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

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

**Buy: www.Documentationconsultancy.com**

**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**

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

**Total 150 files quick download in editable form by e delivery**

To get more information about ISO 15378:2017 Documentation kit [Click Here](#)
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 get 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 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:


<table>
<thead>
<tr>
<th>Chapter No.</th>
<th>Subject</th>
<th>Page No.</th>
<th>ISO 15378:201 Clause Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Company profile</td>
<td>1 – 2</td>
<td>----</td>
</tr>
<tr>
<td>2.</td>
<td>Table of contents</td>
<td>1 – 2</td>
<td>----</td>
</tr>
<tr>
<td>3.</td>
<td>Control and distribution</td>
<td>1 – 2</td>
<td>----</td>
</tr>
<tr>
<td>4.</td>
<td>Context of the Organization</td>
<td>1 – 3</td>
<td>4.0</td>
</tr>
<tr>
<td></td>
<td>Understanding the organization and its context</td>
<td></td>
<td>4.1</td>
</tr>
<tr>
<td></td>
<td>Understanding the needs and expectations of interested parties</td>
<td></td>
<td>4.2</td>
</tr>
<tr>
<td></td>
<td>Determining the scope of the quality management system</td>
<td></td>
<td>4.3</td>
</tr>
<tr>
<td></td>
<td>Quality management system and its processes</td>
<td></td>
<td>4.4</td>
</tr>
<tr>
<td>5.</td>
<td>Leadership</td>
<td>1 – 5</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>Leadership &amp; Commitment</td>
<td></td>
<td>5.1</td>
</tr>
<tr>
<td></td>
<td>Policy</td>
<td></td>
<td>5.2</td>
</tr>
<tr>
<td></td>
<td>Organizational roles, responsibilities and authorities</td>
<td></td>
<td>5.3</td>
</tr>
<tr>
<td>6.</td>
<td>Planning</td>
<td>1 – 2</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>Action to address risks and opportunities</td>
<td></td>
<td>6.1</td>
</tr>
<tr>
<td></td>
<td>Quality objectives and planning to achieve them</td>
<td></td>
<td>6.2</td>
</tr>
<tr>
<td></td>
<td>Planning of changes</td>
<td></td>
<td>6.3</td>
</tr>
</tbody>
</table>

To get more information about ISO 15378:2017 Documentation kit Click Here

www.globalmanagergroup.com E mail sales@globalmanagergroup.com Tele: +91-79-2979 5322
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
   10. Procedure For Monitoring And Measurement of Processes
D141: DEMO OF ISO 15378:2017 DOCUMENT KIT for primary packaging material for medicinal products GMP

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

Buy: www.Documentationconsultancy.com

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 Validation Report
10. Design Verification Report
11. Design Review Minutes Of Meeting
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. Corrective Action Report
27. Continual Improvement Plan
28. Qualitative Process Monitoring Report
28. Audit Plan / Schedule
29. Preventive Action Report
29. List of license/certificate
30. Vendor Rating
30. Risk analysis sheet
31. Risk analysis sheet
31. Vendor Rating
32. Communication report
32. Communication report
33. Risk Analysis Report
33. Calibration Status Of Instrument / Equipment
34. Communication report
34. Risk Analysis Report
35. Communication report
35. Communication report
36. Temperature & Humidity Monitoring Record – General area
36. Temperature & Humidity Monitoring Record – General area
37. Training Calendar
37. Training Calendar
38. Training Need Cum Records Sheet
38. Training Need Cum Records Sheet
39. Induction Training Report
39. Induction Training Report
40. Job Description and Specification
40. Job Description and Specification
41. Skill Matrix
41. Skill Matrix
42. Training Report
42. Training Report
43. Skill Matrix for QC Personnel
43. Skill Matrix for QC Personnel

To get more information about ISO 15378:2017 Documentation kit Click Here

www.globalmanagergroup.com  E mail sales@globalmanagergroup.com  Tele: +91-79-2979 5322  Page 4 of 8
Complete editable ISO 15378:2017 document kit (Manual, procedures, exhibits, process approach, SOPs, formats, audit checklist etc.)

Buy: www.Documentationconsultancy.com

5. Process approach (12 process 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
11. Process Flow Chart of Stores
12. Process Flow Chart of Training

6. Standard operating procedures (61 SOPs):
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
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 SOP
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 SOP
35. SOP for Handling and storage of controlled samples
36. SOP for SOP
37. SOP for Mock recall
38. SOP for SOP
39. SOP for Failure investigation
40. SOP for SOP
41. SOP for Fundamentals of validation sop
42. SOP for SOP
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
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
52. SOP for Testing And Approval Of Finished Cans

To get more information about ISO 15378:2017 Documentation kit Click Here
Complete editable ISO 15378:2017 document kit (Manual, procedures, exhibits, process approach, SOPs, formats, audit checklist etc.)

Buy: www.Documentationconsultancy.com

7. Audit checklist (more than 500 questions)
It covers sample audit questions based on all the ISO 15378:2017 requirements and GMP implementation. It helps the auditor to make own audit checklist for quick and perfect auditing to ensure all the ISO 15378:2017 requirements are fulfilled.

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.

To get more information about ISO 15378:2017 Documentation kit Click Here
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.

To get more information about ISO 15378:2017 Documentation kit Click Here
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 15378:2017 documents.
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.
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

To get more information about ISO 15378:2017 Documentation kit Click Here

www.globalmanagergroup.com  E mail sales@globalmanagergroup.com  Tele: +91-79-2979 5322