Ensuring Patient Safety and Quality

Quality and Patient Safety in Processes and Products

Protecting patients and consumer health through 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, testing 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 and our comprehensive Global Quality policies, procedures and guidelines. These 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 work to incorporate relevant external quality guidelines, from across the world, 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, Code of Federal Regulations and the EU Excipient Risk Assessment for ascertaining the GMPs and regulatory expectations for 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.

Our operations are subject to robust quality systems, standards and processes designed for product quality. These programs are designed and implemented across our global operations and covered by and expected to comply with statutory and regulatory requirements such as current Good Manufacturing Practices (cGMP), Good Documentation Practices (GDocP), Good Pharmacovigilance Practices (GPvP), Good Distribution Practices (GDP) and Good Clinical Practices (GCP) for all markets that they serve.

In addition to the quality standards for the development, manufacture and distribution of pharmaceutical products, several sites across our network have obtained external certification of their quality management systems, including but not limited to:

- ISO 9001 for general quality management
- ISO 13485 for quality management of medical devices
- Distribution of Medical Devices for medical device marketing

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

- Managerial oversight and responsibility
- Ongoing learning and continuous improvement programs
- Management of data integrity and data governance
- Recurring scheduled internal site and external supplier, contractor, distributor and service provider audits. In addition, we have a program to support Viatris sites with learning, application and process for site self-inspection.
- Testing practices and compendial compliance
- Product risk assessment - The Product Health Evaluation Program (PHE) was launched in early 2024.
    - The Product Health Evaluation program serves as a continuous improvement initiative and augments the existing Annual Product Review (APR/PQR), Continued Process Verification and investigation trending. This program provides a set of tools and resources to identify and implement enhancements to manufacturing and testing processes.
- Continual compliance monitoring and communication
- Incident investigation, complaints and corrective and preventive actions
    - The Human Error Prevention (HEP) Program was launched in 2023 to further provide a structured approach to identify the underlying reasons and solutions for human error and reduce the likelihood of reoccurrence.
- Standardized document control and change management
- Compilation, trending and review of key quality metrics

Key programs within our Quality Management organization 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, learning management, policy, auditing, etc.

- A comprehensive cleaning program to facilitate production of quality products and a rigorous cleaning validation program that supports the implementation and ongoing utilization of robust cleaning methodology across our manufacturing network.
- Ongoing enhancements in our Quality Culture program, including leadership messaging and colleague engagement to reinforce the importance of quality compliance and the impact of non-compliance.
- Ongoing Learning Management System (LMS) enhancements to improve end-use training experience and development of additional reporting tools to monitor training completion and compliance.
- Our Product Health Evaluation (PHE) program proactively facilitates life-cycle management and continuous improvement 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, to facilitate supply continuity.

Quality Governance and Organization

Viatris has established a Chief Quality Officer, who reports directly to the CEO, and the following functions are within the overall Global Quality structure:

- Global Operations Audit and Supplier Quality Management
- Global Quality Learning and Continuous Improvement
- Global Quality Regulatory Oversight and Compliance
- Global R&D and Technical Quality
- Global OSD Quality
- Global Injectables Quality
- Global Dermatologics Quality
- Global Medical Device Compliance
- Global Clinical and Bioanalytical Quality
- Global Quality Systems and IT Quality
- Global Quality Complaints Management
- Global Quality Document Control and Change Management
- Global Quality Investigations
- Global External Supply Quality and Supply Chain Quality

While these organizational changes are already in place, we will continue to evolve our quality organization for alignment with our business operations and to support compliance with applicable standards. This transition further supports our commitment to ensuring that global quality resources are embedded within operational verticals to align closely with business units and drive consistency across sites.

As we completed our planned divestitures and the parallel consolidation and integration of Viatris' internal network, areas of particular focus included supplier quality oversight, the transition of quality standards and services as part of continued integration to support the continuation of supply and active efforts to instill the concept of continuous improvement. Also, as part of progressing integration activities, our Global Quality Policies were further evaluated and enhanced to capture best practices and to reflect current guidance, requirements and health authorities' expectations. As part of this work, we included reviews of the requirements of applicable quality guidance documents such as the FDA, EMA and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) to help ensure that Viatris' quality systems have appropriate controls designed to prevent, identify and/or manage risk with respect to product quality. Additionally, activities are ongoing for the successful consolidation and integration of the final phase of the Upjohn integration for the Tuas site in Singapore into Viatris' systems and programs, scheduled for completion in May 2026.

