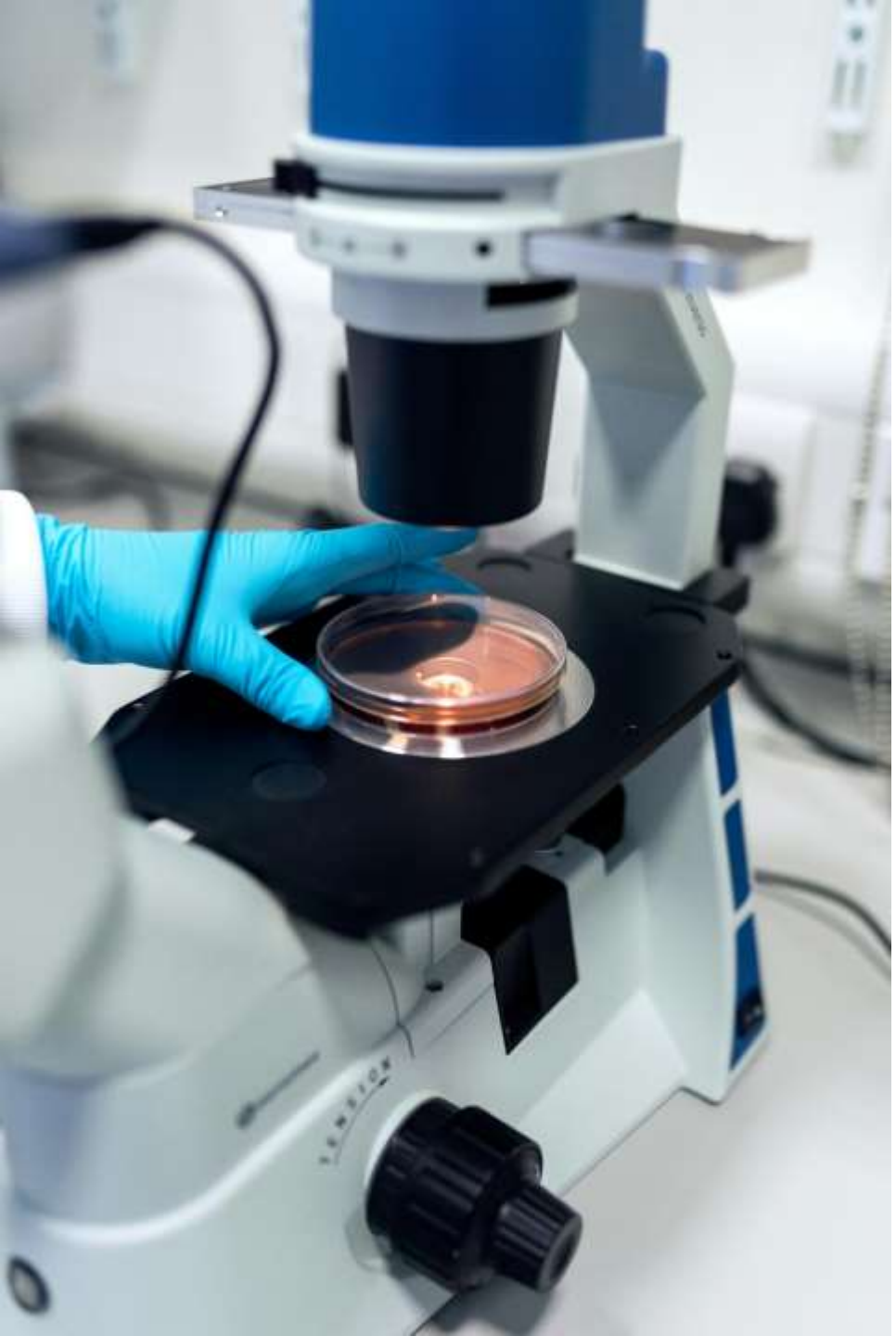

Quality Manual

By: Pharmaguidehub

About Document:

This Document has been written by Pharmaguidehub based on the PHARMACEUTICAL QUALITY SYSTEM ICH Q10.

Content Ownership: *The actual content of the Quality Manual belongs to the pharmaceutical company. A Quality Manual is a core document in the pharmaceutical industry. It serves as a roadmap outlining your organization's Pharmaceutical Quality Management System (PQMS).*

Final Authority: *The pharmaceutical company has ultimate ownership and responsibility for the accuracy of the information within the Quality Manual .*

About us:

- *In the continuously developing world of pharmaceuticals, ensuring compliance and quality can feel awesome. **Pharmaguidehub** steps in as your trusted partner, navigating the complex web of regulations. We specialize in creating customized pharmaceutical documents that meet the industry's strictest standards.*

