the authority to escalate incidents to senior quality leadership.
- At the global level, senior quality leadership routinely reviews and monitors key performance indicators from each vertical/site and their respective corrective/preventive actions for incidents and trends.

The global internal operations audit program includes expedited timelines for the issuance of observations and increased site leadership engagement to ensure the immediate remediation of the identified observations. We maintain a strong focus on global investigations' oversight, third-party management and surveillance across our sites and further enhanced our investigatory and surveillance programs throughout 2023.

Following each internal operations audit, the inspected site is required to submit a corrective and preventive action (CAPA) plan to remediate any identified discrepancies. These CAPAs are submitted to our Global CAPA Management team for review and approval. Furthermore, all CAPAs from critical, major and/or minor observations are reviewed and verified for completion by the Global Operations Audit Team prior to observation closure. In addition, CAPAs from critical and/or major observations are subject to additional review upon the next scheduled internal operations audit to ensure compliance and the CAPA plan's effectiveness.

Quality Culture

Colleagues are provided training on quality culture to ensure personnel have a clear understanding of our commitment to quality. Key components of our quality culture include the following:

- Excellence via Quality: We must all do what's right, not what's easy. We focus on getting our work done right the first time. We follow our robust processes and pay close attention to detail. And we understand the science.
- Integrity via Quality: If you see something that isn't right, speak up. Our reputation depends on it. We are all accountable for operating with integrity and empowered to take action to do what is right.
- Accountability via Quality: At Viatris, we are all accountable for operating with a quality-first mindset. Our commitment to quality gives patients the assurance they need to be empowered to live healthier at every stage of life.
- Proactivity via Quality: We are proactive and seek to address issues before they become problems. We collaborate with others to generate solutions and implement them quickly.
- Reliability via Quality: A focus on simplification — overly complex processes can lead to mistakes. We never settle for "good enough." Business continuity is enabled by a commitment to quality.

In 2023, we launched our Human Error Prevention (HEP) program to provide a structured approach to identify the underlying reasons and solutions for human error and reduce the likelihood of reoccurrence. HEP focuses on why a person made an error, exploring external causal factors such as environment, support systems and culture, which can be more effective than retraining or counseling alone. A quality mindset is essential to support a strong quality cultural baseline and the HEP program provides an additional step in maintaining that strong foundation.

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 Harmonisation 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

Contract Manufacturer Organization Quality Oversight

Viatris' CMOs are subject to robust quality systems, standards and processes which are designed to ensure product quality and patient safety. These are designed to comply with statutory and regulatory requirements, such as cGMP, GPvP, GDP and GCP for all markets served. Viatris systematically engages with CMOs on changes, complaints and investigations. In 2023, we further augmented our supplier quality oversight by establishing a new dedicated team for supplier qualification with a global scope.

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.

- Health authority inspections provide extensive external certification of Viatris' internal sites and our external contractors/ suppliers and provide authorization for further production and marketing.
- We work diligently to address all observations identified by health authorities and at this time have closed all FDA Warning Letters.[1]
- In 2023, more than 95 health authority inspections were conducted across our facilities. The number of health authority inspections has continued to increase globally to account for normal health authority inspection cycles and sites that were not inspected during the COVID pandemic due to health and safety concerns related to COVID-19.

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Viatris Quality representatives routinely participate in multiple events with health authorities such as the U.S. FDA and industry bodies such as Parenteral Drug Association and the International Society for Pharmaceutical Engineering. These forums are designed to share experiences and approaches to facilitate sustained compliance with cGMPs by addressing emerging risks to manufacturing and supply chain reliability. The forums provide an opportunity for open discussion between FDA representatives and industry experts, offering opportunities for practical insights into building an effective quality assurance program in accordance with cGMP and global regulations.

