DEMO OF ISO 13485:2016 Medical Device Document KitTotal

editable documentation package

Complete editable document tool kit (Quality manual, procedures, exhibits, formats, SOPs, process flow chart, audit checklist, medical device file etc.)

Buy: www.Joinconsultant.com

Chapter-1.0 CONTENTS OF ISO 13485:2016 DOCUMENT KIT (More than 125 document files)

A. The Total Editable Document kit has 8 main directories as below in Ms. Word & Ms. Excel

Sr. No.	List of Directory	Document of Details
1.	Quality Manual	40 Pages in Ms. word
2.	Procedures	19 procedures in Ms. word
3.	Exhibits	04 exhibits in Ms. Word
4.	Formats / Templates Name of departments	61 formats in Ms. Word & Ms. Excel
	Purchase (PUR)	05 formats in Ms. Word
	Stores (ST)	02 formats in Ms. Word
	DND	04 formats in Ms. Word
	Engineering (ENG)	03 formats in Ms. Word
	Marketing (MKT)	05 formats in Ms. Word
	Operation (OPN)	15 formats in Ms. Word
	Services (SER)	03 formats in Ms. Word
	System (SYS)	17 formats in Ms. Word & Ms. Excel
	Training (TRG)	07 formats in Ms. Word
5.	Standard Operating Procedures (SOPs)	06 SOPs in Ms. word
6.	Process Flow Chart	12 process flow charts in Ms. word
7.	Audit Checklist	02 files of more than 900 audit questions
8.	Medical Device File	21 files in Ms. word

Total 125 files quick download in editable form by e delivery

Complete editable document tool kit (Quality manual, procedures, exhibits, formats, SOPs, process flow chart, audit checklist, medical device file etc.)

B. ISO 13485:2016 requirementwise documents list:

Document No	Clause No./Document Title
Clause No. 04 Quality Management System	
4.1	**General Requirements**
QM 01	Quality manual
4.2	**Documentation Requirements**
PRO/SYS/02	Procedure for Document and Data control (Ref Clause 4.2.3)
F/SYS/01	Master List Cum Distribution List Of Documents
F/SYS/02	Change Note
PRO/SYS/03	Procedure for Record control (Ref Clause 4.2.4)
F/SYS/04	Master list of records
E/SYS/01	Exhibit for Documents codification system
GFI/TECH/01/xx	Medical device file
Clause No. 05 Management Responsibility	
5.1	**Management commitment**
QM 01	Quality Manual
5.2	**Customer Focus**
E/SYS/02/MKT	Process Approach for Marketing
5.3	**Quality Policy**
	Annex IV of Quality Manual
5.4	**Planning**
F/SYS/05	Quality Objective Monitoring Report
F/SYS/09	Continual Improvement Plan
5.5	**Responsibility, Authority and communication**
F/TRG/04	Job Description and Specification
E/SYS/02/MR	Process Approach for Management Representative
5.6	**Management Review**
PRO/SYS/01	Procedure for management Review (Ref Clause 5.6)
F/SYS/05	Quality Objective Monitoring Report
F/SYS/09	Continual Improvement Plan
Clause No. 06 Resource Management	
6.1	**Provision of Resources**
QM 01	Quality manual

