Quality Healthcare

Committed to Quality and Equitable Healthcare

Access to safe and effective medicines is an important prerequisite for universal health coverage. We are committed to providing high-quality medications to patients and healthcare professionals worldwide.

With a team of 3,000+ skilled Research and Development (R&D) professionals coupled with strategic R&D investments (representing 6.7% of our sales in FY24), we focus on developing specialty, branded generics and generic medications across various therapeutic areas targeted at improving healthcare access for our patients. Our strong distribution network of distributors, stockists, and wholesalers, ensures global access to medical products for patients in need.

Patient Safety

We conduct rigorous reviews and quality assurance to maintain high standards of quality for our products and ensure compliance with all regulations. Promptly identifying and addressing potential health and safety risks is imperative for product quality, safeguarding patient safety, and building trust with our stakeholders[33]. We continuously assess the risk-benefit profile of our offerings by adhering to globally benchmarked quality and regulatory compliance standards while rigorously monitoring product safety[34].

Pharmacovigilance at Sun Pharma

Our Pharmacovigilance department adopts a proactive approach to mitigating risk and ensuring product safety. Our pharmacovigilance system continuously monitors product safety and swiftly addresses any adverse events[35]. The Product Safety Committee supports our Global Pharmacovigilance Policy, and the Independent Pharmacovigilance Quality Assurance team reports to the Chief Quality Officer.

Our pharmacovigilance team focuses on contingency planning, risk mitigation and resolution of adverse events to enhance quality control, workforce training, and patient safety. We utilise advanced IT solutions for efficient data processing. Comprising around 100 qualified professionals, including physicians and scientists, our pharmacovigilance team handles Adverse Drug Reaction (ADR) cases, expedited reporting, risk management, safety signal management and consolidating safety data into a centralised database for reporting to global regulatory authorities.

The Product Safety Committee oversees pharmacovigilance processes, ensuring compliance with standards addressing safety issues and setting necessary remedial measures. Our Chief Quality Officer monitors an independent pharmacovigilance quality audit, guided by a five-year strategy and annual plan. We also undergo regular inspections by regulatory bodies, including US Food and Drug Administration (US FDA), European Medicines Agency (EMA), UK Medicines and Healthcare products Regulatory Agency (UK MHRA), Health Canada (HC), the Pharmaceuticals & Medical Devices Agency (Japan PMDA) and other such regulatory agencies to ensure compliance. Further details on some of the US FDA inspections can be found in our FY24 Annual Report on page 276 via the link - https://sunpharma.com/wp-content/uploads/2024/07/SPIL-Annual-Report-2023-24.pdf

Product Quality

Our **'Quality Vision'** aims to globalise, standardise, and streamline Good Practices (GxP) processes, promoting a culture of Quality excellence and sustainability. We are dedicated to continuously improving our Quality Management System (QMS) and using latest generation electronic systems for better functionality. Our focus on employee development, empowerment, and training helps us in fostering a culture centered on product quality.

We have created a comprehensive approach to quality management under our 'Quality Vision', aligning our global QMS with industry best practices and assurance processes. Our quality standards also cover procurement, product distribution, stakeholder complaint management, investigations, and corrective and preventive measures.

Our dedicated quality management team ensures strict adherence to quality and safety standards. Our strategy focuses on sustainable quality design, data governance, process harmonisation, and global quality metrics implementation.

[33]GRI 3-3 | [34]GRI 416-1 | [35]GRI 416-2

Quality Management System (QMS)

- Global QMS
- Cross-functional implementation of QMS including R&D, quality, and operations
- Adopting best practices, tools and procedures to ensure a comprehensive end-to-end product quality

Quality Practices

- Sustainable quality design
- Quality data governance
- Process harmonisation for enhanced compliance
- Global Quality metrics
- Sharing of internal and external learnings

Key QMS Elements

- **Procedural Documents:** Electronic document management systems - access controlled, printing control, and version control
- **Deviation and Investigation Analysis:** Periodic trend analysis
- **Training:** Instructor-led and electronic learning management systems, including a focused training course on Advanced Pharmacovigilance
- **Good Documentation Practices:** Implementation of good documentation practices in line with SOPs
- **Corrective and Preventive Actions (CAPA):** Robust product quality complaint management encompassing preliminary assessment, investigation, and corrective actions
- **Management Review Meeting:** Sun Pharma's senior management ensures the quality system governance through periodic quality reviews

Quality Assurance Process

Compliance with GxP and country-specific regulations	Periodic inspections by regulatory agencies at manufacturing sites ensure compliance with cGMP certification requirements	Release of input and packaging material post qualification and testing
Ensuring product quality through in-process testing, finished goods testing, and stability testing	Stringent compliance is ensured with specifications relevant to each market/ geographical requirement	Prevention of recurring deviations, failures, and discrepancies by recording, of investigation in the QMS
Comprehensive QMS system including change management, deviation, and investigation management, CAPA, adverse events management, field alert reporting, complaint management, and recall process	Periodic audits conducted by the Company's Corporate Quality team at all manufacturing facilities contract manufacturing sites, a and vendor locations	Training of employees involved in GxP activities through modules curated for job-specific roles