We provide comprehensive and effective training designed to facilitate access to and delivery of knowledge to global operations personnel in coordination with vertical and site-based training programs. The program coordinates and standardizes training requirements, content, techniques and training delivery methods to continually strengthen our corporate learning culture. Training and learning history records are delivered and maintained as part of a validated Learning Management System (LMS) through the utilization of defined curricula and/or assignment profiles that are monitored and tracked to facilitate training compliance for all applicable personnel. To further facilitate knowledge sharing and continuous improvement, we maintain a regulatory intelligence program that provides personnel access to current global regulations, publications and industry trends.

Quality Culture

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

- Excellence via Quality: We must all do what's right, not what's easy. We must focus on getting our work done right the first time. We must follow our robust processes and pay close attention to detail. And we must 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 must be proactive and seek to address issues before they become problems. We must collaborate with others to generate solutions and implement them quickly.

All Viatris employees are mandated to take applicable trainings on an annual basis. We provide comprehensive and effective training designed to facilitate access to and delivery of knowledge to global operations personnel in coordination with vertical and site-based training programs. The program coordinates and standardizes training requirements, content, techniques and training delivery methods to continually strengthen our corporate learning culture. Training and learning history records are delivered and maintained as part of a validated Learning Management System (LMS) through the utilization of defined curricula and/or assignment profiles that are monitored and tracked to facilitate training compliance for all applicable personnel. To further help enable knowledge sharing and continuous improvement, we maintain a regulatory intelligence program that provides personnel access to current global regulations, publications and industry trends.

- Reliability via Quality: A focus on simplification — overly complex processes can lead to mistakes. We must never settle for "good enough." Business continuity is enabled by a commitment to quality.

In 2026, we are continuing to enhance our Cultural Excellence program to engage employees and reinforce the importance of quality compliance and the impact of non-compliance. Specific training sessions, town hall meetings and messaging are part of the culture program enhancement, focusing on building individual awareness about quality, reinforcing a culture of real-time feedback on quality issues and robust oversight and accountability for compliance.

Our Human Error Prevention (HEP) program provides 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. We continue to maintain the HEP program, and sites have seen reductions in the incidence of human error.

Quality Monitoring and Assurance in Our Operations

Our Global Operations Audit program oversight is facilitated by a specially trained and qualified team of internal global audit/regulation experts, augmented and supported by independent third-party auditors and/or consultants. The global proactive internal audit program is a key component of our strategy, oversight and surveillance of the quality performance and compliance across our own network, CMOs, suppliers and service providers. It is designed to help support our goal of compliance with the Global Quality Management/Good Quality Practice and global/local cGMP regulations. Validated electronic systems are in place to track audit data, corrective actions and preventive actions (CAPAs), and to capture metrics.

- Escalation processes are in place to expedite notification of any significant findings or delays in generation/completion of CAPAs.
- Dedicated audit colleagues are assigned to Quality Operations within each vertical to participate in internal audits within that vertical.
- Site and vertical leadership are required to collaborate to enable continued, robust processes and to periodically evaluate existing processes and risk mitigation mechanisms.

The Quality Surveillance Program at Viatris is an independent assessment intended to analyze product/process events with common causes and to identify potential trend signals.

- Internal sites are required to formally respond to all observations from the Global Operations Audit team and take appropriate corrective and preventive actions in response to any observations, including set timelines for remediation and implementation.
- Quality Council teams at each site oversee and monitor key performance indicators, track quality incidents and identify trends that are reported globally. Additionally, the Quality Council teams have the authority to escalate incidents as appropriate.
- At the global level, quality leadership routinely reviews and monitors key performance indicators provided by the site Quality Council from each vertical/site and their respective corrective/preventive actions for incidents and trends.

The Global Operations Audit internal audit program includes expedited timelines for the issuance of observations and increased site leadership engagement to help 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 2025.

Internal operations audits are performed on a one- to three-year cycle based upon facility type (manufacturing facility internal operations audits are performed at least annually), historical regulatory inspection performance and potential risk for each production/API site, packaging site, distribution site and laboratory site.

In 2025, Viatris evolved the Global Operations Audit program for both internal and external audits to a hybrid model that incorporates both on-site and virtual audits.