6.2	Human Resource
PRO/SYS/05	Procedure for Training (Ref Clause 6.2.2)
E/SYS/02/HRD	Process approach for Training
E/HRD/01	Exhibits for Skill requirements
F/TRG/01	Training Calendar
F/TRG/02	Training Need Cum Records Sheet
F/TRG/03	Induction Training Report
F/TRG/04	Job Description and Specification
F/TRG/05	Skill Matrix
F/TRG/06	Training Report
F/TRG/07	Skill Matrix for QC Personnel
F/SYS/15	Risk analysis sheet
F/SYS/16	Risk identification sheet
6.3	**Infrastructure**
E/SYS/02/ENG	Process approach for Engineering
F/ENG/01	Breakdown History Card
F/ENG/02	Preventive Maintenance Schedule
F/ENG/03	Equipment Wise preventive maintenance checkpoints
6.4	**Work Environment and contamination control**
PRO/SYS/08	Procedure for control of monitoring of work environment (Ref Clause 6.4)
F/OPN/01	Temperature Record
F/OPN/02	Validation Of Autoclave By Biological Indicator
F/OPN/03	Temperature And Relative Humidity Record (Parentral)
F/OPN/04	Temperature And Relative Humidity Record (Washing & Sterilization)
F/OPN/05	Temperature And Relative Humidity Record (Filling and Manufacturing)
F/OPN/06	Differential Pressure Monitoring Record (Parentral)
F/OPN/07	Differential Pressure Monitoring Record (Washing & Sterilization)
F/OPN/08	Differential Pressure Monitoring Record (Ointment)
F/OPN/09	Temperature & Humidity Monitoring Record – General area
F/OPN/10	Microbial Monitoring Of Production Area By Settling Plate Method
F/OPN/11	Microbial Monitoring Of Production Area By Settling Plate Method – Ointment preparation
F/OPN/12	Microbial Monitoring By Swab /Surface Contact Technique – Parenteral in preparation.
F/OPN/13	Microbial Monitoring – Microbial Testing Of Sterile Garments
F/OPN/14	Testing Of Personnel By Finger Dab
F/OPN/15	Microbial Monitoring By Swab /Surface Contact Technique

Clause No. 07 Product realization and implementation and operation	
7.1	**Planning Of Product Realization**
E/QCD/01	Quality Plan
7.2	**Customer Related processes**
E/SYS/02/MKT	Process approach for Marketing
F/MKT/01	Order form/ confirmation
F/MKT/02	Customer Complaint report
F/MKT/03	Customer Feed Back Form
F/MKT/04	Medical Practitioner Feedback Form
F/MKT/05	Customer Property Monitoring Register
F/SYS/17	Communication report
7.3	**Design and Development**
E/SYS/02/DND	Process Approach for Design and Development
F/DND/01	Design and Development Plan
F/DND/02	Design review meeting
F/DND/03	Design Verification report
F/DND/04	Design Validation report
7.4	**Purchasing**
PRO/PUR/01	Procedure for purchasing (Ref Clause 7.4)
F/SYS/13	Vendor Rating
E/SYS/02/PUR	Process approach for Purchase
F/PUR/01	Purchase Order
F/PUR/02	Indent cum Incoming inspection report
F/PUR/03	Approved Vendor list cum open purchase order
F/PUR/04	Supplier Registration form
F/PUR/05	Open Purchase Order
7.5	**Production and Service Provision**
7.5.1	**Control of Production and Service Provision**
E/SYS/02/PRD	Process approach for Production
E/SYS/02/QCD	Process approach for Quality Control
E/QCD/01	Quality Plan
E/SYS/02/STR	Process approach for Stores
7.5.2	**Cleanliness of the product**
QM 01	Quality manual

7.5.3	**Installation activities**
E/SYS/02/INS	Process approach for Installation and commissioning
F/SER/03	Installation and commissioning record
7.5.4	**Service activities**
E/SYS/02/SER	Process approach for Servicing
F/SER/01	Service Report
F/SER/02	Repairing card
7.5.5	**Particular requirements for sterile medical devices**
PRO/SYS/09	Procedure for validation of sterilization process (Ref Clause 7.5.2)
7.5.6	**Validation of Processes for Production and Service Provision**
PRO/SYS/09	Procedure for validation of sterilization process (Ref Clause 7.5.2)
7.5.7	**Particular requirements for validation of processes for sterilization and sterile barrier systems**
PRO/SYS/09	Procedure for validation of sterilization process (Ref Clause 7.5.2)
7.5.8	**Identification**
PRO/STR/01	Procedure for identification of products(Ref Clause 7.5.3.1)
7.5.9	**Identification and Traceability**
PRO/STR/02	Procedure for traceability (Ref Clause 7.5.3.2)
7.5.10	**Customer Property**
F/MKT/05	Customer Property Monitoring Register
7.5.11	**Preservation of Products**
E/SYS/02/STR	Process approach for Stores
7.6	**Control of Measuring and Monitoring Equipment**
PRO/SYS/07	Procedure for control of monitoring and measuring equipments (Ref Clause 7.6)
F/SYS/03	Calibration Status Of Instrument / Equipment
Clause No. 08 à Measurement, Analysis and improvement	
8.1	**General**
QM 01	Quality manual
8.2	**Monitoring And Measurement**
8.2.1	**Feedback**
8.2.2	**Customer complaint**
8.2.3	**Reporting to regulatory authorities**
PRO/MKT/01	Procedure for customer feedback
F/MKT/02	Customer Complaint report
F/MKT/03	Customer Feed Back Form
F/MKT/04	Medical Practitioner Feedback Form
F/SYS/17	Communication report