Product Safety & Risk Management

Our Product Safety & Risk Management (PSRM) function has a Pharmacovigilance (PV) system, which is global in scope with robust processes described in more than 120 global policies, standard operating procedures and work instructions, designed to help ensure patient care and safety in relation to the use of our products during both their development and their placement on the market. To support Viatris' strategic plan and safeguard a reliable supply of medicine, members of the PSRM function participate in various acquisition and divestment efforts and collaborate with the selling or buying parties to ensure applicable products have uninterrupted risk-benefit profile monitoring and regulatory compliance.

As part of our global PV procedures, the risk-benefit profile of all our products is continuously monitored and assessed through various core PV activities, such as Individual Case Safety Report (ICSR) management, aggregate data review and reporting, Signal Management and Risk Management Planning.

Applicable global PV governance committees, such as the Corporate Product Safety Committee and the Pharmacovigilance System Oversight Committee, are responsible for the periodic and ad-hoc evaluation of new safety-relevant information so that the timely communication of important new safety information to the regulatory authorities, healthcare professionals and patients is ensured, and they also facilitate full oversight of the compliance and performance of the Viatris PV system.

We have highly skilled and trained cross-functional teams of more than 1,000 medical and scientific professionals who review and report our risk and benefit assessments to regulatory authorities worldwide.

There is currently no globally harmonized international standard on what constitutes a recall. Viatris has established standard best practices through the implementation of a global standard operating procedure detailing the notification and assessment of critical quality events to determine whether notification to the national health authorities, and/or a recall will be conducted. Such decisions are made in alignment across Quality, Pharmacovigilance, Legal Regulatory and Communications teams including the oversight of the Chief Quality Officer. Each site must develop and maintain a written procedure to govern the recall of products based upon local health authority regulatory requirements in the territories in which their respective products are provided. A product recall serves to safeguard the health of patients, demonstrating our responsibility and the efficacy of the Quality Management System (QMS).

It is relevant to point out that as the vast majority of recalls are voluntary and not mandated by health authorities, the level of conservatism demonstrated by a company can influence its total number of recalls. This number is also heavily impacted by the type and number of products within a company's portfolio, along with other factors.

Conducting Responsible Clinical Development

Clinical operations, including clinical trials, are key to advancing access to medicine for patients across the world. Viatris is committed to conducting clinical trials in an ethical way and promoting patient safety and the protection of patient rights throughout a study's lifecycle. Our clinical research program and applicable standard operating procedures are global in scope and designed to adhere to international best practice as defined in the Declaration of Helsinki, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) framework and Good Clinical Practice (GCP).

Key events in 2023 included increasing collaborations with our partners, vendors and investigators with development plans in multiple regions throughout the world. Our active programs in 2023 included COPD studies in India and China, anxiety and depression studies in Japan and women's health studies in North America.

In 2023, we continued research activities across diverse regions in which patients may experience various healthcare and/or economic challenges and in therapeutic areas that are part of expanding Viatris' offering to patients. We launched new studies in 2023 in areas including Greater China, India, Japan, Europe and North America. Our research encompassed varied therapeutic areas, including mental health disorders, COPD, chronic plaque psoriasis and women's health, among others.

We conduct clinical trials in many regions of the world as part of the process to eventually make treatments available to patients globally. To support the further expansion of Viatris' portfolio and bring more products to more patients with diverse needs, we are increasing the number of trials in new settings. Moving forward, Viatris will continue to work to include patient representatives of the regions where approval is sought, focusing on improving patient access to needed therapies globally.

Diversity in Clinical Trials

Viatris supports efforts focused on diversity in clinical trials and works to include diverse patient populations for global studies that will be submitted for approval to health authorities around the world. Considerations for diversity include both demographic criteria (e.g., gender, race and ethnicity) as well as non-demographic criteria (e.g., co-morbidities, organ dysfunction, the extremes of weight ranges). Viatris is committed to working with health authorities to enhance safety, scientific rigor and diversity in our clinical trials. Health authorities across the globe have called for increased pediatric research to support accurate labelling for pediatric populations. Viatris is committed to complying with applicable GCP requirements to ensure pediatric clinical trial requirements are implemented with a focus on patient safety and integrity.

