D141: DEMO OF ISO 15378:2017 DOCUMENT KIT for primary packaging material for medicinal products GMP Price 899 USD

Complete editable ISO 15378:2017 document kit (Manual, procedures, exhibits, process approach, SOPs, formats, audit checklist etc.)

Website: https://www.certificationconsultancy.com/iso-15378-certification-documents-manual.htm

Chapter-1.0 CONTENTS OF ISO 15378:2017 DOCUMENT KIT for primary packaging industry GMP

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

ISO 15378:2017 Editable Document kit

Sr. No.	List of Directory	Document of Details
1.	System Manual	10 chapter and 04 annexure in MS Word
2.	Procedures	18 procedures in MS Word
3.	Exhibits	04 exhibits in MS Word
4.	Formats	43 formats in MS Word / excel
	Engineering (ENG)	03 formats in MS Word
	Purchase (PUR)	05 formats in MS Word
	DND	04 formats in MS Word
	Marketing (MKT)	04 formats in MS Word
	Operation (OPN)	01 formats in MS Word
	Stores (STR)	02 formats in MS Word
	System (SYS)	17 formats in MS Word / Excel
	Training (TRG)	07 formats in MS Word
5.	Process approach	12 process approach in MS Word
6.	Standard operating procedures	61 standard operating procedure in MS Word
	Maintenance (MNT)	03 standard operating procedure in MS Word
	Production (PRD)	17 standard operating procedure in MS Word
	Quality Assurance (QA)	24 standard operating procedure in MS Word
	Quality Control (QCD)	11 standard operating procedure in MS Word
	Safety (SFT)	03 standard operating procedure in MS Word
	Stores (STR)	02 standard operating procedure in MS Word
	Information Technology (IT)	01 standard operating procedure in MS Word
7.	Audit checklist	More than 800 questions

Total 150 files quick download in editable form by e delivery

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B. Documentation:-

Our document kit is having sample documents required for ISO 15378:2017 certification 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 gotmany ideas for system establishment to reduce the cost and effort with all necessary controls and your total documentsare ready. We had given all type of templates and organization use it as per their need and many organizations 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 ISO 15378:2017 for and user can edit it in line with their own processes.

1. ISO 15378:2017 Manual:

It covers sample copy of ISO 15378:2017 manual. It covers 10 chapter and 04 annexure as well as list of procedures as well as overview of covers tier1 of ISO 15378:2017 documents.

ISO 15378:2017Manual Index

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	Communication		7.4
	Documented information		7.5
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	Operational planning and control		8.1
	Requirements for products and services		8.2
	Design and development of products and services		8.3
	Control of externally provided processes, products and services		8.4
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	Internal audit		9.2
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ANX–II	Glossary of terms	1 – 1	==========
ANX–III	Company activity process flow chart	1 – 2	==========
ANX–IV	Organization structure	1 – 1	==========

2. Procedures (18 Procedures):

It covers sample copy of mandatory procedures covering all the details of ISO 15378:2017.

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 Monitoring of work environment
9. Procedure for Validation of sterilization process

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10. Procedure For Monitoring And Measurement of Processes
11. Procedure For Analysis of Data
12. Procedure For Risk Management
13. Procedure for Customer satisfaction survey
14. Procedure for Purchasing
15. Procedure for Control of Non–Conforming Products
16. Procedure for Identification of products
17. Procedure for Traceability
18. Procedure for Preservation

3. Exhibits (04 exhibits).

It covers sample copy of exhibits covering all the details of ISO 15378:2017.

List of exhibits

1. Skill Requirements
2. Disposal of Non–conforming Products
3. Quality Plan
4. Document codification system

4. Blank Formats (43 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. Purchase Order
2. Indent cum Incoming inspection report
3. Approved Vendor list cum open purchase order
4. Supplier Registration form
5. Open Purchase Order
6. Daily Stock Statement
7. Gate Pass
8. Design And Development Plan
9. Design Review Minutes Of Meeting
10. Design Verification Report
11. Design Validation Report
12. Breakdown History Card
13. Preventive Maintenance Schedule
14. Equipment Wise preventive maintenance checkpoints
15. Order form/ confirmation
16. Customer Complaint report
17. Customer Feed Back Form
18. Customer Property Monitoring Register
19. Master List Cum Distribution List Of Documents
20. Change Note
21. Calibration Status Of Instrument / Equipment
22. Master list of records
23. Quality Objective Monitoring Report
24. Audit Plan / Schedule
25. Internal Audit Non–Conformity Report
26. Clausewise Documentwise Audit Review Report
27. Continual Improvement Plan
28. Corrective Action Report
29. Preventive Action Report
30. Qualitative Process Monitoring Report
31. Vendor Rating
32. List of license/certificate
33. Risk analysis sheet
34. Risk indemnification sheet
35. Communication report
36. Temperature & Humidity Monitoring Record – General area
37. Training Calendar
38. Training Need Cum Records Sheet
39. Induction Training Report
40. Job Description and Specification
41. Skill Matrix
42. Training Report
43. Skill Matrix for QC Personnel

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5. Process approach (12process approaches):

It covers sample copy of process approach covering all the details of ISO 15378:2017.

