Conducting business responsibly and with care

At Sun Pharma, we prioritise the health and safety of our patients across the globe. In this regard, we ensure strict adherence to quality and regulatory compliance. We regularly monitor product safety and ensure continuous assessment of the risk-benefit profile of our products throughout their life cycle.

Pharmacovigilance

We established our global pharmacovigilance unit in 2005, pioneering the concept in the Indian pharmaceutical landscape. Our pharmacovigilance system adopts a 'beyond-compliance' approach to monitor the safety of all our products and swiftly implement risk mitigation measures. We have established a global pharmacovigilance policy, which is supported by a Product Safety Committee.

Our pharmacovigilance policy showcases our commitment and efforts towards patient safety, backed by support from the top management. Our pharmacovigilance team is led by the VP-Medico-regulatory Affairs, Clinical Data Reporting (MACR) & Global Pharmacovigilance (GPV). The team supports us with robust business continuity measures, safeguards from litigation and helps implement requisite measures to ensure patient safety. The team provides periodic safety update reports, risk evaluation and mitigation strategies, health hazard evaluations and training and quality control among others. We also follow a strategic process to ensure efficient handling of Individual Case Study Reports (ICSR).

Glimpse of our product stewardship management approach

The imperative	Cornerstones of our approach	Strategic enablers	Aspirations
A robust product stewardship approach ensures: Enhanced product health and safety profile Increased transparency and trust with stakeholders Enhanced culture of innovation across the organisation	Established Quality Vision Quality, Compliance and PV Management System Seamless and strategic Quality Assurance Process	Established global pharmacovigilance policy Robust presence of global pharmacovigilance and quality team and Product Safety Committee	We remain committed to the superior quality and responsible use of our products. We further aim to enhance awareness regarding the safe use and disposal of our products to accelerate our efforts towards a sustainable tomorrow

GRI 103-1, GRI 103-2, GRI 103-3, GRI 416-1

Approach towards Individual Case Study Reports (ICSR)

- ICSRs are received from a myriad of platforms, such as published literature, patient support programmes, market research programmes, clinical studies and business partners. They are communicated to the respective country's pharmacovigilance office.
- The ICSRs received further undergo a triage sequence to be appropriately classified as assessment and undergo assessment to review the seriousness of the causality.
- If no further clarification is required, the case undergoes a thorough quality review check.
- A final case report is then prepared for submission to the Drug Regulatory Authority.

Pharmacovigilance at Sun Pharma

Periodic inspections from regulatory authorities, such as US FDA, UK MHRA, Health Canada, URPL Poland and OGYI Hungary, among others.

The Independent Pharmacovigilance QA reports to the Global Quality Head

Global pharmacovigilance quality audits are driven by a 5-year strategic audit plan and an annual audit plan

~98 qualified team members of physicians, PhDs, graduates and postgraduates in science/pharmacology as part of our pharmacovigilance team at Gurugram and Mumbai, India.

Product quality

At Sun Pharma, quality is core to our manufacturing operations and business activities. Given our strong Quality Vision and a robust Quality Management System (QMS), we have established dedicated practices that guide a sustainable quality culture at Sun Pharma. Additionally, some of our API and drug product manufacturing sites are ISO 9001:2015 certified, and we aspire to have all our sites certified. There have been no incidence of non-compliance concerning health and safety impact of products as well as product information and labeling.

