D135: DEMO OF ISO 15189:2022 DOCUMENT KIT Price 649 USD

Complete editable ISO 15189:2022 document kit (Manual, procedures, SOPs, exhibits, formats, audit checklist etc.)

Website: http://www.certificationconsultancy.com/medical-lab-qms-15189-certification-documents.htm

Chapter-1.0 CONTENTS OF ISO 15189:2022 DOCUMENTATION KIT (More than 120 files)

A. This editable documentation kit has 9 main directories in Word/Excel, as below:

Sr. No.	Directory	Details of Documents
1.	Quality Manual	01 Files in MS Word
2.	Quality Procedures	34 Procedures in MS Word
3.	Exhibits	08 Exhibits in MS Word
4.	Standard Operating Procedures	07 Standard operating procedures in MS Word
5.	Blank Formats /Templates Name of departments	62 Blank Formats in MS Word / excel
	Collection (CCC)	03 formats in MS Word
	Customer service (CSD)	05 formats in MS Word
	Operation (OPN)	07 formats in MS Word
	Purchase (PUR)	08 formats in MS Word
	Quality control (QCD)	09 formats in MS Word / excel
	Store (STR)	03 formats in MS Word
	System (SYS)	16 formats in MS Word / excel
	Training (TRG)	11 formats in MS Word
6.	Job description	06 Job description in MS Word
7.	ISO 15189:2022 Audit checklists	More than 500 questions
8.	Sample Risk Assessment and Opportunity Sheet	01 File in MS Excel
9.	ISO 15189:2022 document compliance matrix (Requirement wise reference documented information)	01 File in MS Excel

Total 120 files in editable form; Quick Download by e-delivery

For more information about ISO 15189:2022 Documentation kit Click Here

B. Documented information package:

Our documentation kit contains sample documents required for ISO 15189:2022 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 15189:2022, documented information (procedures, 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, 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/excel document as per the details given below.

1. Quality Manual:

It covers sample copy of quality manual for ISO 15189:2022 standard. It describes how all requirement of ISO 15189:2022 standard requirements. It covers list of procedures as well as overview of organization and covers tier1 of ISO 15189:2022 documents.

(A) Table of Contents

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2. Quality Procedures (34 procedures):

Sample copies of mandatory quality procedures as per ISO 15189:2022 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 Quality Procedures

1.	Procedure for maintaining impartiality	2.	Procedure for verification of examination method
3.	Procedure for confidentiality of patient's information	4.	Procedure for validation of examination method
5.	Procedure for personnel and training	6.	Procedure for evaluation of measurement uncertainty (MU)
7.	Procedure for equipment	8.	Procedure for monitoring the validity of results
9.	Procedure for equipment acceptance procedure	10.	Procedure for reporting the results
11.	Procedure for responding to any manufacturer's recall	12.	Procedure for automated selection, review, release and reporting of results
13.	Procedure for equipment calibration	14.	Procedures for issue of amended or revised results
15.	Procedure for reception, storage, acceptance testing and inventory management of reagents and consumables	16.	Procedures for identification, access, storage, preservation and safe disposal of clinical samples
17.	Procedure to establish and periodically review agreements for providing laboratory activities	18.	Procedures for identification and control of non–conformities
19.	Procedure for externally provided products and services	20.	Procedures for management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties
21.	Selecting and evaluating referral laboratories and consultants	22.	Procedure for continuity and emergency preparedness planning
23.	Procedure for all pre-examination activities and make them accessible to relevant personnel	24.	Procedure for control of documents
25.	Procedure for managing oral requests for examinations	26.	Procedure for control of records
27.	Procedures for the collection and handling of primary samples	28.	Procedure for risk assessment
29.	Transportations of samples	30.	Corrective action
31.	Procedure for sample receipt	32.	Procedure for internal audit
33.	Procedure and appropriate facilities for securing patient samples, ensuring sample integrity and preventing loss or damage during, handling, preparation and storage	34.	Procedure for management review

3. Exhibits (08 exhibits):

It covers Skill requirements, Codification system, Calibration periodicity, Secrecy rules, Recommended conditions for sample collection, transport and storage for conventional cytogenetic analysis, Minimum retention period for identified records, Impartiality policy, Patient's right etc. as per. ISO 15189:2022.

