1. AUTHORIZATION

Function	Name	Signature	Date
Author	<name>		
Document Owner	<name>		
QA Approver	<name>		

Effective Date:		Revision Date:	

2. PURPOSE

The purpose of this document is to describe the framework and principles of the YOUR COMPANY Quality Management System, and to define the quality policy, standards, and management responsibilities within YOUR COMPANY.

3. SCOPE

This SOP applies to the Pharmaceutical Quality System (PQS) of YOUR COMPANY.
This SOP does not apply to <text>.

4. ROLES AND RESPONSIBILITIES

Role/Function	Responsibility
Document Owner / Author	Responsible to update and maintain this document with access to SMEs to ensure accuracy of document content. Signs document as responsible author.
Document User	Uses only the effective version of this document. Read and understood this procedure. Apply this procedure correctly.
Senior Management	Ultimate responsible to ensure an effective Pharmaceutical Quality System is in place, adequately resourced and that roles, responsibilities, and authorities are defined, communicated and implemented throughout the organization.
Quality Assurance	Ensure establishment, implementation, and maintenance of PQS. Develop measurements used by managers during performance reviews.

5. DEFINITIONS AND ABBREVIATIONS

5.1 Definitions

Key word	Definition
Data integrity	The extent to which all data are complete, consistent, and accurate throughout the data lifecycle (ALCOA+ definition).
Divergences	The collection of all events (planned and unplanned) which will change or have changed the predicted situation from procedural or regulatory expectations.
Finished product	A product ready for use, including (where applicable) leaflet and primary/secondary packaging as registered with the authorities or comparable institutes.
Function	A department, group or person (not limited), having a defined role in the organization.
Quality culture	A YOUR COMPANY's culture comprising shared values, beliefs, expectations, and commitments toward quality which are supported by structural and managerial elements and processes that enhance the quality.

5.2 Abbreviations

Abbreviation	
CMO	Contract Manufacturing Organization
CLO	Contract Laboratory Organization
GMP	Good Manufacturing Practice
PQS	Pharmaceutical Quality System

6. PROCEDURE

6.1 General

This quality manual will communicate the Companies quality policy and quality objectives to the staff, and make the staff familiar with the processes used to achieve compliance with quality requirements.

The quality manual facilitates the implementation of the PQS and ensures its maintenance and required updates during altering circumstances. It provides guidance to the minimum requirements and operational standards to ensure that the quality, and with that the business objectives, are met.

Lastly, the quality manual also allows effective communication and control of quality related activities and a documented base for quality system audits.

