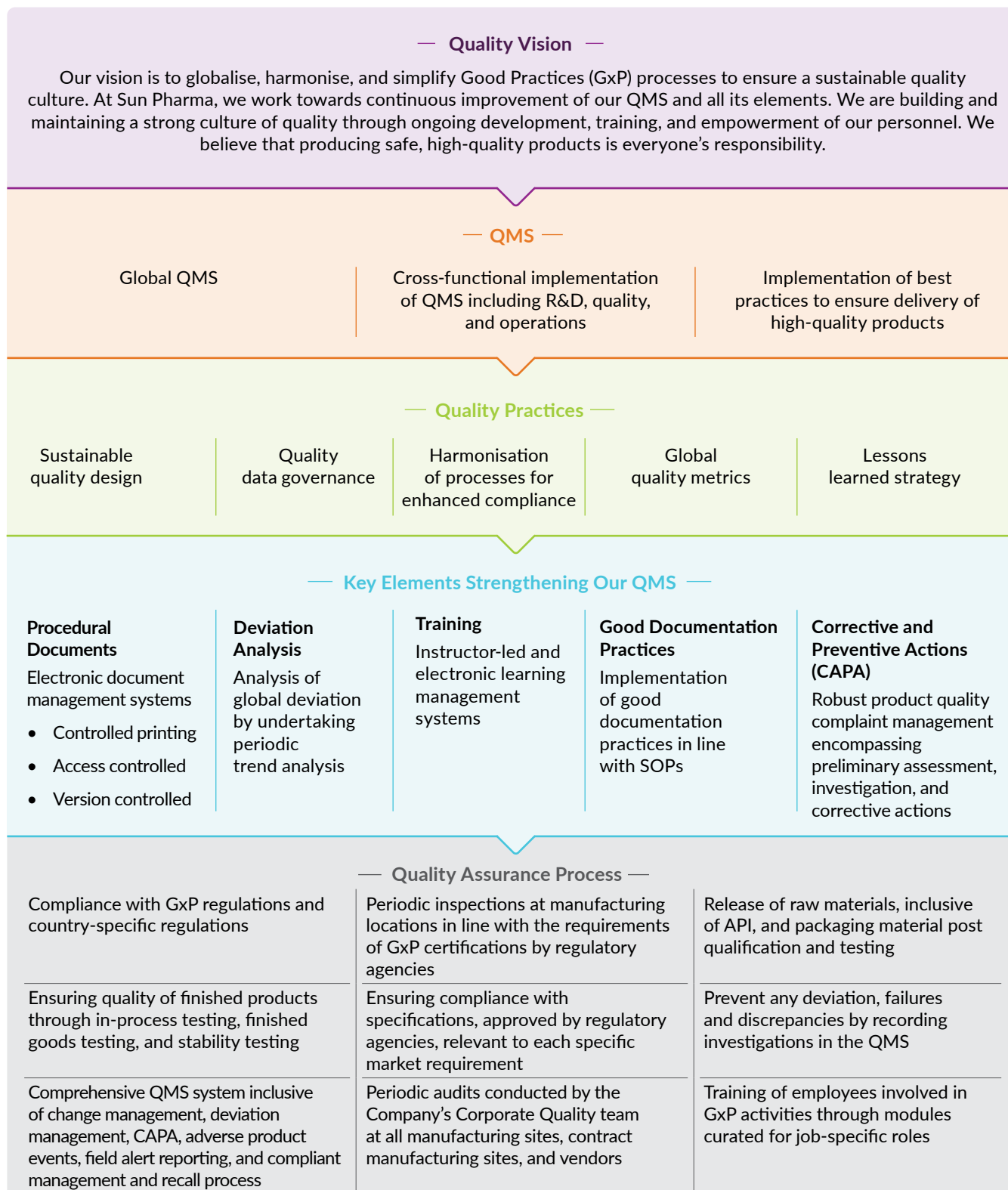## Co-creating a Responsible Future (continued)
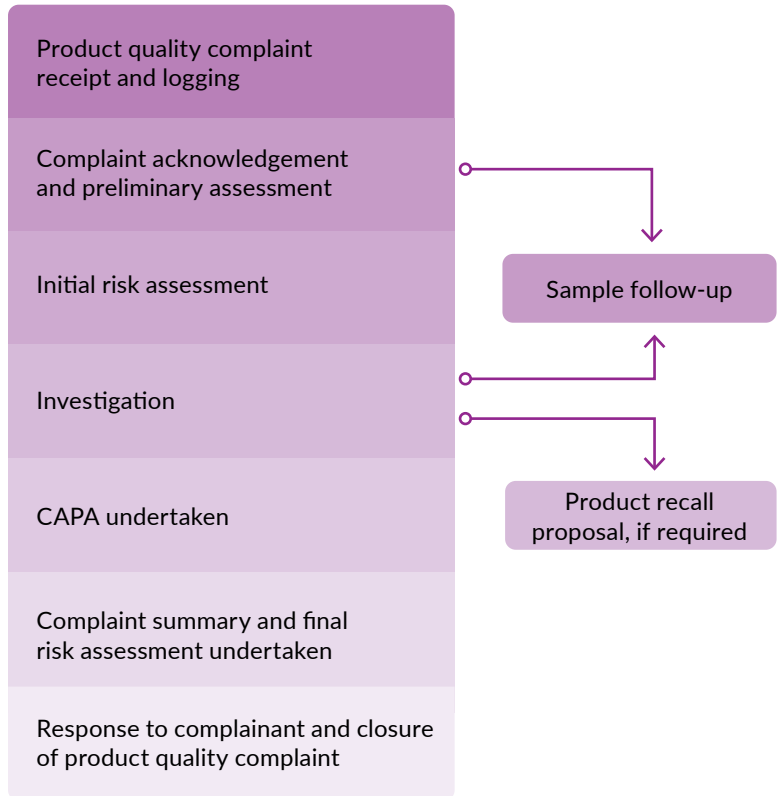
# Product Quality