- In total, 667 GMP, 81 Clinical (GCP-GLP) and 55 Pharmacovigilance (PV) audits were conducted by Viatris' Global Operations Audit team at our internal facilities and external suppliers, contractors and service providers.

Following each internal Global Operations Audit, the inspected site is required to submit a CAPA plan to remediate any identified discrepancies. These CAPAs are submitted to our Global Operations Audit 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 Risk Management is central to our approach to quality. We apply the principles outlined in the International Conference of Harmonization (ICH) Q9 Quality Risk Management as well as those in the ICH Q10 Pharmaceutical Quality System.

A High-Quality External Supply Chain

Viatris relies on our partners to deliver high-quality medicines. 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.

- After selection, those suppliers and third parties execute an agreement that specifically details our expectations and the right to conduct regular on-site audits to evaluate ongoing compliance with regulations, maintain applicable regulatory reporting requirements and allow access to all records related to the supplied products, among other requirements.
- As part of our external audit process with suppliers, contractors and service providers, auditees are required to provide formal responses to observations cited as part of the audit to the Global Operations Audit team.

To support external suppliers in meeting quality standards, we may place company Quality personnel at the site of a supplier to engage, monitor and mentor the site's team and foster continued quality compliance.

- Our Global Operations Audit team conducts routine audits to assess the strength and performance of suppliers' QMS. The frequency of these audits, every two to five years, is based upon cyclical audit requirements by facility type, historical regulatory inspection performance and key product launches. Cyclical audit requirements are supported by health authority audit requirements and/or recommendations.

Contract Manufacturing Organization Quality Oversight

Viatris' CMOs are subject to robust quality systems, standards and processes. 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. A dedicated team for supplier qualification with a global scope is currently in place.

Working with Health Authorities

We constantly review our products, processes and facilities throughout our network and work closely with external health authorities to facilitate 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 we have one open FDA Warning Letter at our oral finished dose manufacturing facility in Indore, India. The FDA also issued an import alert related to this facility affecting 11 products that will no longer be accepted into the U.S. until the warning letter is lifted. Viatris provided a formal response to the FDA Warning Letter with our comprehensive corrective/preventive action plan to address the concerns raised by the FDA. We have been in regular communication with FDA during this process and will continue to work to ensure that the FDA is satisfied with the steps we have taken to resolve all the points raised. For more information, see our other public disclosures.

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

In 2025, >95 health authority inspections were conducted across Viatris 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 industry-wide 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). We are active participants in ISPE's Core Team on Advancing Pharmaceutical Quality (APQ) program, an industry-led quality management maturity assessment and benchmarking program.

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.

Global Product Safety and Risk Management

The Product Safety & Risk Management (PSRM) function operates a Global Pharmacovigilance (PV) system, supported by highly skilled, experienced medical and scientific professionals. The system is underpinned by comprehensive and robust processes, described in more than 120 global policies, standard operating procedures and work instructions, that are designed to comply with applicable statutory and regulatory requirements, such as EU Good Pharmacovigilance Practices (GVP) and General Data Protection Regulation (GDPR), across the markets we serve. These processes are focused on effective monitoring of patient safety throughout product development and during post-marketing use.

We continuously monitor and assess the benefit-risk profile of all our products through core Pharmacovigilance activities, including Individual Case Safety Report (ICSR) management, aggregate data review and reporting, signal management, risk management planning and associated implementation of interventional measures, safety communication, quality management and Key Performance Indicator monitoring.

In 2025, Viatris managed the safety of its diverse product portfolio — including prescription medicines, over-the-counter medicines, combination products, medical devices, food supplements and cosmetics and its processes by:

- Submitting over 350,000 ICSRs and more than 700 aggregate safety reports to regulatory authorities and business partners with a high compliance rate

PSRM is engaged in several Post-Authorization Safety Studies (PASS) to help ensure ongoing safety surveillance for approved products and to support implementation of appropriate risk minimization measures.

- Maintaining more than 500 risk management plans and associated implementation of interventional measures designed to ensure that our products are used safely and effectively

In 2025, 55 audits were performed by Viatris' Global Operations Auditing function. In addition, two self-inspections were concluded and seven audits were performed as part of the Risk Evaluation and Mitigation Strategy (REMS) Consortium activities, in which Viatris participated as a stakeholder. The PSRM function also hosted nine PV inspections by regulatory authorities, nine PV audits by business partners and responded to 32 questionnaires from regulatory authorities and business partners.

