D177: DEMO OF ISO 14155:2020 DOCUMENTATION AND AWARENESS TRAINING KIT Price 699 USD

Totally editable documentation package and awareness training package for quick process improvement to implement the sector specific management system in your organization

Completely editable documentation and training toolkit (Manual, procedures, exhibits, SOPs, formats, audit checklist, PPT presentation and student manual etc.)

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Chapter–1: Contents of ISO 14155:2020 documentation and awareness training kit (More than 85 files)

This editable documentation and awareness training kit has 2 main parts as below:

Sr. No.	Directory	Details of Documents
Part – 1: Documentation		
1.	Quality Manual	01 file in MS Word
2.	Quality Procedures	21 procedures in MS Word
3.	Exhibits	06 exhibits in MS Word
4.	Standard operating procedures	05 standard operating procedure in MS Word
5.	Formats	49 formats in MS Word / excel
6.	Audit checklist	More than 180 questions
7.	ISO 14155:2020 document compliance matrix	01 file in MS Excel
Part – 2: Training: ISO 14155:2020 awareness training		
A.	PPT Presentation	No. of Slides
1.	Awareness of ISO 14155:2020	16 slides
2.	ISO 14155:2020 requirements	113 slides
3.	Control of Documents and Records	14 slides
4.	Step for ISO 14155:2020 Installation & Certification	06 slides
B.	Literature	
	A literature to understand ISO 14155:2020 subject well in 04 chapters, 02 workshops and 01 case study	Approx. 60 pages in MS word
C.	Workshops and Case study	20 questions to solve and 1 Case study with 5 questions
Total 85 files quick download in editable form by e delivery		

For more information about ISO 14155:2020 Documentation and Awareness Training kit Click Here

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Part-1: Documentation:

Our documentation kit contains sample documents required for ISO 14155:2020 certification as listed below. All documents are in MS-Word/Excel files and you can edit them. You can make changes as per your organization's need and within few days your entire documents with all necessary controls will be ready. In the ISO 14155:2020, documented information (procedures, SOPs, etc.) are required a few places only. But for making the system better, we have provided many editable templates from which a user can select templates as per their own requirement and make some minor changes in them to make own system. Two types of documented information are provided in this kit, as listed below:

1. Maintain documented information (Scope, Manual, etc.)

2. Retain documented information (Forms / Templates)

Under the main directories, further files are provided in MS Word document as per the details given below.

1. Quality Manual:

It is a sample copy of quality manual having clause-wise details of how ISO 14155 system is implemented. The quality manual is tier-1 of ISO 14155 documents and covers list of procedures as well as overview of organization. This manual has total 10 chapters covering company profile, amendment sheet, index, clause-wise details as per ISO 14155 for implementation, sample quality policy and organization chart.

ISO 14155:2020 Manual Index

Chapter No.	Subject		Amendment No.	Page No.	ISO 14155 Clause Ref.
1	Cover page, Table of contents, amendment record sheet and glossary of terms (abbreviation)		00	1 – 6	==========
2	Authorization statement and profile and context of organization		00	7 – 8	==========
3	Control and distribution		00	9 – 10	==========
4.0	**Summary of good clinical practice (GCP) principles**		00	11 – 12	**4.0**
5.0	**Ethical Consideration**				**5.0**
	5.1	General	00	13	
	5.2	Improper Influence or Inducement	00	13	
	5.3	Compensation and additional health care	00	13	
	5.4	Registration in publicly accessible database	00	13	
	5.5	Responsibilities	00	13	
	5.6	Communication with the ethics committee (EC)	00	13 – 15	
	5.7	Vulnerable populations	00	15	
	5.8	Informed consent	00	15 – 21	

For more information about ISO 14155:2020 Documentation and Awareness Training kit Click Here

2. Quality Procedures (21 Procedures):

Sample copies of mandatory procedures as per ISO 14155 are provided, which cover all the details like purpose, scope, responsibility, how procedure is followed as well as the list of exhibits, reference documents and formats. The list of sample procedures provided in the kit is given below.