For more information about ISO 15189:2022 Documentation kit Click Here

List of Exhibits

1. Skill requirements
2. Codification system
3. Calibration periodicity
4. Secrecy rules
5. Recommended conditions for sample collection, transport and storage for conventional cytogenetic analysis
6. Minimum retention period for identified records
7. Impartiality policy
8. Patient's right

4. Standard operation procedures (07 SOPs):

It covers sample standard operating procedures covering all the specific practice areas and provides details for operation of training organization.

List of SOPs

1. SOP for Collection and transportation of sample
2. SOP for Specimen acceptance & rejection criteria
3. SOP for Treatment and disposal of biomedical waste
4. SOP for Housekeeping
5. SOP for Use of PPE and personal safety
6. SOP for Examination by lateral flow method
7. SOP for Examination of COVID–19 by CT Value

5. Blank sample formats for all the departments (62 sample formats)

It covers sample copy of blank 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 blank formats

1. Sample collection register
2. Method verification report
3. Sample disposal register
4. Goods inward register
5. PPE kit and consumable disposal register
6. Stock register
7. Request for examination
8. Gate pass
9. Customer feedback form
10. Masterlist and Distributionlist of documents
11. Complaint register
12. Change Note
13. Complaint report
14. Corrective action report
15. Inward register
16. Master List of Records
17. Equipment history card
18. Quality objectives (key performance indicator)
19. Preventive maintenance schedule
20. Audit Plan / Schedule
21. Equipment wise preventive maintenance checkpoints
22. Internal audit non–conformity report
23. Control of nonconformity work report
24. Clause wise document wise audit review report

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25.	Housekeeping report	26.	Impartiality check report
27.	Result of suspected case of Influenza (category C)	28.	Calibration status of equipment
29.	Line List for Reporting by the laboratories	30.	Audit Observation Report
31.	Purchase order	32.	Circular – MRM Agenda
33.	Indent (purchase requisition)	34.	Minutes of management review meeting
35.	Approved vendor list	36.	Periodic document review report
37.	Supplier registration form	38.	Improvement log
39.	Inspection report	40.	Risk assessment and opportunity sheet
41.	Supplier evaluation form	42.	Training calendar
43.	Evaluation for Referral Lab	44.	Training report
45.	Sub–contractors / External service provider's agreement	46.	Induction training report
47.	Four Year Plan for Quality Control	48.	Job description and specification
49.	IQC Analysis report	50.	Skill matrix
51.	ILC Analysis report	52.	Impartiality and Confidentiality agreement
53.	Critical consumables	54.	Appointment letter
55.	Environment condition monitoring report	56.	Employee competence report
57.	Daily Medical facility and collection centre checklist	58.	Management system training effectiveness report
59.	Method validation report	60.	Competence assessment report
61.	In-house calibration report	62.	Immunization report

6. Job description (06 job description)

Sample copies of job description as per ISO 15189:2022 are provided. The list of sample job description provided in the kit is given below.

List of Job description

1. Job description for Director
2. Job description for Quality Manager
3. Job description for Technical Manager
4. Job description for Lab Technicians / Microbiologist
5. Job description for Sampling Technicians
6. Job description for Receptionist

7. ISO 15189:2022 Audit checklist (more than 500 questions)

It covers sample audit questions based on all the ISO 15189:2022 requirements. It helps the auditor to make own audit checklist for quick and perfect auditing to ensure all the ISO 15189:2022 requirements are fulfilled by the organization. A total of more than 500 questions are prepared on the basis of ISO 15189:2022.

For more information about ISO 15189:2022 Documentation kit Click Here

8. Sample Risk Assessment Sheet

A ready-to-use risk assessment sheet is given in editable form to prepare the risk document for the organization. It is given in an excel format and can be used as a template.

9. ISO 15189:2022 Compliance Matrix

This compliance matrix contains ISO 15189:2022 requirement wise list of documented information for easy reference of users and to understand how this system is made.

Chapter-2.0 ABOUT COMPANY

Global Manager Group 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.

Global Manager Group 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 Documentation 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 DOCUMENTATION KIT

1. By using these documents, you can save a lot of your precious time while preparing the ISO documents.
2. The kit takes care of all the sections and sub-sections of ISO 15189:2022 standards and helps you to establish better system.
3. This documentation kit enables you to change the contents and print as many copies as you need. The users can modify the documents as per their industry requirements and create their own ISO 15189:2022 documents for their organization.
4. It will save much cost in document 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 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 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 15189:2022 Documentation kit Click Here