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Chapter–1: Contents of ISO 14155:2026 Clinical Investigation of Medical Devices Documentation And Awareness Training Kit (Total 95 files)

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

Sr. No.	Directory	Details of Documents / Presentation
Part – 1: Documentation		
1.	Quality Manual	01 file in MS Word
2.	Quality Procedures	21 procedures in MS Word
3.	Exhibits	07 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	01 file in MS Word (400+ questions)
7.	ISO 14155:2026 document compliance matrix	01 file in MS Excel
Part – 2: Training: ISO 14155:2026 Awareness Training		
A.	PPT Presentation	No. of Slides
1.	Awareness of ISO 14155:2026	23 ppt slides
2.	ISO 14155:2026 requirements	180 ppt slides
3.	Control of Documents and Records	23 ppt slides
4.	Steps for ISO 14155:2026 Installation & Certification	10 ppt slides
B.	Literature	
	Comprehensive literature to understand ISO 14155:2026 subject well (04 chapters)	Approx. 60 pages in MS word files
C.	Workshops and Case study	02 workshops (20 questions to solve) and 1 Case study (with 5 questions)
Total 95 files in editable form; quick download by e-delivery		

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Part-1: Documentation:

Our documentation kit contains sample documents required for ISO 14155:2026 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 14155:2026, 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 documentation 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 14155:2026 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	==========
3	Control and distribution		00	8-9	==========
4.0	**Summary of good clinical practice (GCP) principles**		00	10-11	**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	

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6.0	**Clinical investigation planning**				6.0
	6.1	General	00	22	
	6.2	Risk management	00	22 – 23	
	6.3	Justification for the design of the clinical investigation	00	24	
	6.4	Clinical investigation plan (CIP)	00	24	
	6.5	Investigator's brochure (IB)	00	25	
	6.6	Case report forms (CRFs)	00	25	
	6.7	Monitoring plan	00	25-26	
	6.8	Investigation site selection	00	26-27	
	6.9	Agreement(s)	00	27	
	6.10	Labelling	00	27	
	6.11	Data monitoring committee (DMC)	00	27	
	6.12	Clinical events committee	00	27-28	
7.0	**Clinical investigation conduct**				7.0
	7.1	General	00	29	
	7.2	Investigation site initiation	00	29	
	7.3	Investigation site monitoring	00	29	
	7.4	Adverse events and device deficiencies	00	29 – 31	
	7.5	Clinical investigation documents and documentation	00	31 – 32	
	7.6	Additional members of the investigation site team	00	32	
	7.7	Subject privacy and confidentiality of data	00	32	
	7.8	Document and data control	00	32 – 35	
	7.9	Investigational device accountability	00	35 – 36	
	7.10	Accounting for subjects	00	36	
	7.11	Auditing	00	36 – 37	
8.0	**Suspension, termination, and close-out of the clinical investigation**				8.0
	8.1	Completion of the clinical investigation	00	38	
	8.2	Suspension or premature termination of the clinical investigation	00	38 – 39	
	8.3	Routine close-out	00	39 – 40	
	8.4	Clinical investigation report	00	40 – 41	
	8.5	Risk assessment and conclusions	00	41	
	8.6	Document retention	00	41	
9.0	**Responsibilities of the Punyam**				9.0
	9.1	Clinical quality management	00	42	
	9.2	Clinical investigation planning and conduct	00	42 – 48	
	9.3	Outsourcing of duties and functions	00	49	
	9.4	Communication with regulatory authorities.	00	50	

For more information about ISO 14155:2026 Documentation and Awareness Training kit Click Here

10.0	**Responsibilities of the principal investigator**				**10.0**
	10.1	General	00	51	
	10.2	Qualification of the principal investigator	00	51	
	10.3	Qualification of investigation site	00	51	
	10.4	Communication with the EC	00	51 – 52	
	10.5	Informed consent process	00	52	
	10.6	Compliance with the CIP	00	52 – 53	
	10.7	Medical care of subjects	00	53 – 54	
	10.8	Safety reporting	00	54	
Annexure					
ANX–1	List of procedures		00	50	==========

Note → The amendment number given above is at the time of issue of this manual. If any page is amended then latest amendment number of such pages is recorded in amendment record sheet and on the table of content given above.

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 on decisions/opinions

3. Exhibits (07 exhibits)

It covers sample copy of exhibits covering all the details of ISO 14155:2026.

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
7. Clinical Investigation Report

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

For more information about ISO 14155:2026 Documentation and Awareness Training kit Click Here

6. **ISO 14155:2026 Audit Checklist (more than 400 questions)**

   This covers audit questions based on the ISO 14155:2026 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 approx. 450 questions are prepared on the basis of ISO 14155:2026 requirements.

7. **ISO 14155:2026 Compliance Matrix**

   This compliance matrix contains ISO 14155:2026 requirement wise list of documents and records for easy reference of users and to understand how this system is made.

Part-2: Training: ISO 14155:2026 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. **Overview and Awareness of ISO 14155:2026**

   It covers awareness of Clinical investigation of medical devices for human subjects – Good clinical practice system, benefits and summary of overall system. It also covers new features of ISO 14155:2026 standard compared to previous edition.

2. **ISO 14155:2026 requirements (clause wise)**

   It covers ISO 14155:2026 requirements to establish the system. It gives explanation for many concepts and given in plain English.

3. **Control of Documents and Records**

   It covers ISO 14155:2026 documents and records requirements and areas where the standard demands for documented information. List of documents and records with clause reference is given.

4. **Step for ISO 14155:2026 Installation & Certification**

   It covers how to establish ISO 14155 system, steps for ISO 14155:2026 certification, some common non-conformances and what happens during a certification audit.

B. Literature to understand ISO 14155:2026 subject well:-

Total 4 handouts are given for ready reference to the participant for reading and understanding the above mentioned topics to get in depth knowledge of ISO 14155 standard.

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

Chapter No.	Name of chapter
1.	Awareness of ISO 14155:2026
2.	ISO 14155:2026 requirements
3.	ISO 14155:2026 Documents and Records
4.	Steps for ISO 14155:2026 Installation & Certification

C. Total 02 workshops and 01 case study to understand ISO 14155:2026 requirements:-

This topic covers 2 workshops and 1 case study with some questions asking participants to find out the ISO 14155:2026 applicable clause number. This will help to check effectiveness of training.

Chapter-2.0 ABOUT COMPANY

Punyam Academy Pvt. Ltd. is a progressive company promoted by a group of qualified engineers and management graduates having rich experience of more than 30 years in ISO and management area consultancy and online training as well. 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 have **more than 4500 clients in more than 101 countries**. **Our ready-made editable documents kit helps the client in making their documents with ease and helps them comply with the related ISO standard faster.**

1. Our promoters and engineers have experience in providing management training, ISO series consultancy for **more than 4500 companies** globally. We have clients **in more than 101 countries.**
2. We are a highly qualified team of 80 members (M.B.A., Degree Engineers). Our director has a rich professional experience in this field (since 1991).
3. We have 100% success rate in ISO series certifications for our clients from reputed certification bodies. We possess a branded image and are a leading name in the global market.
4. We also 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. We have spent more than 60000 man-days (170 man-years) in the preparation of documents and training slides.

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We are committed for:

1. Personal involvement and commitment from the day one
2. Optimum charges
3. Professional approach
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.

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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 14155:2026 standards and helps you to establish better system.
3. This training and 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 14155:2026 documents for their organization.
4. It will save much cost in document and training 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

Visit our website for more details on the training and documentation kit:

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