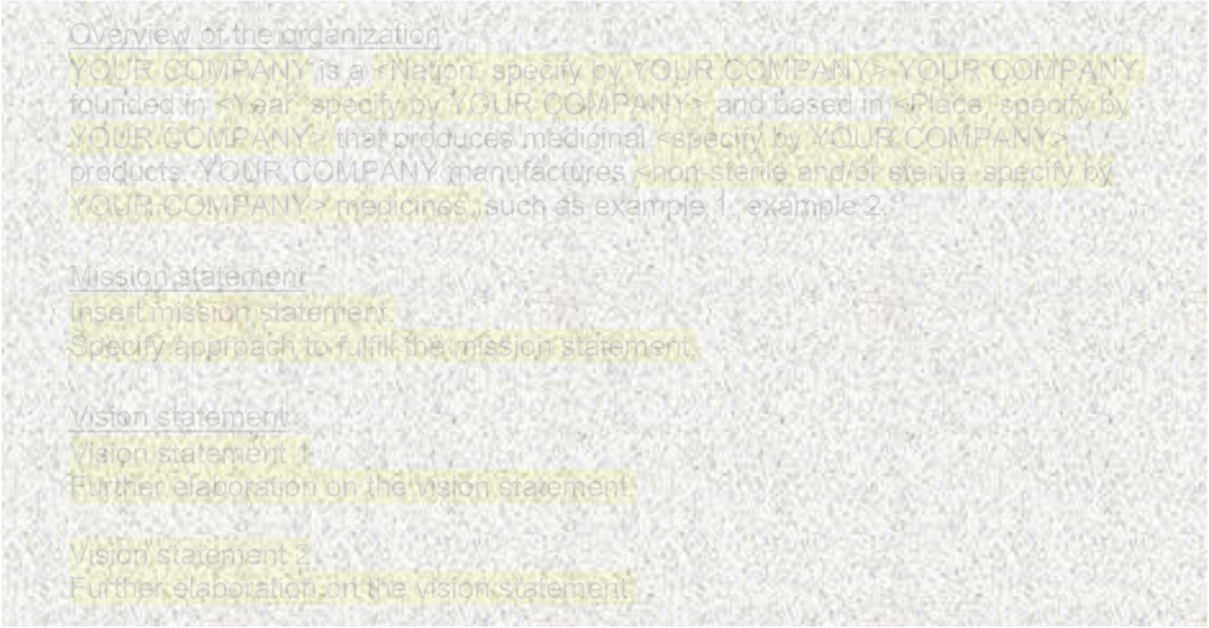
6.2 Quality Statement

YOUR COMPANY gives its commitment to comply with the principles of GMP as laid down in the relevant law and guidelines in accordance with the manufacturing licenses, market authorizations and standards within the market for those products developed or in development, manufactured or procured by the YOUR COMPANY.

YOUR COMPANY recognizes the absolute requirements for quality, safety, and efficacy in all its products, and places these as a priority above commercial considerations, to safeguard the health of the patients.

YOUR COMPANY also places a commitment to monitor all products held under their responsibility and will ensure due diligence and appropriate actions for product safety through its actions, and those of its employees, distributors, and partners.

6.3 Introduction to the Quality Manual



6.4 PQS Documentation

The Pharmaceutical Quality System is documented through a combination of:

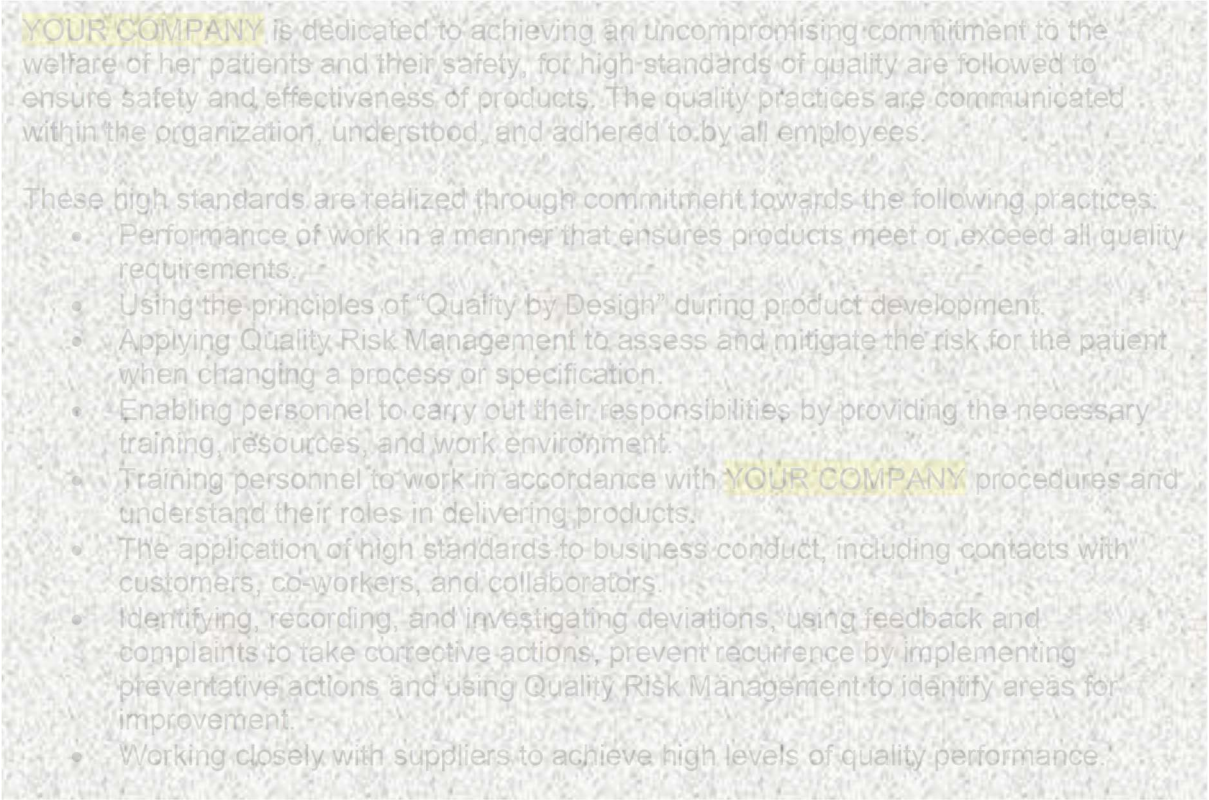
- Quality policies
- Standard Operating Procedures (SOPs)
- Records
- Templates

