D139: DEMO OF GMP ICH Q7 DOCUMENT KIT Price 599 USD

(Applicable for Pharmaceuticals manufacturer based on Active Pharmaceutical ingredients (API)

Complete editable Good Manufacturing Practices (GMP) Q7 document kit
(Manual, procedures, process approach, exhibits, SOPs, formats, audit checklist etc.)

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Chapter-1.0 CONTENTS OF GMP ICH Q7 DOCUMENT KIT
Good Manufacturing Practices for Pharmaceutical companies based on API

(More than 165 document files)

The Total Editable Document kit has 7 main directories as below.

GMP- ICH Q7 Editable Document kit for API manufacturer

Sr. No.	List of Directory	Document of Details
1.	GMP Manual	15 chapter and 05 annexurein MS Word
2.	Procedures	08procedures in MS Word
3.	Process approach	10 process approach in MS Word
4.	Standard operating procedures	74standard operating procedure in MS Word
	Personnel and administration (PA)	17 Standard operating procedure in MS Word
	Quality Assurance (QA)	52 Standard operating procedure in MS Word
	System (SYS)	05 Standard operating procedure in MS Word
5.	Exhibits	06 Exhibits in MS Word
6.	Formats	53 formats in MS Word
	Engineering (ENG)	03 formats in MS Word
	Purchase (PUR)	05 formats in MS Word
	Despatch (DES)	05 formats in MS Word
	Housekeeping (HKC)	04 formats in MS Word
	Marketing (MKT)	03 formats in MS Word
	Production (PRD)	05 formats in MS Word
	Quality control (QCD)	06 formats in MS Word
	Stores (STR)	05 formats in MS Word
	System (SYS)	11 formats in MS Word
	Training (TRG)	06 formats in MS Word
7.	Audit checklist	More than 800 questions

Total 165 files quick download in editable form by e delivery

To get more information about GMP Q7 Documentation kit Click Here

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B. Documentation:-

Our document kit is having sample documents required for GMP Q7certification as listed below. You need to study it do necessary changes as per your company need and within 4 days your entire editable documents with all necessary details are ready as well as your team will got many ideas for system establishment to reduce the cost and effort with all necessary controls and your total documents are ready. We had given all type of templates and organization use it as per their need and many organization are certified globally in 1st trial with the help of our documents from any kind of stringent lead appraisal audit.

Under this directory further files are made in word document as per the details listed below. All the documents are related to GMP Q7 for and user can edit it in line with their own processes.

1. GMP Manual:

It covers sample copy of manual for GMPQ7 ICH Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. It covers 15 chapter and 05 annexure as well as list of procedures as well as overview of covers tier1 of GMP Q7 documents.

GMP Q7 Manual Index

To get more information about GMP Q7 Documentation kit Click Here

6.2	Equipment Cleaning and Use Record	
6.3	Records of Raw Materials, Intermediates, API Labelling and Packaging Materials	
6.4	Master Production Instructions (Master Production and Control Records)	
6.5	Batch Production Records (Batch Production and Control Records)	
6.6	Laboratory Control Records	
6.7	Batch Production Record Review	
7.1	General Controls	1 – 2
7.2	Receipt and Quarantine	
7.3	Sampling and Testing of Incoming Production Materials	
7.4	Storage	
7.5	Re-evaluation	
8.1	Production Operations	1 – 2
8.2	Time Limits	
8.3	In-process Sampling and Controls	
8.4	Blending Batches of Intermediates or APIs	
8.5	Contamination Control	
9.1	General	1 – 2
9.2	Packaging Materials	
9.3	Label Issuance and Control	
9.4	Packaging and Labeling Operations	
10.1	Warehousing Procedures	1 – 1
10.2	Distribution Procedures	
11.1	General Controls	1 – 2
11.2	Testing of Intermediates and APIs	
11.3	Validation of Analytical Procedures	
11.4	Certificates of Analysis	
11.5	Stability Monitoring of APIs	
11.6	Expiry and Retest Dating	
11.7	Reserve/Retention Samples	
12.1	Validation Policy	1 – 2
12.2	Validation Documentation	
12.3	Qualification	
12.4	Approaches to Process Validation	
12.5	Process Validation Program	
12.6	Periodic Review of Validated Systems	
12.7	Cleaning Validation	
12.8	Validation of Analytical Methods	
13.0	Change control	1 – 1
14.1	Rejection	1 – 2
14.2	Reprocessing	
14.3	Reworking	

2. Procedures (08 Procedures):

It covers sample copy of mandatory procedures covering all the details of Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

List of procedure

1. Procedure for management review
2. Procedure for document and data control
3. Procedure for Control of Records
4. Procedure for internal audit
5. Procedure for Training
6. Procedure for corrective and preventive action
7. Procedure for Control of Monitoring and Measuring equipments
8. Procedure for Control of Non–Conforming Products

3. Process approach (10process approach):

It covers sample copy of process approach covering all the details of Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