- *Our team of **expert's** develop SOPs (Standard Operating Procedures), Qualification, risk assessment, compliance, dossier, cleaning validation and a comprehensive range of other documents tailored to your specific needs. We don't offer generic templates – we take the time to understand your processes and create documents that consistently integrate with your existing quality system.*

- ***Pharmaguidehub** goes beyond document creation. We help you implement these documents effectively, leading to a more robust and efficient quality system. By bridging the gap between regulations and practical application, we empower you to achieve and maintain the highest quality standards. Let **Pharmaguidehub** be your guide to pharmaceutical excellence.*

Our Knowledge Sharing Platform:

To get regular updates on Pharmaceutical industry you can join us at our following knowledge sharing platforms:

- *Web address: www.pharmaguidehub.com*
- *Telegram Link: https://t.me/pharmaguidehub*
- *LinkedIn: www.linkedin.com/in/pharmaguidehub*
- *Facebook Page Link: https://www.facebook.com/profile.php?id=61557224322551*
- *Twitter Link: https://x.com/pharmaguidehub*
- *WhatsApp Group Link: https://chat.whatsapp.com/HY09XT4iEL07oCE4Am3JUW*

What is Quality Manual?

- *In the pharmaceutical industry, a quality manual is a critical document that describes the company's entire Quality Management System (QMS). It serves as a roadmap for ensuring consistent production of safe and effective medications.*

Which Guideline follow for preparat of Quality Manual?

- ***ICH Q10:*** *"Pharmaceutical Quality System" by the International Council for Harmonization (ICH) provides a foundational framework for PQMS.*
- ***GMP:*** *Follow the Good Manufacturing Practices (GMP) guidelines set by your regulatory authority (e.g., US FDA EU GMP, WHO).*

About Quality Manual :

- *A Quality Manual is a core document in the pharmaceutical industry. It serves as a roadmap outlining your organization's Pharmaceutical Quality Management System (PQMS).*

Content of Quality Manual:

- APPROVAL
- INTRODUCTION
- QUALITY MANAGEMENT SYSTEM
- GENERAL INFORMATION
- RESPONSIBILITIES OF QUALITY ASSURANCE DEPARTMENT
- RESPONSIBILITIES OF QUALITY CONTROL DEPARTMENT
- DOCUMENTATION MANAGEMENT
- MANAGEMENT RESPONSIBILITIES
- RESOURCES MANAGEMENT
- PRODUCTION REALISATION
- MEASUREMENT, ANALYSIS AND IMPROVEMENT
- WATER SYSTEM
- REFERENCES
- APPENDIX

APPROVAL

- *It contain the detail of prepare, checker and approver of Quality Manual.*

INTRODUCTION

- *Organization Background*
- *Scope of the Manual*
- *Quality Policy Statement*
- *Document Control*

QUALITY MANAGEMENT SYSTEM

- *Quality Policy Statement*
- *Quality Policy*
- *Quality Objective*
- *Product Life Cycle*
- *Production System*
- *Facilities and Equipment System*
- *Laboratory Control System*
- *Material System*
- *Packaging and Labeling System*
- *Quality System*

GENERAL INFORMATION

- Company Presentation
- Regulatory Role (if applicable)
- Role and Scope of the Manual and QMS
- Management Commitment

RESPONSIBILITIES OF QUALIT ASSURANCE DEPARTMENT

- *This part describe the responsibility of Quality Assurance Department*

RESPONSIBILITIES OF QUALIT CONTROL DEPARTMENT

- This part describe the responsibility of Quality Control Department

DOCUMENTATION MANAGEMENT

- Document Pyramid
- Control of Document
- Access to Documents and Records
- Change Control
- Deviation / Incident

MANAGEMENT RESPONSIBILITIES

- Management Commitment
- Planning
- Corporate Objectives
- Quality Plan
- Responsibility, Authority and Communication
- Management Review

RESOURCES MANAGEMENT

- Human Resource
- Training
- Infrastructure
- Vendor Evaluation
- Validation / Qualification Policy
- Validation Program
- Types of Validations

PRODUCTION REALISATION

- Planning of Product Realization
- Material Requirement Plan
- Purchasing
- Material Control on Receipt
- Production Planning
- Method, Process and Cleaning Validation
- Production / Process Control

MEASUREMENT, ANALYSIS AND IMPROVEMENT

- Self Inspection
- External Audit
- Annual Product Review
- Trend Analysis
- Corrective and Preventive Action

WATER SYSTEM

- Description and Information of Water System
- Water Quality Management
- Monitoring and Control

REFERENCES

- Standards and Regulations
- Quality Procedures and Work Instructions
- External References

APPENDIX

- Organogram of Quality Assurance & Quality Control
- Key Personnel's of Quality Assurance & Quality Control
- Total Number of Employee in QA & QC
- Job Responsibilities of QA & QC Employee
- Floor Plan of QA & QC

Contact us at:

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