D135: DEMO OF ISO 15189:2012 DOCUMENT KIT Price 450 USD

Complete editable ISO 15189:2012 document kit (Manual, procedures, SOPs, exhibits, formats, audit checklist etc.)

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Chapter-1.0 CONTENTS OF ISO 15189:2012 DOCUMENT KIT

(More than 170 document files)

The Total Editable Document kit has 6 main directories as below.

ISO 15189:2012 Editable Document kit for medical laboratories

Sr. No.	List of Directory	Document of Details
1.	Quality Manual	01 files in MS Word
2.	Procedures	30 Procedures in MS Word
3.	Standard operating procedure	40 Standard operating procedure in MS Word
	Collection (CCC)	08 Standard operating procedure in MS Word
	Operation (OPN)	16 Standard operating procedure in MS Word
	Testing (EXM)	16 Standard operating procedure in MS Word
4.	Exhibits	06 exhibits in MS Word
5.	Formats	94 formats in MS Word / Excel
	Clinical Biochemistry (CBC)	20 formats in MS Word / Excel
	Collection (CCC)	07 formats in MS Word / Excel
	Customer service (CSD)	09 formats in MS Word
	Front Office & Patient Registration (FPR)	04 formats in MS Word
	HR and Training (TRG)	11 formats in MS Word
	Operation (OPN)	04 formats in MS Word
	Purchase (PUR)	09 formats in MS Word
	Quality control (QCD)	17 formats in MS Word / Excel
	System Formats (SYS)	11 formats in MS Word
	Stores (STR)	02 formats in MS Word
6.	Audit checklist	More than 350 questions

Total 170 files quick download in editable form by e delivery

To get more information about ISO 15189:2012 Documentation kit Click Here

B. Documentation:-

Our document kit is having sample documents required for ISO 15189:2012 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 and many medical laboratories are accredited globally in 1st trial with the help of our documents from any kind of stringent accreditation assessment.

Under this directory further files are made in word Document as per the details listed below. All the documents are related to any kind of medical laboratories.

1. Quality Manual:

It covers sample copy of quality manual for medical laboratory. It describes how all requirement of ISO 15189:2012. It covers list of procedures as well as overview of medical laboratories and covers tier 1 of ISO 15189:2012 documents.

ISO 15189:2012 Manual Index

Table Of Contents

2. Procedures (30 Procedures):

It covers sample copy of mandatory procedures covering all the details of ISO 15189:2012 standard.

List of procedure

1. Receipt, handling, storage and disposal of samples in line with the legal requirements
2. Control of documents
3. Establishment and review of agreements for providing medical laboratory services to its customers / patients
4. Selecting and evaluating referral laboratories and consultants
5. Purchasing
6. Management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties
7. Identification and control of non–conformities
8. Corrective action
9. Preventive action
10. Control of records
11. Internal audit
12. Management review
13. Personnel and training
14. Facility maintenance and environment
15. Selection, purchasing and management of equipment
16. Safe handling, transport, storage and use of equipment to prevent its contamination or deterioration
17. Calibration of equipment
18. Reception, storage, acceptance testing and inventory management of reagents and consumables
19. Pre–examination process
20. Collection and handling of primary samples
21. Transportations of samples
22. Sample receipt
23. Pre–examination handling, preparation and storage
24. Validation of examination procedures

25. Ensuring the quality of examination results
26. Review of examination results
27. Identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples
28. Reporting the results
29. Release of examination results
30. Confidentiality of patient's information

3. Standard operating procedure (40 SOPs):

It covers sample copy of standard operating procedures covering all the details of ISO 15189:2012 standard.

List of standard operating procedure (SOPs)

1. Collection & Transport of Specimens for Biochemistry Examinations
2. Patient Preparation Instructions
3. Needle Stick Injury – Care & Precaution
4. Specimen Acceptance & Rejection Criteria
5. Treatment and Disposal of Biomedical Waste
6. House Keeping Procedure
7. Personnel Safety Procedure
8. Sample Preparation and Storage
9. Sample collection
10. Sample rejection
11. General departmental procedure
12. Quality control procedure
13. Equipment maintenance & operating procedure
14. Measurement of Uncertainty
15. Monitoring Turn-Around-Time
16. Critical Alert Level Values / Panic Values
17. Repeat Test
18. Data backup plan
19. Generation of test results
20. Housekeeping
21. Personal protection and safety
22. Treatment and Disposal of Biomedical Waste