Pharmacovigilance Audits

The PV system is subject to internal operations audits, business partner audits and inspections by regulatory authorities worldwide. The internal audit schedule is risk-based covering all PV system processes, with audits conducted annually for global processes, every three years for global service providers and approximately once every four years or less for affiliates.

Robust processes are in place to address any observations identified during audits and inspections. These observations are thoroughly analyzed for their root cause and assessed for their impact and corrective and preventive actions are implemented, as appropriate. The effectiveness of these actions is tracked to ensure ongoing compliance with global pharmacovigilance regulations.

Pharmacovigilance Governance and Oversight

Our global PV governance committees, such as the Corporate Product Safety Committee and the Pharmacovigilance System Oversight Committee, perform periodic and ad-hoc evaluations of new safety-relevant information, helping to ensure timely communication of important new safety information to regulatory authorities, healthcare professionals and patients while providing comprehensive oversight of the compliance and performance of the Viatris PV system.

We have robust processes designed to ensure that PV obligations are consistently considered for all new, updated and terminated business relationships with third parties. PSRM collaborates with

In 2025, the PSRM function held two notable events.

In May, Affiliate Safety Representatives (ASRs) from our Developed Markets and Emerging Markets regions met in London with global subject matter experts, to discuss key initiatives, share market insights and challenges and recognize successes. These collaborations served to strengthen knowledge sharing in our internal network, act as a springboard for continued growth and success and contribute to the wellbeing and safety of patients worldwide.

In September, the PSRM team enjoyed celebrating World Patient Safety Day (WPSD) with Viatris colleagues across the globe. With events being held at Viatris locations, WPSD provided teams with an opportunity to engage, to remind colleagues of the importance of Product Safety and timely safety reporting and to showcase some of the excellent work done by the Safety teams in their respective countries. The celebrations provided a meaningful opportunity to reinforce our unwavering commitment to patient safety, reminding us that at the heart of everything we do, patients remain our top priority.

We provide training in accordance with the company's Pharmacovigilance Training Standards policy, which defines the curriculum, frequency, effectiveness measurements, documentation and other requirements. All employees involved in our PV system are assigned professional development training courses based on individual experience. In 2025, over 40,000 individuals, including Viatris' colleagues, temporary workers and contractors, completed the mandatory annual Basic PV training, reinforcing our commitment to patient safety and continuous professional development.

such parties to identify and asses ss PV requirements. Where necessary, a Pharmacovigilance Agreement (PVA) is established and implemented. Currently, the company manages more than 1,000 active PVAs across various business relationships.

We continuously strive to innovate and enhance our systems. In 2025, we explored emerging technologies, including cloud-based solutions, automation, artificial intelligence (AI), data analytics and digital communication interfaces to potentially strengthen product safety evaluation, communication and risk mitigation. Any implementations of these innovations will be done in accordance with Viatris' security and privacy procedures.

Our global PSRM function operates under the Pharmacovigilance Business Continuity Plan, which provides a comprehensive framework for risk management, staffing and safety systems to ensure uninterrupted operations during unplanned disruptions.

Product Testing

All ingredients used in our products undergo rigorous testing designed to ensure they meet registered specifications. For all products, as regulated by cGMP, we conduct extensive testing, including raw materials as well as intermediate and finished products. As required by applicable regulations, we also conduct post-distribution stability testing.

Product Recall Management

Effective quality and product safety management systems are designed to detect and manage potential risks. These programs may result in Health Authority Notifications (such as Field Alert Reports) and/or product recalls as part of their design. Health Authority Notifications can be used to quickly identify potential quality defects in distributed drug products that may present a possible risk. Recalls are largely initiated voluntarily as a precautionary measure in cases of possible risk to the quality and safety of the product and/or the patient.

However, a recall decision is not always driven by quality concerns in the medicine itself and may be conducted for other reasons such as changes to artwork or labeling. 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

Viatris' PSRM Function continuously monitors the benefit-risk profile of company products through its robust Pharmacovigilance activities and governance, ensuring timely and compliant communication of safety information. These efforts demonstrate our commitment and responsibility to patient safety and strong governance.

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 Head of Global Quality Operations. 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).