Management and Oversight

The Head of Global Clinical Operations reports to the Head of Global Medical Affairs. Our Global Quality Management System (QMS) is at the core of our clinical investigations. It includes procedures on internal processes associated with drug development as well as processes for overseeing and auditing outsourced activities completed by our vendor partners. Dedicated independent members of our Quality team conduct periodic assessments and audits across our operations and at our vendors. Any potential or actual incidents are managed through clear processes and escalated to senior management as appropriate. Our QMS requires the ongoing review of procedures to ensure continued alignment with GCP regulations and guidance documents.

Global Standards for Responsible Clinical Operations

Regardless of where clinical trials are conducted and whether they

Viatris' governance councils, quality committees and clinical development teams oversee the conduct of clinical trials, including the regular monitoring of ongoing trials, and partner with internal and external experts and investigational sites to promote patient safety and data integrity across our clinical development programs. In addition, we use quality councils, governance boards and independent data monitoring committees when appropriate to support quality, safety and protection of participants in our clinical development programs.

Our standard operating procedures specifically address the requirements associated with the development of investigator brochures, clinical protocols and informed consent forms to adhere to applicable regulations. A cross-functional development and review process is incorporated into the procedures to ensure that experts in various functions have input into the design and approval of these documents. These documents provide clinical investigators with sufficient background on the investigational product to protect the safety of research participants, validate that the clinical study is scientifically rigorous and ensure participants are well informed of the potential risks and benefits, study goals, procedures and their critical role in clinical research. All employees involved in this aspect of a clinical trial are subject to training for this purpose.

Informed Consent

The company's standard operating procedure governing the informed consent process is part of the QMS. It includes detailed procedures regarding the development, review, approval, implementation and confirmation of the informed consent process for adult and pediatric trials.

- Informed consent documents are written in a manner that allows potential trial participants, regardless of reading skills and local language, the ability to make an informed decision that considers the potential risks and benefits of trial participation.
- Local independent ethics committees review and approve informed consent forms prior to patient participation in a clinical study.
- The clinical investigator ensures that patients understand the informed consent document prior to participation in the clinical study.
- As part of adhering to GCP, trial participants are provided instructions for contacting clinical site staff to address questions and concerns during the course of the clinical trial.

Viatris' Product Security team conducts industry leading monthly threat assessments of products in our portfolio that may be at a higher risk for counterfeiting, diversion or subject to intellectual property theft. This assessment takes into consideration several aspects including therapeutic category, dosage type, regulatory and medical affairs concerns, and previous incident history. Products with higher levels of risk are monitored across a variety of online forums, including business to business, business to consumer, consumer to consumer, social media platforms and the dark net.

In addition to internal training of colleagues, Viatris has an outreach program that has delivered educational awareness on product security to law enforcement and regulatory partners in Africa, the Middle East, Europe and Latin America, with plans to expand the program to the Asia Pacific region.

External Stakeholder Collaboration

We conduct proactive investigations when there is suspicion of counterfeit or at-risk products and to support health authorities and law enforcement investigations. In addition to internal resources, we collaborate with external stakeholders such as online sales platforms and customs agencies to further identify and prevent the distribution of counterfeit products by removing illicit online sites and disrupting and seizing illicit products.

Our laboratory also has a mobile testing capability that can provide dynamic support in time-critical situations.

Suspicious Order Monitoring

We have controls to guard against theft and diversion of controlled substances and operate a system to identify suspicious orders of controlled substances. We have a cross-functional team including members from Compliance, Customer Relations, Controlled Substance Monitoring, Global Security, Distribution, Regulatory Legal and Regulatory Affairs that works to operate our strong programs designed to detect and prevent diversion within the supply chain. This cross-functional team has established partnerships with customs agents, local and federal law enforcement and state and local licensing officials. At the same time, we take steps to help ensure that patient care is not interrupted by disruptions in the flow of medication to our customers across the globe.

The Global Security team also operates an outreach training program designed to raise awareness and build capacity and capability with law enforcement and regulatory partners. We are active members of a variety of industry and brand protection groups regionally as well as specialist forensic groups.