The table on the next page provides an overview of the relationship of the documentation within YOUR COMPANY's PQS.

Level	Description
1	*Policies = Quality Manual, Site Master File (SMF) and Validation Master Plan (VMP)* Articulation of the vision of senior management and its commitment to quality for all levels of the organization.

2	*Procedures = SOPs* SOPs that describe key aspects of the YOUR COMPANY's PQS and other more specific procedures. SOPs may contain procedures that are department, or method specific.
3	*Records* Quality records generated by the YOUR COMPANY's PQS. Records include but are not limited to, completed Manufacturing Records, QC Records, PQS audit reports, equipment calibration and maintenance records, and customer complaints. These are collected or audited and archived by QA.
4	*Templates* Templates are used to generated agreement. The need for agreements will be generated by policies or SOPs from YOUR COMPANY PQS.

6.5 Quality Policy



6.6 Responsibilities

The management team is responsible for ensuring that an effective PQS is established, implemented, and maintained. The success of the PQS is impacted through a binding statement of commitment, and the demonstration and communication of that commitment by senior management and departmental heads.

The QA Manager is responsible for ensuring that the PQS is established, implemented, and maintained. Other responsibilities of the QA Manager include the developing measurements which are used by managers during performance reviews to ensure the PQS is meeting established requirements.

It is the responsibility of department- and line managers to ensure communication, implementation, and practice that is in compliance with the PQS requirements.

All employees are responsible for adhering to policies, procedures and supporting the PQS in both the letter and spirit of its meaning.

YOUR COMPANY ensures that organizational charts are available to show the arrangements for GMP-related activities.

YOUR COMPANY ensures that definitions of the responsibilities are available for each person working in a GMP-controlled environment.

6.7 Activities

6.10 Quality Risk Management

Quality Risk Management is integrated throughout the framework of the PQS. Quality Risk Management is not a separate part or element of the PQS, but is a systematic approach for the assessment, control, communication, and review of risks that affect the quality of the product throughout the product lifecycle. Risk management will be additionally described in the risk management procedure.

6.11 Materials and services control system

Suppliers and subcontractors will be identified and chosen for their ability to provide materials or services to defined requirements. Through assessment procedures, YOUR COMPANY monitors suppliers on an ongoing basis to ensure they meet and comply with specified purchase requirements and arrangements defined in Quality Agreements. The Suppliers Vendor Management describes when these Quality Agreements are required. The extent of supplier assessment will be dependent on the significance of the product or service and, where applicable, upon previously demonstrated performance.

All purchased materials and services intended for use in production processes used for finished products will be specified in purchasing documents and Quality Agreements where applicable.