Global Clinical Operations is embarking on a concerted effort to bring new medicines (NMEs) to market, thus improving patient access to needed therapies. Key events in 2025 included increasing collaborations with our partners, vendors and investigators with development plans in multiple regions throughout the world.

In 2025, 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' mission to promote access to medicines for research participants and patients around the world. Clinical studies continued in Europe, Africa, Asia-Pacific and North America. We expanded studies in 2025 in areas including Egypt, Lebanon, Jordan, Japan and more. Our research continued in various therapeutic areas including mental health disorders, COPD, chronic and progressive autoimmune disease 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.

Clinical Trials

Clinical trials that include a wide range of patients can yield better, more robust results. As a global healthcare company serving more than 165 countries and territories, Viatris works to include varied patient populations for global studies that will be submitted for approval to health authorities around the world.

Viatris works with health authorities to enhance safety and scientific rigor 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. In addition,

- Viatris is supporting drug development in multiple regions around the world with applicable development programs that allow for enrollment across a broad range, including both children and adults.
- Further, women of child-bearing potential may also enroll with adequate birth control measures in place.

Management and Oversight

To further support the direction of Viatris' portfolio with increasingly innovative assets, 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 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

Whether our clinical trials are performed in-house or by a qualified third party, the same global standards apply including adherence to GCP and promoting adherence to applicable policies, procedures and regulatory requirements.

Patient safety and data integrity are at the core of our program. We develop clinical study protocols for each clinical trial that contain criteria and procedures for the conduct of every trial. The procedures for clinical site assessments are developed prior to the selection of investigators. The company maintains procedures that require ongoing evaluation of a clinical site's conduct of clinical studies from the study's initiation through the study's completion. We work with partners to help ensure that clinical investigators are carefully screened prior to being selected to participate in a clinical study and require that clinical investigators conduct careful screening and selection of patients consistent with written study protocols.

Further, we require that all clinical studies receive review and approval from institutional review boards/independent ethics committees (IRB/IEC). These committees evaluate and provide ongoing review of clinical trials with a primary goal of ensuring patient rights and safety.

- The review of each clinical study must be properly documented for every clinical site participating in a clinical study for the company.
- IRB/IEC documentation of review/approval must be available for all clinical sites that participate in a clinical study.
- Additionally, health authorities may place clinical study activities on hold should there be concerns that warrant such action.

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.

- 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 help 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.

Risk Management in Clinical Development

The QMS provides procedures on assessing potential risks associated with the various aspects of clinical development, such as study design, vendor selection, site selection and patient populations. The application of data analytics supports efficient trial management and oversight.

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 works to ensure 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 clinical trial.

Site staff are likewise provided company clinical development team contacts who are available to provide support as needed.

Trial Data Transparency

Viatris' QMS governs the publication of clinical-trial data in publicly accessible registries, as required by global regulations to promote transparency. We publish results of applicable clinical trials in publicly accessible registries including www.clinicaltrials.gov and others. As part of complying with GCP, we adhere to the Food and Drug Administration Amendments Act (FDAA) 801 and the Final Rule requirements for disclosure and results posting in the U.S. and adhere to EU and other regional requirements for clinical trial transparency.

Further, Viatris maintains procedures that describe a scientifically rigorous process for the preparation and dissemination of scientific articles addressing the results of clinical trials to ensure that HCPs and patients have access to information on the results of clinical trials.

Viatris' Global Clinical Operations endeavors to continuously improve the clinical trials process through process optimization, the implementation of end-to-end innovative clinical trial solutions, as well as globally aligned systems and processes. Our priorities will always be patient safety, regulatory and protocol compliance and data integrity.

Animal Studies

We do not conduct animal testing unless it is required by national regulations. We are committed to the "3R" approach (Replacement, Reduction and Refinement) with respect to ethical animal testing. Facilities performing animal testing on our behalf are required to comply with regional scientific procedures for laboratory animal science. These facilities use and/or are approved by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Our Global Operations Audit (GOA) team performs regular audits on entities and facilities involved in animal testing to help ensure compliance. In 2025, GOA audited 13 AAALAC-certified facilities.

Promoting Product Security and Fighting Illicit Medicines

Viatris operates a holistic product security program to mitigate the risks from counterfeit and other illicit products — including unlawfully diverted, IP infringing or mimic medicines — and help protect patients, the quality and efficacy of our products, the communities we serve and the trust in our brand.