In line with our Quality Vision, we have adopted an integrated and comprehensive quality management approach, encompassing our global QMS and best-in-class quality practices and quality assurance procedures. Additionally, we follow a robust quality complaint management procedure to ensure investigation of complaints received and integration of corrective actions. A number of our API and formulations manufacturing sites are ISO 9001: 2015 certified; we aim to increase the coverage of certified sites in future.

### — 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 QMS and all its elements. We are building and maintaining a strong culture of quality through ongoing development, training, and empowerment of our personnel. We believe that producing safe, high-quality products is everyone's responsibility.

### — QMS —

| Global QMS | Cross-functional implementation of QMS including R&D, quality, and operations | Implementation of best practices to ensure delivery of high-quality products |
|---|---|---|

### — Quality Practices —

| Sustainable quality design | Quality data governance | Harmonisation of processes for enhanced compliance | Global quality metrics | Lessons learned strategy |
|---|---|---|---|---|

### — Key Elements Strengthening Our QMS —

| **Procedural Documents** | **Deviation Analysis** | **Training** | **Good Documentation Practices** | **Corrective and Preventive Actions (CAPA)** |
|---|---|---|---|---|
| Electronic document management systems<br>• Controlled printing<br>• Access controlled<br>• Version controlled | Analysis of global deviation by undertaking periodic trend analysis | Instructor-led and electronic learning management systems | Implementation of good documentation practices in line with SOPs | Robust product quality complaint management encompassing preliminary assessment, investigation, and corrective actions |

### — Quality Assurance Process —

| | | |
|---|---|---|
| Compliance with GxP regulations and country-specific regulations | Periodic inspections at manufacturing locations in line with the requirements of GxP certifications by regulatory agencies | Release of raw materials, inclusive of API, and packaging material post qualification and testing |
| Ensuring quality of finished products through in-process testing, finished goods testing, and stability testing | Ensuring compliance with specifications, approved by regulatory agencies, relevant to each specific market requirement | Prevent any deviation, failures and discrepancies by recording investigations in the QMS |
| Comprehensive QMS system inclusive of change management, deviation management, CAPA, adverse product events, field alert reporting, and compliant management and recall process | Periodic audits conducted by the Company's Corporate Quality team at all manufacturing sites, contract manufacturing sites, and vendors | Training of employees involved in GxP activities through modules curated for job-specific roles |

## Our Product Quality Complaint Management Process

At Sun Pharma, we implement an all-inclusive approach towards product quality complaints. The complaints received are logged into the system, which is followed by a preliminary assessment. An initial risk assessment is conducted as part of the investigation procedure. A sample follow-up is carried out during the course of the investigation. Based on the outcome, CAPA are undertaken. A complaint summary is noted and assessment is conducted. A response to the complainant is submitted, leading to the closure of the complaint.

**Number of Product Recalls**

**2**
Class I

**19**
Class II

Product quality complaint receipt and logging

Complaint acknowledgement and preliminary assessment

Initial risk assessment

Investigation

CAPA undertaken

Complaint summary and final risk assessment undertaken

Response to complainant and closure of product quality complaint

Sample follow-up

Product recall proposal, if required