23. Data backup plan, Linearity and range of testing, Accuracy& Precision
24. Equipment calibration plan procedure
25. Test procedure – Serum – Alanine Amino Transferase Cobas c501
26. Test procedure – Serum – Albumin – Cobas c501
27. Test procedure – Serum – Bicarbonate – Cobas c311
28. Test procedure – Serum – Bilirubin Total – Cobas c501
29. Test procedure – Serum – Calcium – Cobas c501
30. Test procedure – Serum – Creatinine – Cobas c501
31. Test procedure – Serum – GGT – Cobas c501
32. Test procedure – Serum – Glucose – Cobas c501
33. Test procedure – Serum – HDL Cholesterol – Cobas c311
34. Test procedure – Serum – Phosphours – Cobas c501
35. Test procedure – Serum – Aspartate Amino Transferase – Cobas c501
36. Test procedure – Serum – TGL – Cobas c501
37. Test procedure – Serum – Total Cholesterol – Cobas c501
38. Test procedure – Serum – Total Protein – Cobas c501
39. Test procedure – Serum – Urea – Cobas c501
40. Test procedure – Serum – Uric Acid – Cobas c501

4. Exhibits (06 Exhibits):

It covers sample copy of exhibits covering all the details of ISO 15189:2012 standard.

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

5. Blank Formats (94 Formats):

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

List of Formats

1.	Accident / Incident Record	2.	Equipment Maintenance Breakdown Record
3.	Calibration Register - Clinical Chemistry	4.	PT / EQAS / ILC / corrective action report
5.	Critical Alert Results Register	6.	Equipment History Record
7.	Equipment Maintenance Log	8.	Housekeeping Record
9.	Kit in Use Log Form	10.	LJ chart Template for Lab Mean
11.	LJ chart Template for Product Insert Mean	12.	Non Conformance Register
13.	Record Label	14.	Repeat Test Result Register
15.	Sample integrity register	16.	Sample Rejection Register
17.	Sample storage and discadal register	18.	Monitoring STAT
19.	Monitoring TAT	20.	Temperature Log Form - Room
21.	Bleeding Time & Clotting Time Register	22.	Housekeeping Register
23.	Non Conformance Register	24.	Sample Collection Register
25.	Sample rejection Register	26.	Sample Rework Register
27.	Temperature Log Form – Room	28.	Request for examination – serum / fluoride plasma
29.	Request for examination – urine	30.	Request for examination – Serum
31.	Request for examination – whole blood / serum	32.	Request for examination – whole blood with EDTA
33.	Customer feedback form	34.	Complaint register
35.	Complaint report	36.	Inward register
37.	Test Instruction Slips	38.	Final Test Report
39.	HIV Consent Form	40.	Test Amendments Form
41.	Training Calendar	42.	Training Report
43.	Induction training report	44.	Job Description and Specification
45.	Skill Matrix	46.	Confidentiality Agreement
47.	Appointment Letter	48.	Employees Competence Report
49.	ISO 15189 effectiveness check report	50.	Employee history card
51.	Immunization report	52.	Equipment history card
53.	Preventive maintenance schedule	54.	Equipment wise preventive maintenance checkpoints
55.	Disposal of non–conformities	56.	Purchase order
57.	Indent (purchase requisition)	58.	Approved vendor list cum open purchase order
59.	Supplier registration form	60.	Open purchase order
61.	Material specification sheet	62.	Evaluation for Referral Lab
63.	Stock register	64.	Supplier evaluation form
65.	Four Year Plan for Quality Control	66.	Re–test plan / execution report
67.	Z score report	68.	Uncertainty of Measurement
69.	Re - Test Analysis	70.	Critical consumables
71.	Environment condition monitoring report	72.	pH Meter Calibration Report
73.	Inspection report	74.	Normality record sheet
75.	Intermediate check report – weighing balance	76.	Intermediate check report – oven
77.	Housekeeping checklist	78.	Checklist for Medical Laboratory Collection Centre / Facility
79.	Quality control plan method	80.	Design / Planning of the method validation
81.	Validation report	82.	Master List Cum Distribution List of Documents
83.	Change Note	84.	Corrective action report
85.	Master List of Records	86.	Quality objectives (key performance indicator)

87. Audit Plan / Schedule
88. Internal audit non–conformity report
89. Clause wise document wise audit review report
90. Preventive Action Report
91. Calibration status of equipment
92. Audit Observation Report
93. Goods inward register
94. Stock register

6. Audit checklist (more than 350 questions)

It covers sample audit questions based on all the ISO 15189 requirements. It helps the auditor to make own audit checklist for quick and perfect auditing to ensure all the ISO 15189 requirements are fulfilled by the medical laboratories.

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.

Global Manager Group 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

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 15189:2012 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.

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 15189:2012 documents.
2. Take care for all the section and sub sections of ISO 15189:2012 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 15189:2012 documents for their medical laboratories.
4. Save much time and cost in document preparation.
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 on line delivery of our products to user by sending e mail of user name and password

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