We have a Product Security Governance board (PSG), with senior leaders from across our business who meet monthly to leverage our collective expertise and provide oversight of our product security efforts. Viatris' Product Security team conducts comprehensive 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, North America and Latin America, with plans to expand the program further across the Asia Pacific region. We are training and partnering with global law enforcement bodies such as Interpol and the World Customs Organization to maximize our reach.

Required Training

Throughout 2025, we have delivered training and awareness sessions to multiple Law Enforcement units via the World Customs Organisation (WCO) and Interpol specialist pharma crime units. This material included specialist forensic training, product security strategies and profiling indicators. Our training was designed not only to raise awareness, but also to improve capability, capacity and interoperability.

Our program is built on four key strategic pillars:

- Prepare
- Prevent
- Pursue
- Protect

External Stakeholder Collaboration

We conduct proactive investigations when there is suspicion of counterfeit or at-risk products 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 to law enforcement and regulatory partners in time-critical situations.

Viatris Supply Chain Quality, in collaboration with Global Security and with the support of Corporate Affairs, has previously arranged workshops alongside the Egyptian Drug Authority (EDA) and Qatari Ministry of Health. The topic of these workshops was "Combating Illicit Medicines." Our unwavering commitment to patient safety and the quality of pharmaceutical products throughout the supply chain served as the driving force behind this initiative.

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. 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

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.

The outreach training program operated by the Global Security team is 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.

- 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.

Governments around the world continue to enact regulations requiring serialization, with requirements varying by market. Viatris meets these requirements to help ensure patients' access to high-quality, affordable and authentic medications. As serialization regulations continue to expand globally, Viatris' serialization organization now supports distribution across 53 countries, with newly implemented markets in 2025 including Greece and Azerbaijan, further strengthening our presence across the EU and emerging regions.

In 2025, we continued to manage one of the industry's largest and most complex serialization portfolios, with more than 20,000 serialized SKUs actively maintained across multiple packaging levels and nearly 9,000 SKUs processed during the year, demonstrating operational scale and lifecycle management capability.

To further improve communication and service to key stakeholders, we enhanced our digital infrastructure and data governance capabilities in 2025, reinforcing system reliability, data accuracy and end-to-end traceability across markets.

In May 2025, Viatris successfully met the regulatory deadline for manufacturers under the U.S. Drug Supply Chain Security Act (DSCSA), achieving full compliance with enhanced traceability requirements. The purpose of the 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 requirement, unique IDs are applied to each unit of sale (bottles, cartons, bundles, cases and pallets) and used to secure, track and authenticate the distribution process.

A dedicated cross-functional team, comprising colleagues from our U.S. distribution center, Serialization, IT, Supply Chain, Internal Sites, Quality and Customer Relations, collaborates closely to maintain compliance, enhance data exchange processes and support trading partner readiness. Key capacities include:

- An alert ticketing system to capture, triage and respond to data-related events and exceptions on inbound product to our U.S. distribution center
- Maintenance of 24-hour response to customer verification requests
- Status monitoring and tracking of sending successful Electronic Product Code Information Services data to downstream trading partners
- Continuous review of customer scorecards to solve discrepancies between product and data

Beyond meeting U.S. DSCSA standards, our U.S. customer satisfaction rating averages 99%.

In 2025, we achieved a 22% year-over-year reduction in both "Batch not found" and serial number alerts under the EU Falsified Medicines Directive (FMD), reflecting continued improvements in data accuracy, message quality and end-to-end system reliability. A robust Contract Manufacturing Organization (CMO) network remains essential to maintaining serialization consistency worldwide, and in 2025 we managed more than 400 CMOs globally, onboarding 28 new partners during the year, reflecting our continued focus on partner enablement, compliance readiness and operational integration.

Serialization capabilities also supported multiple market launches, including the launch of Inpefa in the United Arab Emirates, which was done in accordance with regional traceability requirements in a key strategic market.

These operational advancements were reinforced by internal site enhancement initiatives, where upgrades to line-level serialization systems were complemented by process optimization efforts designed to streamline DSCSA readiness for wholesalers, strengthen data flows, increase compliance efficiency and safeguard production continuity.

Collectively, these efforts demonstrate the resilience, operational rigor and sustained innovation of the serialization organization as we work to build a robust, future-ready ecosystem that protects patients and supports a secure and sustainable supply chain.

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