List of process approach

1. Process Flow Chart of Customer Service
2. Process Flow Chart of Dispatch
3. Process Flow Chart of Engineering
4. Process Flow Chart of Marketing
5. Process Flow Chart of Production
6. Process Flow Chart of Purchase
7. Process Flow Chart of Quality Control
8. Process Flow Chart of System Coordinator processes
9. Process Flow Chart of Stores
10. Process Flow for Training Activity

To get more information about GMP Q7 Documentation kit Click Here

4. Standard operating procedures (74SOPs):

It covers sample copy of standard operating procedures covering all the details of Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

List of standard operating procedures (SOPs)

1.	SOP for personnel and administration	2.	SOP for medical checkup of employees
3.	SOP for personnel hygiene	4.	SOP for cleaning & sanitization of factory premises
5.	SOP for garbage disposal	6.	SOP for maintenance of building
7.	SOP for scrap disposal	8.	SOP for security system
9.	SOP for safety training	10.	SOP for first aid training
11.	SOP for induction training	12.	SOP for pest control
13.	SOP for entry and exit for visitors	14.	SOP for cleaning procedure for uniforms
15.	SOP for dress code	16.	SOP for record of specimen signature
17.	SOP for job responsibility	18.	SOP for SOP
19.	SOP for Control of Version, Archival and Retrieval of Data	20.	SOP for Receipt and Handling of Market Complaints
21.	SOP for Product recall	22.	SOP for Handling of market returns
23.	SOP for Change control system	24.	SOP for Deviation and Investigation
25.	SOP for Quality audit	26.	SOP for Internal audit (self inspection)
27.	SOP for Non-conformance Procedure	28.	SOP for Non-conformance of Materials
29.	SOP for Vendor quality audit	30.	SOP for Purchasing quality materials from approved vendors
31.	SOP for Calibration and Preventive Maintenance of Equipment/Instrument	32.	SOP for Out of Calibration (OOC)
33.	SOP for Out of specification (OOS)	34.	SOP for Generation and Movement of Artwork
35.	SOP for Rework procedure	36.	SOP for Numbering and Codification System For Master Documents
37.	SOP for Sampling procedure for finished product analysis	38.	SOP for Entry Procedure for Sampling Area
39.	SOP for In-process Inspection During Manufacturing	40.	SOP for Cleaning of sampling equipments
41.	SOP for Disposition of rejected materials	42.	SOP for Destruction procedure for samples
43.	SOP for Handling and storage of raw material control samples	44.	SOP for Shelf life of finished product formulations
45.	SOP for Annual review of finish products	46.	SOP for Printed product label control
47.	SOP for Printed product carton control	48.	SOP for Line clearance
49.	SOP for Disposition of components and products	50.	SOP for Batch reconciliation
51.	SOP for Handling and storage of controlled samples	52.	SOP for Retain samples and its disposal
53.	SOP for Preparation of Master Batch Manufacturing Record	54.	SOP for Stability study
55.	SOP for Corrective and Preventive Action	56.	SOP for Mock recall
57.	SOP for Training system	58.	SOP for Batch release of Finished Products
59.	SOP for Equipment Status Labeling and Equipment Logbook Entry	60.	SOP for Failure investigation
61.	SOP for Introduction to validation	62.	SOP for Fundamentals of validation sop
63.	SOP for Guidelines for DQ, IQ, OQ & PQ	64.	SOP for Design qualification guideline for minimizing the risk of product cross-contamination by air handling unit
65.	SOP for Validation glossary	66.	SOP for Revalidation
67.	SOP for Guidelines for area validation: clean area	68.	SOP for Validation of HVAC system
69.	SOP for Analyst validation	70.	SOP for Prevention of Cross Contamination
71.	SOP for Housekeeping & Cleaning	72.	SOP for Building Maintenance and General Facilities
73.	SOP for Cleaning of Doors, Windows, Walls and Tube light and Fan	74.	SOP for Personal Hygiene

5. Exhibits (06exhibits):

It covers sample copy of exhibits covering all the details of Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

List of exhibits

1. Skill requirements
2. Multi Skill requirements
3. Control of non–conforming products
4. Document codification system
5. Quality Plan
6. Raw material specification

6. Blank Formats (53 Formats):

It covers sample copy of blank forms required to maintain records as well as establish control and make system. The samples given are as a guide and not compulsory to follow to change the same to suit own requirements.