Quality Vision

Our vision is to globalise, harmonise and simplify Good Practices (GxP) processes to ensure a sustainable quality culture. At Sun Pharma, we work towards continuous improvement of our Quality Management System (QMS) and all its elements. We are building and maintaining a strong culture of quality through on-going development, training, and empowerment of our personnel. We believe that producing safe, high-quality products is everyone's responsibility

Quality Management System

- Presence of a global QMS
- Implementation across different functions, inclusive of research & development, quality and technical operations
- Use of best practices to ensure the delivery of consistent and high-quality products to patients

Quality Practices

- Harmonisation of Compliance Processes
- 'Lessons Learned' Strategy
- Global Quality Metrics
- Quality by Design Principle (QbD) for Sustainable Quality
- Quality Data Governance

Our Quality Assurance Process

- Compliance to cGMP regulations and country-specific regulations
- Routine inspections of manufacturing sites by regulatory agencies for GMP certifications
- Qualification, testing and release of all raw materials, inclusive of API and packaging material
- Adequate in-process checks and testing of finished products, inclusive of stability testing
- Compliance to specifications approved by the regulatory agency for specific markets
- QMS to record and investigate any deviations, other failures and discrepancies
- QMS is inclusive of a robust change management, CAPA, adverse drug events, field alert reporting, and recall process
- All manufacturing facilities, contract manufacturing facilities and vendors of Sun Pharma are qualified and audited by our corporate quality team
- All employees of Sun Pharma involved in GxP activities are qualified and trained based on need assessment derived from their respective job roles

We also have 5 key elements to strengthen the QMS, which supports us in ensuring global compliance to respective regulations and enables new product registrations, among others.

Procedural documents
Electronic document management systems
* Non-printable
* Access controlled
* Version controlled

Deviation management
Ensuring periodic trend analysis of any global deviations

Trainings
Learning Management Systems
* Electronic
* Instructor-led

Good documentation practices
Robust presence of global quality SOPs for GDP

CAPA
Presence of robust quality management software systems

GRI 103-1, GRI 103-2, GRI 103-3, GRI 416-2, GRI 417-2

Product accessibility

The support of our extensive network of carrying and forwarding agents (CNFs), stockists, distributors and wholesalers enables us to meet our patients needs with regular supply of our products to retailers in India. Sub-stockists purchase products from our stockists to enhance the availability and accessibility of our products, particularly in areas of need as well as in lower-tier cities and rural areas. Additionally, the presence of our robust distribution network has supported us to enhance our outreach and deliver products to more than 500,000 pharmacies in India, across metro and large cities as well as semi-urban and rural areas.

Product information marketing and labelling

Product information is made available to relevant stakeholders depending on market and local requirements. This includes Pharmacokinetics, safe use of product, sourcing of ingredients, composition, mechanism of action, clinical pharmacology, drug interactions and side effects, and guidance on appropriate storage conditions, among others.

Responsible product disposal

At Sun Pharma, we prioritise the responsible use of our products and have established robust internal capabilities and systems to deliver sustainable and cost-effective solutions to our stakeholders. To integrate sustainability and responsible practices across our business activities and products, we have established guidelines for the safe disposal of returned or recalled drug products. We ensure strict adherence to local regulations regarding safety and environmental protection while disposing of drugs. We have established a process for safe product disposal across all our markets and this is managed as per country-specific requirements at the destination where the product is received for destruction. Additionally, the identification of product, quantity, method of destruction and date of destruction are documented for further action.

Anti-counterfeit awareness

Counterfeit and illegal products pose a threat to public health and safety. We immediately report any complaint or query in suspicion of counterfeit related to our products to respective regulatory agencies for necessary action. We have also introduced the 'Track and Trace' technology to prevent the sale of counterfeit drugs and to ensure the authenticity of our products. Feedback and complaints are received from the complainant and marketing representative. We then enhance our product packaging configuration to establish an efficient mechanism for our customers that distinguishes genuine medicines from counterfeits. We have appropriate procedures in place to ensure seamless management of quality complaints with regard to suspected or confirmed counterfeit products.

At Sun Pharma, the trademarks team and Learning & Organisation Development (L&OD) team are responsible for training the entire field force to identify counterfeits and also provide reports to the team for necessary legal action. Additionally, we have established a dedicated taskforce that includes senior field members across clusters. Each member is assigned relevant KPIs and specifically trained to identify counterfeit products. We are constantly striving towards standardised and unique packaging to ensure protection from counterfeit risks.

GRI 417-1