List of process approach

1. Process Flow Chart of Customer Service
2. Process Flow Chart of Design and Development
3. Process Flow Chart of Despatch
4. Process Flow Chart of Engineering
5. Process Flow Chart of Marketing
6. Process Flow Chart of Production Planning and Control
7. Process Flow Chart of Production
8. Process Flow Chart of Purchase
9. Process Flow Chart of Quality Control
10. Process Flow Chart of Risk & Opportunity
11. Process Flow Chart of Stores
12. Process Flow Chart of Training

6. Standard operating procedures (61SOPs):

It covers sample copy of standard operating procedures covering all the details of ISO 15378:2017.

List of standard operating procedures (SOPs)

1.	Preventive & Breakdown Maintenance Process	2.	Cleaning & Housekeeping
3.	Rodent & Fly Control Maintenance Process	4.	Manufacturing Process of Alluminium Collapsible Tubes
5.	Packing Process Of Alluminium Collapsible Tubes	6.	In-process Checking Frequency Of Different Parameters Of All Products
7.	Operation & Cleaning Of Extrusion Press	8.	Operation & Cleaning Of Trimming Machine
9.	Operation & Cleaning Of Annealing Machine	10.	Operation & Cleaning Of Lacquering Machine
11.	Operation & Cleaning Of Coating & Printing Machine	12.	Operation & Cleaning Of Latex Lining Machine
13.	SOP for Process For Making Purchases Of Raw Materials	14.	SOP for Process For Issuing Line Clearance
15.	SOP for Operation Of Necking & Bidding Machine	16.	SOP for Process Of Washing For Cans
17.	SOP for Process For Running Capping Machine	18.	SOP for Process For Production Of Laminated Tubes
19.	SOP for Process For Printing Of Laminated Web	20.	SOP for Manufacturing Of Plastic Bottles
21.	SOP for SOP	22.	SOP for Control of Version, Archival and Retrieval of Data
23.	SOP for Receipt and Handling of Market Complaints	24.	SOP for Product recall
25.	SOP for Handling of market returns	26.	SOP for Change control system
27.	SOP for Deviation and Investigation	28.	SOP for Vendor quality audit
29.	SOP for Out of Calibration (OOC)	30.	SOP for Out of specification (OOS)
31.	SOP for Generation and Movement of Artwork	32.	SOP for Rework procedure
33.	SOP for In-process Inspection During Manufacturing	34.	SOP for Printed product label control
35.	SOP for Handling and storage of controlled samples	36.	SOP for Retain samples and its disposal
37.	SOP for Mock recall	38.	SOP for Batch release of Finished Products
39.	SOP for Failure investigation	40.	SOP for Introduction to validation
41.	SOP for Fundamentals of validation sop	42.	SOP for Re-validation
43.	SOP for Guidelines for area validation–clean area	44.	SOP for Validation of HVAC system
45.	SOP for Handling Customer Complaint	46.	SOP for Testing And Approval Of Extruded Tubes
47.	SOP for Testing And Approval Of Trimmed Tubes	48.	SOP for Testing and Approval Of Annealed Tubes

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49. SOP for Testing And Approval Of Lacquered Tubes
50. SOP for Testing And Approval Of Coated & Printed Tubes
51. SOP for Testing And Approval Of Latex Lined Tubes
52. SOP for Testing And Approval Of Finished Cans
53. SOP for Leak Testing In Tubes
54. SOP for Testing And Approval Of Laminated Tubes
55. SOP for Leakage Testing Of Laminated Tubes
56. SOP for Maintaining Safety Standards In Tool Room
57. SOP for Maintaining Safety Standards In Plant
58. SOP for Maintaining Safety Standards For Storage
59. SOP for Receipt of Raw & Packaging Materials
60. SOP for Receipt, Storage& Dispatch of Finished Goods
61. SOP for IT

7. Audit checklist (more than500 questions)

It covers sample audit questions based on all the ISO 15378:2017requirements and GMP implementation. It helps the auditor to make own audit checklist for quick and perfect auditing to ensure all the ISO 15378:2017requirements are fulfilled.

Chapter-2.0 ABOUT COMPANY

Global Manager Groupis 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 ofindustries 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 ISOstandard 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 ISOseries 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 ISO 15378:2017 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.

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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 ISO 15378:2017documents.
2. Take care for all the section and sub sections of ISO 15378:2017 standard helps you in establishing better system.
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 ISO 15378:2017 documents.
4. Save much time and cost in document preparation.
5. You will get better control in your system due to our proven formats.
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 online delivery of our products to user by sending email of username and password.

For Purchase Click Here ➡ Contact Us

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