List of Formats

1. Master List & Distribution List of Documents
2. Change Note
3. Corrective Action Report
4. Master List of Records
5. Quality Objectives Monitoring Sheet
6. Audit Plan / Schedule
7. SYS Internal Quality Audit Non–Conformity Report
8. GMP Clause wise Audit Review Report
9. Quality Objective Plan
10. Calibration Status of Instrument / Equipment
11. List of License / certificates
12. Training Calendar
13. Employee Wise Training & Competence Record Sheet
14. Induction Training Report
15. Job Description & Specification
16. Training Report
17. Skill Matrix
18. Purchase Order
19. Indent And Incoming Inspection Record
20. Approved external provider list & Annual purchase order
21. External Provider Registration Form
22. Annual Purchase Order
23. Order Form / Order Confirmation
24. Customer Complaint Report
25. Customer Feed Back Form
26. Breakdown History Card
27. Preventive Maintenance Schedule
28. Preventive Maintenance Check Points
29. Gate pass
30. Material Issue Slip
31. Preservation Assessment Report
32. Goods Receipt Note
33. Unloading Vehicle Checking Report
34. Production Plan
35. Disposal of Non-Conforming Products
36. Blending Data Sheet
37. Tray Dryer Log Sheet
38. Spin Flash Dryer Log Sheet
39. Sample Test Request Slip For Incoming materials
40. Sample Test Request Slip For In process / Finish product
41. Normality Record Sheet
42. pH Meter Calibration Report
43. Stability Study Report
44. Equipment Cleaning Validation Report
45. Packing Report / Slip
46. Bag / Other Packing Material Inspection Report
47. Screen Checking Report
48. Label issue register
49. Loading Vehicle Checking Report
50. Cleaning and Sanitation Report
51. Visitor's Entry Report
52. Sanitation Audit Report
53. Equipment Cleaning Report

7. Audit checklist (more than 800 questions)

It covers sample audit questions based on all the GMP Q7 good manufacturing practice guidance requirements based on GMP ICH standard. It helps the auditor to make own audit checklist for quick and perfect auditing to ensure all the Q7 good manufacturing practice guidance requirements are fulfilled.

To get more information about GMP Q7 Documentation kit Click Here

Chapter - 2.0 ABOUT COMPANY

Global Manager Group is a progressive company and promoted by a group of qualified engineers and management graduates having rich experience of 25 years in ISO consultancy and management areas. The company serves the global customers through on-site and off-site modes of service delivery systems. We offer a full range of consulting services geared towards helping all types of industries and laboratories to achieve competitiveness, certifications and compliance to international standards and regulations. So far we had **more than 1800 clients in more than 45 countries**. **Our readymade training and editable document kit helps the client in making their documents easy and make them complying to related ISO standard faster.**

1. Our promoters and engineers have experience of **more than 1800 companies** globally for management training, ISO series consultancy. We had clients **in more than 45 countries.**
2. Highly qualified 50 team members (M.B.A., Degree engineers) and owner is having rich professional experience (since 1991).
3. We have 100% success rate for ISO series certification of our clients from reputed certifying body and branded image and leading name in the market.
4. Suggest continual improvement and cost reduction measures as well as highly informative training presentations and other products gives payback within 2 months against our cost.
5. So far more than 50000 employees are trained by us in ISO series certification.
6. We had spent more than 60000 man-days (170 man years) in preparing ISO documents and training slides.

Global Manager Group is committed for:

1. Personal involvement & commitment from first day
2. Optimum charges
3. Professional approach
4. Hard work and update the knowledge of team members
5. Strengthening clients by system establishment and providing best training materials in any areas of management to make their house in proper manner
6. To establish strong internal control with the help of system and use of the latest management techniques.

Chapter - 3.0 USER FUNCTION

A. Hardware:-

- Our document kit can be better performed with the help of P3 and above computers with a minimum 10 GB hard disk space.
- For better visual impact of the power point Document you may keep the setting of colour image at high colour.

B. Software used in Document kit

- Documents written in Ms Office 2003 and window XP programs. You are therefore required to have office 2003 or above with window XP

3.2 Features of Document kit:-

- Contains all necessary documents as listed above and comply with the requirements of GMP Q7 Standards.
- Written in Plain English
- It will save much time in typing and preparation of documents alone.
- User-friendly and easy to learn.
- Developed under the guidance of experienced experts.
- Provides model of a Management system that is simple and free from excessive paperwork.

Chapter - 4.0 BENEFITS OF USING OUR DOCUMENT KIT

1. By using these documents, you can save a lot of your precious time while preparing the GMP Q7documents.
2. Take care for all the section and sub sections of GMP-ICH Q7 standard helps you in establishing better system applicable for manufacturer of Active pharmaceutical ingredients (API).
3. Document kit enables you to change the contents and print as many copies as you need. The user can modify the documents as per their industry and create own GMP Q7 documents.
4. Save much time and cost in document preparation.
5. You will get better control in your system due to our proven formats. We had helped to more than 20 companies globally to get GMP certificate from reputed certifying agency
6. You will get better control in your system due to our proven documents and templates developed under the guidance of our experts and globally proven consultants having rich experience of more than 25 years in ISO consultancy.
7. Our products are highly sold globally and used by many multinational companies and had provided total customer satisfaction as well as value for money.
8. In preparation of document kits; it is been verified and evaluated at various levels of our team and more than 1000 hours are spent in preparation of this product kit.
9. Prepared by globally proven team of leading consultant.

Chapter-5.0 METHOD OF ONLINE DELIVERY

On secured completion of purchase we provide user name and password to download the product from our ftp server. Thus we are providing instant on line delivery of our products to user by sending e mail of user name and password.

For purchase Click Here ➡ BUY

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