8.2.4	**Internal Audit**
PRO/SYS/04	Procedure for internal audit (Ref Clause 8.2.2)
E/SYS/02/QCD	Process approach for Quality Control
F/SYS/06	Audit Plan / Schedule
F/SYS/07	Internal Audit Non–Conformity Report
F/SYS/08	Clausewise Document wise Audit Review Report
8.2.5	**Monitoring and measurement of product**
E/QCD/01	Quality Plan
8.2.6	**Monitoring and measurement of processes**
PRO/SYS/10	Procedure for monitoring and measurement of process (Ref Clause 8.2.3)
F/SYS/05	Quality objective monitoring report
F/SYS/12	Qualitative process monitoring report
8.3	**Control of Non confirming products**
PRO/PRD/01	Procedure for control of non confirming products (Ref Clause 8.3)
E/PRD/01	Exhibit for disposal of non confirming products
8.4	**Analysis of Data**
PRO/SYS/11	Procedure for Analysis of data
8.5	**Improvement**
PRO/SYS/12	Procedure for issue and implementation of advisory notice (Ref Clause 8.5.1)
PRO/SYS/06	Procedure for corrective and preventive actions (Ref Clause 8.5.2 and 8.5.3)
F/SYS/10	Corrective Action Report
F/SYS/11	Preventive Action Report
Master Reference Guideline	
PRO/SYS/13	Procedure for Hazard Analysis
F/SYS/14	Hazard Analysis
F/SYS/15	Risk analysis sheet
F/SYS/16	Risk indemnification sheet
Clause wise audit questionnaire Department wise audit questionnaires	

Part: C Documentation:-

Our document kit is having sample documents required for implementation of ISO 13485:2016. The documents are prepared by the highly experienced team of people with rich experience of process improvement and process enhancement and many companies are certified successfully under ISO 13485:2016 with our help. You need to study the document kit and do necessary changes as per your company need and within 1 week your entire documents 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 many files are made in word Document as per the details listed below. All the documents are related to ISO 13485:2016 for and user can edit it in line with their own processes.

1. Quality Manual:

It covers sample copy of quality manual and requirement wise details for how ISO 13485:2016 is implemented. It covers sample policy for all process areas, Quality policy and organization structure and covers 1st tier of ISO 13485:2016 documents.

(A) Table Of Contents

2. Procedures (19 Procedures):

It covers sample copy of procedures covering all the specific practice areas of 19 processes. Our procedures help the organization to make the best system and quick process improvements. All proceduresare as listed below.

List of Procedures (19 procedures)

Sr. No.	Procedure No.	Name of Procedure	Total Page
1.	PRO/SYS/01	Procedure for Management review	03
2.	PRO/SYS/02	Procedure for Document and Data Control	07
3.	PRO/SYS/03	Procedure for Control of records	03
4.	PRO/SYS/04	Procedure for Internal Audit	03
5.	PRO/SYS/05	Procedure for Training	03
6.	PRO/SYS/06	Procedure For Corrective And Preventive Action	04
7.	PRO/SYS/07	Procedure For Control of Monitoring And Measuring Equipments	04
8.	PRO/SYS/08	Procedure for Control of Monitoring of work environment	02
9.	PRO/SYS/09	Procedure for validation of sterilization process	03
10.	PRO/SYS/10	Procedure For Monitoring And Measurement of Processes	03
11.	PRO/SYS/11	Procedure For Analysis of Data	02
12.	PRO/SYS/12	Procedure For Issue And Implementation of Advisory Notices	02
13.	PRO/SYS/13	Procedure For Hazard Identification	01
14.	PRO/MKT/01	Procedure for customer satisfaction survey	02
15.	PRO/PUR/01	Procedure for Purchasing	05
16.	PRO/PRD/01	Procedure for Control of Non–Conforming Products	02
17.	PRO/STR/01	Procedure for identification of products	02
18.	PRO/STR/02	Procedure for traceability	02
19.	PRO/STR/03	Procedure for preservation	02
		Total Pages ➔	**55**

3. Exhibits (04 Exhibits):

It covers sample copy of guidelines covering all the details and for training to the user toimplement the processes and get detail ideas for process implementation and improvement.