List of procedure

1. Procedure for recruiting subjects and advertising materials
2. Procedure for clinical investigations on vulnerable populations
3. Procedure for risk assessment
4. Procedure for preparation, review and changes or corrections in case report forms
5. Procedure for the control of documents and document changes
6. Procedure for decoding blinded/masked clinical investigations
7. Procedure for electronic clinical data system
8. Procedure for Investigational device accountability
9. Procedure for audit
10. Procedure for suspension or premature termination and resuming the clinical investigation after temporary suspension
11. Procedure for assuring and maintain clinical quality
12. Procedure for identification and access to the regulatory requirements
13. Procedure for training and competence assessment of personnel
14. Procedure for the control of suppliers
15. Procedure for possible emergency situations

16. Procedure for verification, validation, and securing of electronic clinical data systems
17. Procedure to maintain and protect subject privacy
18. Procedure for data retention
19. Procedure for recording, reporting, and analyzing CIP deviations
20. Procedure for cleaning, disinfection, or sterilization
21. Procedure for appeal of its decisions/opinions

3. Exhibits (06 exhibits)

It covers sample copy of exhibits covering all the details of ISO 14155:2020.

List of exhibits

1. Exhibit for codification system
2. Exhibit for skill requirement
3. Exhibit for secrecy rules
4. Exhibit for communication process
5. Exhibit for clinical investigation plan
6. Exhibit for employee competence requirement

4. Standard operating procedures (05 SOPs):

It covers sample copy of SOPs 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. The list of standard operating procedures provided in the kit is given below.

List of SOPs

1. SOP for Needle Stick Injury – Care & Precaution
2. SOP for Housekeeping Procedure
3. SOP for Personnel Safety Procedure
4. SOP for Data backup plan
5. SOP for Treatment and Disposal of Biomedical Waste

5. Blank Formats (49 Formats):

This directory includes sample copy of blank forms that are required to maintain records as well as establish control and create system in the organization. The samples are given for the users as a guide to follow. The organization is free to change the same to suit their own requirements. The blank formats can be used as templates. A total of 49 blank formats are provided as per the list given below.

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List of Formats

1.	Case Report Form	2.	Supplier Evaluation Report
3.	Informed Consent form	4.	Sub–contractors / External service provider's agreement
5.	Subject Recruitment Log	6.	Inspection report
7.	Site Monitoring Report	8.	Master List and Distribution List of Documents
9.	Checklist for Assent Form for vulnerable population	10.	Change Note
11.	Checklist for participants with special consideration	12.	Corrective Action Report
13.	Assent Form vulnerable population	14.	Master List of Records
15.	Unbinding form	16.	Objective Monitoring Report
17.	Monitoring Plan	18.	Audit plan / schedule
19.	Investigator / Investigation Agreement	20.	Internal Audit Non–Conformity Report
21.	Site Delegation Log	22.	Clause-wise Document-wise Audit Review Report
23.	Adverse Event Reporting Form	24.	Risk Assessment sheet
25.	Log of Adverse Event	26.	Clause-wise audit report
27.	Subject Identification Log	28.	Circular – MRM Agenda
29.	Investigational device accountability / inventory log	30.	Minutes of management review meeting
31.	Monitoring Feedback Form	32.	Periodic document review report
33.	Complaint Report	34.	Register of rules and Regulation
35.	Housekeeping Checklist	36.	Training Calendar
37.	Information Brochure	38.	Training Report
39.	Sterilization Report	40.	Induction Training Report
41.	Safety Evaluation Checklist	42.	Job Description And Specification
43.	Purchase Order	44.	Employees Competence Report
45.	Indent	46.	Appointment Letter
47.	Approved External Providers List	48.	Handover Form
49.	Supplier Registration Form		

6. ISO 14155:2020 Audit Checklist (more than 180 questions)

This covers audit questions based on the ISO 14155:2020 requirements. It will be a very good tool for the auditors to make audit questionnaire for auditing. It will bring effectiveness in auditing. A total of more than 180 questions are prepared on the basis of ISO 14155:2020.

7. ISO 14155:2020 Compliance Matrix

This compliance matrix contains ISO 14155:2020 requirement wise list of documented information for easy reference of users and to understand how this system is made.

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Part-2: Training: ISO 14155:2020 awareness training:

A. Presentation:-

Under this directory further files are made in power point presentation as per the chapter listed below.

- Topic wise power point presentation in 4 modules as listed below.

1. Awareness of ISO 14155:2020

It covers awareness of Clinical investigation of medical devices for human subjects – Good clinical practice system, benefits and summary of overall system.

2. ISO 14155:2020 requirements

It covers ISO 14155:2020 systems, Requirements, to establish the systems, It gives explanation for many concepts and given in plain English.