We have developed a dedicated forensics laboratory service that is able to conduct visual and chemical authentication of our products and provide expert reports and testimony to further support our government partners.

Our suspicious order monitoring program includes, for example:

- An experienced compliance team
- A dedicated suspicious order monitoring team
- Data and analytical programs
- Customer due diligence
- Education and training
- Ongoing engagement with state and federal regulators

In addition, we have a dedicated product diversion program that encompasses anonymous reporting mechanisms, which together with our suspicious order monitoring systems supports risk mitigation. We have made significant investments in packaging, information technology and security features to further enhance our ability to detect and prevent the distribution of counterfeit products.

By lowering the likelihood that illicit products will enter the supply chain, we are helping to ensure the integrity of distributed products and continued access to high-quality medicine. The company has global policies to govern validation, operations, serialization and product security. All manufacturing sites have procedures to drive consistency in packaging, management, master data and distribution of serialized product. Among these are processes to track and trace serialized products. An internal product safety group assists in monitoring the supply chain to help ensure it is not breached.

Serialization

Viatris' Center of Excellence for Global Serialization leads our work to track our products along the supply chain based on each market's requirements, helping to ensure that medicines reaching consumers are not counterfeit, stolen or contaminated. These efforts mark a new way of conducting business that is driving the digital supply chain with an emphasis on data and product integrity.

Governments around the world are increasingly enacting regulations requiring serialization, and requirements vary by market. Viatris meets these requirements to ensure access to high-quality, affordable, and authentic medications to ensure patient safety and compliance. We participate in leadership discussions with industry groups such as the GS1, European Medicines Verification Organisation, Medicines of Europe and RxGPS Alliance, a group of multinational pharmaceutical supply chain stakeholders who have a common interest in advancing global alignment of drug serialization and tracing requirements to harmonize various standards among countries.

In 2023, Viatris completed its Drug Supply Chain Security Act (DSCSA) mandate ahead of schedule. The FDA's DSCSA was enacted in 2013 with an original November 2023 deadline. This 10-year implementation outlined the multiple steps and various milestones needed to achieve an interoperable tracing of products. The purpose of the new requirement is for the industry to have the ability to identify and trace prescription drugs as they are distributed throughout the U.S. To achieve this final milestone, unique IDs are now applied to each unit of sale (bottles/cartons, bundles, cases and pallets) and used to secure, track and authenticate the distribution process.

To meet this requirement, a dedicated cross-functional team made up of colleagues from the Greensboro Distribution Center, Serialization, IT, Supply Chain, Internal Sites, Quality and Customer Relations:

- Coordinated 38 internal packaging lines and 50 Contract Manufacturing Organizations (CMOs) and their related packaging lines to deliver DSCSA-compliant product
- Designed and implemented aggregation lines to address 7 million salable units requiring manual aggregation at our Greensboro Distribution Center
- Developed, tested and implemented SAP enhancements (software and hardware) to enable serialized processes at Greensboro
- Onboarded and implemented IT connectivity with more than 80 of our downstream trading partners and customers
- Established an alerts ticketing system to capture, triage and respond to data related events and exceptions
- Analyzed and cleansed our master data for accuracy across multiple systems on more than 1,200 SKUs

Elsewhere, we progressed work with the Rest of World Verification and Traceability Initiative (VTI), a global multi-stakeholder partnership to support countries to reduce the urgent risk of falsified medicines in national supply chains. These markets include Canada, Uzbekistan, Ethiopia, Jordan, Kuwait, Libya and Oman, along with readiness for the India Directorate General of Foreign Trade requirements.

In 2024, serialization teams are preparing to onboard more than 14 new markets, along with the removal of EMVO reporting on UK products (Windsor Framework). In the U.S., the FDA announced a one-year stabilization following the DSCSA Nov 27, 2023, compliance date. While Viatris is compliant, we continue to learn, engage our customers and improve our processes through this stabilization period.