List of Exhibits (04 Exhibits)

Sr. No.	Guideline No.	Name of Guidelines	Total Pages
1.	E/HRD/01	Skill Requirements	01
2.	E/PRD/01	Disposal of Non–conforming Products	01
3.	E/QCD/01	Quality Plan	01
4.	E/SYS/01	Document codification system	01
		Total Pages ➔	**04**

4. Formats (61 Formats)

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

List of Formats (61 Formats)

Sr. No.	Format No.	Name of Format
1.	F/PUR/01	Purchase Order
2.	F/PUR/02	Indent cum Incoming inspection report
3.	F/PUR/03	Approved Vendor list cum open purchase order
4.	F/PUR/04	Supplier Registration form

5.	F/PUR/05	Open Purchase Order
6.	F/ST/01	Daily Stock Statement
7.	F/ST/02	Gate Pass
8.	F/DND/01	Design And Development Plan
9.	F/DND/02	Design Review Minutes Of Meeting
10.	F/DND/03	Design Verification Report
11.	F/DND/04	Design Validation Report
12.	F/ENG/01	Breakdown History Card
13.	F/ENG/02	Preventive Maintenance Schedule
14.	F/ENG/03	Equipment Wise preventive maintenance checkpoints
15.	F/MKT/01	Order form/ confirmation
16.	F/MKT/02	Customer Complaint report
17.	F/MKT/03	Customer Feed Back Form
18.	F/MKT/04	Medical Practitioner Feedback Form
19.	F/MKT/05	Customer Property Monitoring Register
20.	F/OPN/01	Temperature Record
21.	F/OPN/02	Validation Of Autoclave By Biological Indicator
22.	F/OPN/03	Temperature And Relative Humidity Record (Parentral)
23.	F/OPN/04	Temperature And Relative Humidity Record (Washing & Sterilization)
24.	F/OPN/05	Temperature And Relative Humidity Record (Filling and Manufacturing)
25.	F/OPN/06	Differential Pressure Monitoring Record (Parentral)
26.	F/OPN/07	Differential Pressure Monitoring Record (Washing & Sterilization)
27.	F/OPN/08	Differential Pressure Monitoring Record (Ointment)
28.	F/OPN/09	Temperature & Humidity Monitoring Record – General area
29.	F/OPN/10	Microbial Monitoring Of Production Area By Settling Plate Method
30.	F/OPN/11	Microbial Monitoring Of Production Area By Settling Plate Method – Ointment preparation
31.	F/OPN/12	Microbial Monitoring By Swab /Surface Contact Technique – Parenteral in preparation.
32.	F/OPN/13	Microbial Monitoring – Microbial Testing Of Sterile Garments
33.	F/OPN/14	Testing Of Personnel By Finger Dab
34.	F/OPN/15	Microbial Monitoring By Swab /Surface Contact Technique
35.	F/SER/01	Service report
36.	F/SER/02	Repairing card
37.	F/SER/03	Installation commissioning report
38.	F/SYS/01	Master List Cum Distribution List Of Documents
39.	F/SYS/02	Change Note
40.	F/SYS/03	Calibration Status Of Instrument / Equipment

41.	F/SYS/04	Master list of records
42.	F/SYS/05	Quality Objective Monitoring Report
43.	F/SYS/06	Audit Plan / Schedule
44.	F/SYS/07	Internal Audit Non–Conformity Report
45.	F/SYS/08	Clausewise Documentwise Audit Review Report
46.	F/SYS/09	Continual Improvement Plan
47.	F/SYS/10	Corrective Action Report
48.	F/SYS/11	Preventive Action Report
49.	F/SYS/12	Qualitative Process Monitoring Report
50.	F/SYS/13	Vendor Rating
51.	F/SYS/14	Hazard Analysis Report
52.	F/SYS/15	Risk analysis sheet
53.	F/SYS/16	Risk indemnification sheet
54.	F/SYS/17	Communication report
55.	F/TRG/01	Training Calendar
56.	F/TRG/02	Training Need Cum Records Sheet
57.	F/TRG/03	Induction Training Report
58.	F/TRG/04	Job Description and Specification
59.	F/TRG/05	Skill Matrix
60.	F/TRG/06	Training Report
61.	F/TRG/07	Skill Matrix for QC Personnel