Quality Healthcare

Product Quality Complaint Management Process

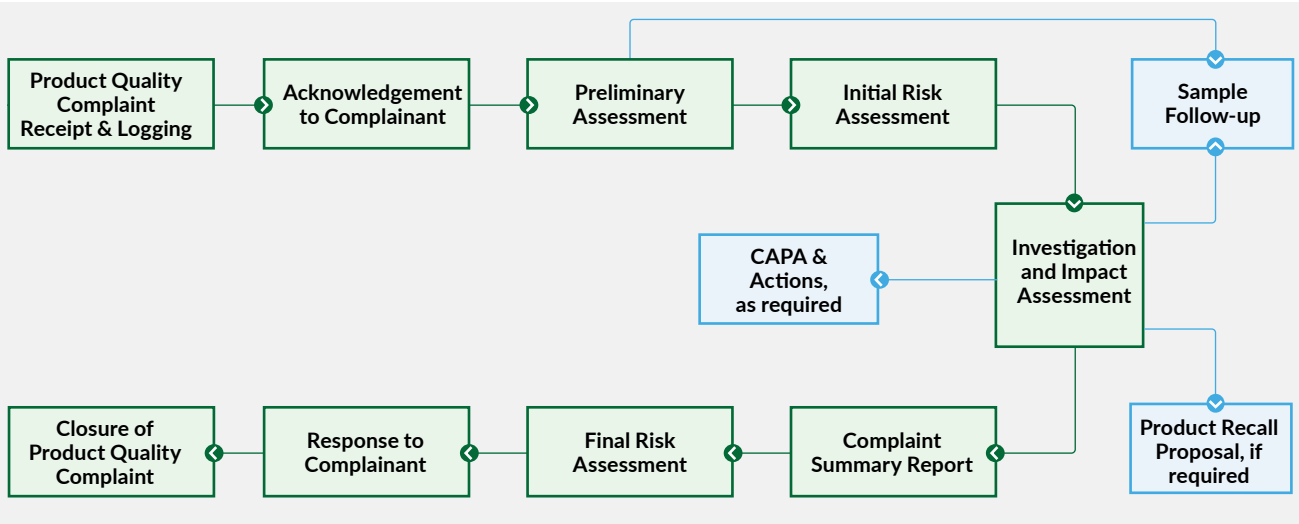
The guidance for managing product recalls and the conditions to determine product recalls are provided in our Global Standard Operating Procedure (GSoP). Product recall steps include, reviewing the suggestions of the Site Recall Committee, processing the proposal for product recall, notification of recall, closure and analysis of trends.

A thorough approach is followed to address the complaints on product quality. After receiving complaints, they are documented on the system and undergo an initial evaluation. During the investigation process, we perform a primary risk assessment along with sample follow ups.

Based on the results, Corrective and Preventive Actions (CAPA) are implemented to resolve identified issues. We record a summary of the complaint throughout this procedure and perform a review. A response is provided to the complainant, facilitating clear communication and resolution of the complaint.

For FY24, we had zero Class-I recalls and 20 Class-II Recalls. The total value of recalled products was $ 0.22 Million. In the reporting year, our manufacturing facilities underwent 48 regulatory inspections conducted by regulatory agencies like USFDA, UK MHRA, EMA, PMDA and others. The USFDA conducted 7 inspections at our manufacturing facilities resulting in 11 Form-483 observations.

Process of Redressal of Product Quality-related Complaints



Responsible Product Stewardship

At Sun Pharma, we are committed to responsible product stewardship, upholding the highest ethical standards throughout a product's lifecycle, from development to manufacturing, labelling, and disposal[36].

Product Accessibility

We aim to improve the accessibility of our product across global markets covering both urban and rural areas. Our distribution network, including retailers, distributors, wholesalers, and carrying & forwarding agencies (CNFs) ensures worldwide availability of our products to our patients.

Product Labelling and Information

We adhere to all regulations related to product labelling and information, including pharmacokinetics, safe use, composition, clinical pharmacology, drug interactions and side effects, and storage requirements, as a part of our commitment to responsible product stewardship[37].

In FY24, there were no incidents of noncompliance, resulting in any fines, penalties, warnings, or breaches of voluntary codes[38].

Responsible Product Disposal

We follow local safety and environmental regulations for the safe disposal of returned or recalled products, ensuring compliance with relevant laws and regional standards. We also maintain records of disposed product quantity and destruction date.

[36]GRI 3-3 | [37]GRI 417-1 | [38]GRI 417-2, GRI 417-3

Foundational Pillars of Product Stewardship

Anti-counterfeit Measures

Awareness and Processes

We are committed to raising awareness about the risks of counterfeit medicines in affected markets by implementing an effective anti-counterfeit governance management system. A dedicated task force has been established to manage these threats and improve safety. This task force ensures seamless monitoring of counterfeit medicines for enhanced safety and security through our trace-and-track technology and complaint management system.

Governance Mechanism

- The trademark and learning and development (L&D) teams train the entire field force for identifying and reporting counterfeit medicines.
- A designated task force of senior field personnel is trained to identify counterfeit medications, supported by a trained field team for detection and reporting on counterfeit medicines. The identification process is linked with associated KPIs.

Management System

- Feedback mechanism in place to receive complaints from the complainant and marketing representatives.
- Prompt reporting of complaints and queries relevant to counterfeit products to concerned regulatory authorities.
- Trace-and-track technology to detect and prevent sale of counterfeit products.
- Improving product packaging for easy distinction between genuine and counterfeit medicines. We continually strive towards standardised and unique packaging to mitigate counterfeit risk.
- Well-established complaint management system for seamless management of suspected cases of counterfeit products.