6.12 Records and document control system

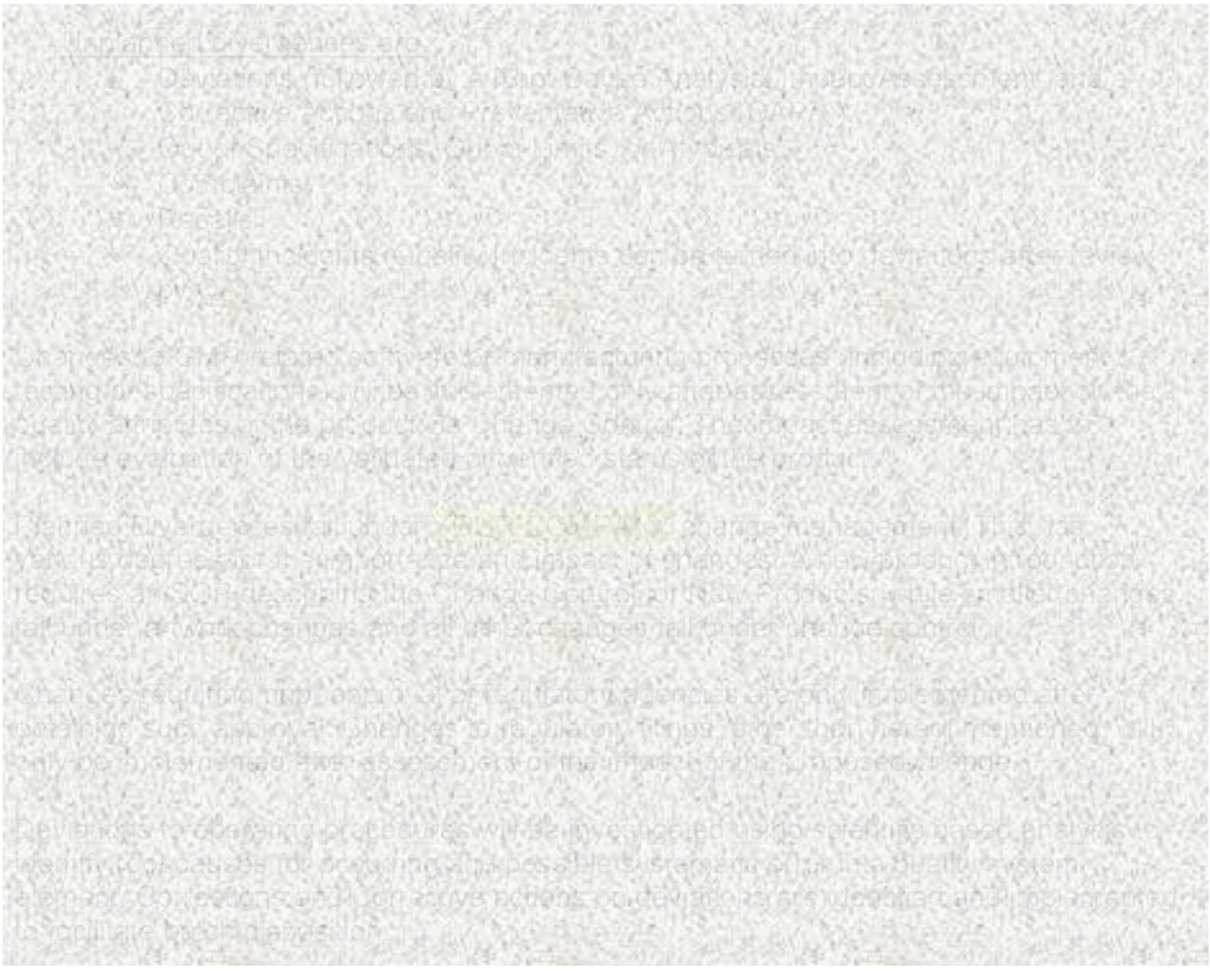
6.14 Divergences control system

Divergences can be placed in two different categories:

- Planned divergences (improvements).
- Unplanned divergences (non-conformances).

Planned divergences are:

- Change management.
- Change control.
- Document Change Control
- Artwork change (Artwork changes do not require QA).
- New product introduction.
- Maintenance (such as “like for like” replacements).
- New Introductions (Product, Materials, Equipment, Testing Methods, etc.)



YOUR COMPANY ensures that all product related complaints are adequately responded to, to ensure patient’s safety, wellness, and satisfaction.