5. Standard Operating Procedures (06 SOPs)

It covers sample copy of work instructions to link with significant aspects issues in the organization. It takes care of all such issues and used as a training guide as well as to establish control and make system in the organization. The samples given are as a guide and not compulsory to follow and organization is free to change the same to suit own requirements.

List of SOPs

Sr. No.	SOP No.	Name of SOP	Total Page
1.	W/OPN/01	Measurement Of Temperature And Humidity	02
2.	W/OPN/02	Validation of Autoclave	03
3.	W/OPN/03	Microbial Monitoring of Production Area	07
4.	W/OPN/04	Temperature Monitoring of Sterility Room and Microbiology Laboratory	02
5.	W/OPN/05	Temperature & Humidity Monitoring	02
6.	W/OPN/06	Clean Room Condition Monitoring	03
		Total Pages ➔	**19**

6. Process Flow Chart

List of Process flow charts

Sr. No.	Process flow chart No.	Name of SOP	Total Page
1.	E/SYS/02/DES	Process approach for Despatch	02
2.	E/SYS/02/DND	Process approach for Design and Development	04
3.	E/SYS/02/ENG	Process approach for Engineering	03
4.	E/SYS/02/HRD	Process approach for Training	03
5.	E/SYS/02/MKT	Process approach for Marketing	05
6.	E/SYS/02/MR	Process approach for Management Representative	02
7.	E/SYS/02/PRD	Process approach for Production	02
8.	E/SYS/02/PUR	Process approach for Purchase	04
9.	E/SYS/02/QCD	Process approach for Quality Control	04
10	E/SYS/02/STR	Process approach for Stores	04
11	E/SYS/02/INS	Process approach for Installation and Commissioning	03
12	E/SYS/02/STR	Process approach for Servicing	03
		Total Pages ➔	**39**

7. ISO 13485:2016 audit questionnaire (02 files of more than 900 Questions)

There covers audit questions based on ISO 13485:2016 requirements as well as for Clausewise questions and department wise question. It will be very good tool for the auditors to make audit Questionnaire / clause wise audit Questionnaire while auditing and make effectiveness in auditing.

8. ISO 13485:2016 medical devices file (21 files)

There covers medical devices technical files for ISO 13485:2016.

Chapter-2.0 ABOUT COMPANY

Joinconsultant is a progressive company and promoted by a group of qualified engineers and management graduates having rich experience of 20 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 organizations 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 standard faster with the establishment of best processes.** **It helps the organization to make the best system with process improvement concepts and helps the organization to get best performances in terms of reduction in costing, efforts and get the things done timely with Quality product. Thus it helps the organization to give full value for money and pay back of our product is less than 2 month.**

1. Our promoters and engineers have experience of **more than 1800 companies** globally for management training, ISO consultancy, process improvement concept implementation and 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 global standards certification including ISO 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 in last 20 years.
6. We had spent more than 10000 man-days (30 man years) in preparing ISO documents, management kits and training slides.
7. Our product gives lot of opportunity for process improvements and gives full benefits to the users.

Joinconsultant 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

3.1 Hardware and Software Requirements

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 and later.

3.2 Features of Document kit:-

- Contains all necessary documents as listed above and comply with the requirements of ISO 13485:2016 guidelines for product and services development technical report.
- 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 your company to the ISO 13485:2016 documents.
2. Take care for all the section and sub sections of ISO 13485:2016 guidelines and 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 13485:2016 documents for their organization
4. Readymade templates and sample documents are available which can reduce your time in document preparation
5. Save much time and cost in document preparation
6. The audit questions helps in making perfect audit checklist
7. You will get better control in your system due to our proven formats and templates