HUTCHMED

HUTCHMED (CHINA) LIMITED

QUALITY MANAGEMENT SYSTEM SUMMARY

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1. Introduction

HUTCHMED's Quality Management System (QMS), which reflects the Company's highest-level commitments to Good Practices (GxP), relates to clinical and nonclinical research, production, and pharmacovigilance activities to ensure patient safety, product quality, and data integrity.

These GxP commitments, which are summarized below, describe the expectations and requirements for maintaining and fostering an environment where quality is recognized, supported, and practiced by everyone at every level to ensure compliance with applicable regulatory requirements and industrial standards of internal operations, external suppliers, clinical investigators, and other partners.

2. HUTCHMED's Quality Commitment

HUTCHMED is committed to delivering the highest quality products and services. All employees are required and expected to focus on adhering to HUTCHMED's quality standards and practicing continual improvement in their work, which include but is not limited to developing new and improved products, research, and services; reducing errors, defects and waste; improving safety; improving responsiveness to customers; and improving productivity and effectiveness in the use of resources.

3. Quality Management System Scope

HUTCHMED is committed to the design and implementation of a proper Quality Management System to comply with all applicable regulatory requirements, policies, procedures, and industry standards with respect to the following GxP components:

- Good Clinical Practice (GCP)
- Good Distribution Practice (GDP)
- Good Laboratory Practice (GLP)
- Good Manufacturing Practice (GMP)
- Good Supply Practice (GSP)
- Good Vigilance Practice (GVP)

4. Senior Management Team's Responsibilities

The Senior Management Team, which includes HUTCHMED's Chief Executive Officer (CEO), Head of Global Quality Assurance and other relevant department heads, is responsible for:

- Ensuring the alignment of quality goals, functions and objectives within the organization;
- Fostering and maintaining a quality environment;
- Providing clear quality directions, priorities and expectations to all employees; and
- Allocating the necessary resources to accomplish and manage quality improvements.

5. Quality Assurance's Responsibilities

HUTCHMED's Quality Assurance, empowered by the entire Senior Management Team, is responsible for:

- Overseeing all quality-related matters;
- Conducting independent audits of internal and external GxP activities;
- Maintaining the GxP-compliant Quality Management System;
- Reporting metrics to the Senior Management Team in order to assess quality; and
- Managing regulatory interactions relating to inspections and quality inquiries.

6. Employees' Responsibilities

Employees at HUTCHMED are expected to be responsible for the following:

- Understanding and meeting applicable quality policies and procedures;
- Being proactive in raising questions and concerns regarding quality issues to the Quality Assurance Department and/or members of the Senior Management Team; and
- Positioning quality as a top priority.

Employees are given appropriate training to ensure they are able to carry out the above mentioned responsibilities.

7. Quality Management System Programs

The following fundamental programs are included to maintain an effective GxP-compliant Quality Management System:

1. Document Control
2. Records and Records Retention
3. Training
4. Management of Contract Research Organizations, Contract Service Providers, Suppliers and Consultants
5. Quality Agreement
6. Audits
7. Change Control
8. Deviations
9. Corrective And Preventive Action (CAPA)
10. Computerized Systems
11. Quality Risk Management
12. Investigational Medicinal Product Management and Withdrawal
13. Clinical Study and Nonclinical Study Management
14. Investigator Initiated Trial Management
15. Complaint Handling
16. Drug Safety/Product Safety and Pharmacovigilance
17. Management and Employee Quality Assurance Responsibilities
18. Medical Disclosures
19. Biometrics and Data Management
20. Quality Risk Management
21. Annual Product Quality Review
22. Materials Management and Purchasing Control
23. Buildings and Facilities
24. Equipment
25. Qualification, Verification and Validation
26. Production and Process Controls
27. Laboratory Control
28. Specifications
29. Stability
30. Batch Inspection, Testing, and Disposition
31. Labeling and Label Control
32. Packaging, Storage, Shipping, and Distribution
33. Product Complaints
34. Recalls and Product Field Alerts
35. Returned and Salvaged Goods