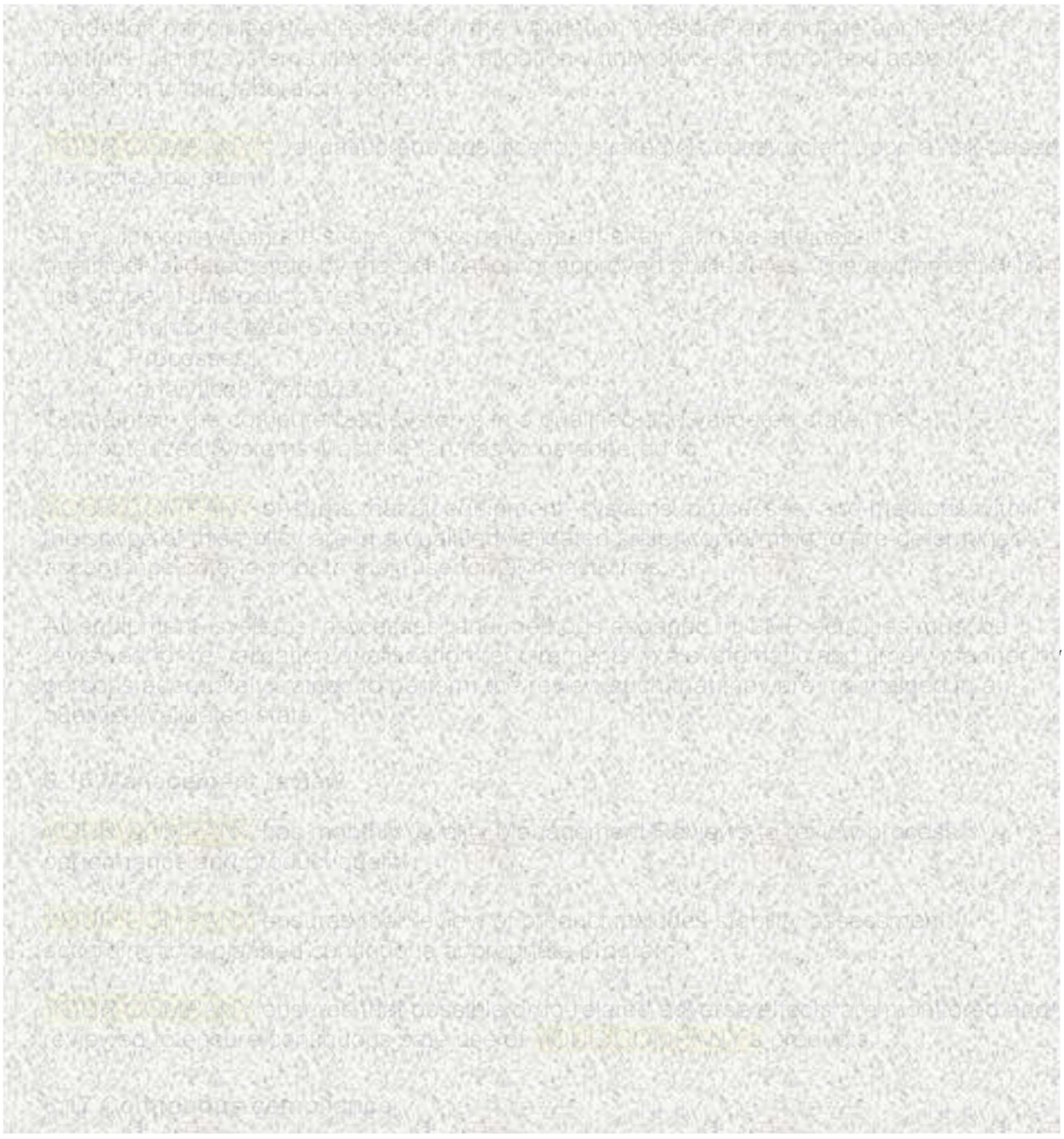
YOUR COMPANY ensures that recalls are executed timely and promptly in full compliance with the appropriate regulatory requirements.

A system for CAPAs is applied as a concept that focuses on investigating, understanding and correcting discrepancies, which include but is not limited to:

- Deviations.
- Findings of internal and external audits.
- Complaints, and/or
- Recalls.

The CAPA system focusses on remedial corrections on identified discrepancies, investigated using scientific and risk-based Root Cause Analysis and identification of Preventative Actions to prevent recurrence of discrepancies. Also Effectiveness of CAPA will be evaluated.

6.15 Validation control system



YOUR COMPANY ensures that continuous compliance is supported by a formal training plan for personnel. Performance review of the quality system is performed during PQS meetings which are held on a weekly basis.

7. REFERENCES

EudraLex Volume 4, Good Manufacturing Practice. Chapter 1 Pharmaceutical Quality System.

8. ATTACHMENTS

Document ID	Title
Attachment 1	Product list

9. REVISION HISTORY

Version	Previous Situation	New situation	Rationale/Justification
1.0	N/A	New Document according to SOP on SOP QA-SOP-001	Initial Quality Manual
2.0			

ATTACHMENT 1

Product list

Name	Strength
Product 1	
Product 2	