3. Control of Documents and Records

It covers ISO 14155:2020 documented information details and list of areas where standard demands for documented information. Such documented information with list against the requirements is given.

4. Step for ISO 14155:2020 Installation & Certification

It covers implementation methodology, steps for ISO 14155:2020 certification, the non-conformances, process, what happens during a certification audit.

B. A literature to understand ISO 14155:2020 subject well:-

This topic covers write up for the ready reference to the participant for understanding and reading the subject to get in depth knowledge on the subject.

It is given in word. You may also use it for further reading and circulations within audience.

Chapter No.	Name of chapter
1.	Awareness of ISO 14155:2020
2.	ISO 14155:2020 requirements
3.	Control of Documents and Records
4.	Step for ISO 14155:2020 Installation & Certification

C. Total 02 workshops and 01 case study to understand ISO 14155:2020 requirements:-

This topic covers 2 workshops and 1 case study questions with details to find out the ISO 14155:2020 applicable clause number to check effectiveness of training gained by students.

For more information about ISO 14155:2020 Documentation and Awareness Training kit Click Here

Chapter-2.0 ABOUT COMPANY

Documentation Consultancy is a progressive company promoted by a group of qualified engineers and management graduates having rich experience of over 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 organizations to achieve competitiveness, certification and compliance to international standards and regulations. So far, we have **more than 2700 clients in more than 36 countries**. **Our readymade training kit and editable documentation kit help the clients in making their documents with ease and complying with the related ISO standard faster.**

1. Our promoters and engineers have rich experience of providing management training and ISO series consultancy for **more than 2700 companies** globally. We have clients **in more than 36 countries.**
2. We are a highly qualified team of 80 members (M.B.A., Degree Engineers). Our Director has rich professional experience in this field (since 1991).
3. We have 100% success rate in ISO series certification for our clients from reputed certifying bodies. We possess a branded image and are a leading name in the global market.
4. We suggest continual improvement and cost reduction measures as well as provide highly informative training presentations and other products that give you payback within 2 months against our cost.
5. So far, we have trained more than 50000 employees in ISO series certification.
6. We have spent more than 60000 man-days (170 man-years) in the preparation of ISO documents and training slides.

Documentation Consultancy is committed for:

1. Personal involvement and commitment from the day one
2. Optimum charges
3. Professional approach and globally helped many companies for this standard.
4. Hard work and updating 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. Establishing 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 documentation kit can better perform with P4 and higher computers with a minimum of 10 GB hard disk space.
- For better visual impact, you may keep the setting at high color.

B. Software

- Documents are written in MS-Office 2007 and Windows XP programs. You are, therefore, required to have MS-Office 2007 or higher versions with Windows XP.

3.2 Features of training document kit

- The kit contains all necessary documents as listed, and complies with the requirements of system standards.
- The documents are written in easy to understand English language.
- This kit will save much time in typing and preparing your documents at your own.
- The kit is user-friendly to adopt and easy to learn.
- The contents of this kit are developed under the guidance of experienced experts.
- The kit provides a model of the management system that is simple and free from excessive paperwork.

Chapter-4.0 BENEFITS OF USING OUR TRAINING DOCUMENT KIT

1. By using these documents, you can save a lot of your precious time while preparing the ISO documents and presentation.
2. The kit takes care of all the sections and sub-sections of ISO 14155:2020 standards and helps you to establish better system.
3. This training documentation kit enables you to change the contents and print as many copies as you need. The users can modify the documents and presentation as per their industry requirements and create their own ISO 14155:2020 documents for their organization.
4. It will save much cost in document and presentation preparation.
5. You will get a better control in your system due to our proven formats.
6. You will also get a better control in your system as our proven documents and templates are developed under the guidance of experts and globally proven consultants. The team has a rich experience of more than 25 years in the ISO consultancy.
7. Our products are highly sold across the globe and are used by many multinational companies. They have got total satisfaction as well as experienced value for money.
8. In the preparation of training documentation kit, our team has verified and evaluated the entire content at various levels. More than 1000 hours have been spent in the preparation of this training documentation kit.
9. The entire kit is prepared by a globally proven team of leading ISO consultants.

Chapter-5.0 METHOD OF ONLINE DELIVERY

On completion of the secured purchase, we provide a username and password to download the product from our FTP server. We provide instant online delivery of the kit to the users by sending an e-mail of username and password.

For purchase, Click Here ➡ BUY

For more information about ISO 14155:2020 Documentation and Awareness Training kit Click Here