# ISO 15189 REQUIREMENTS FOR QUALITY AND COMPETENCE CERTIFICATION

As per International Standards

## UNICHRONE



## Unichrone Training Advantages

- 1 Day Interactive Instructor –led Online/Classroom or Group Training
- Course study materials designed by subject matter experts
- Mock Tests to prepare in a best way
- Highly qualified, expert & accredited trainers with vast experience
- Enrich with Industry best practices and case studies and present trends
- ISO 15189 Requirements For Quality And Competence course adhered with International Standards
- End-to-end support via phone, mail, and chat
- Convenient Weekday/Weekend ISO 15189 Requirements For Quality And Competence Training Course schedule

#### **About Unichrone**

We are a professional training institute with an extensive portfolio of professional certification courses. Our training programs are meant for those who want to expand their horizons by acquiring professional certifications across the spectrum. We train smalland medium-sized organizations all around the world, including in USA, Canada, Australia, UK, Ireland and Germany.



Guaranteed Quality



**Global Presence** 



Handpicked Trainers



Online Training Option









#### Importance of ISO 15189 Requirements For Quality And Competence Training

- ISO 15189 standard represents the true degree of competence in this area. Accreditation to this standard represents a laboratory's core values that reflect a high level of practice. This precision and accuracy help provide reliable and accurate results that enable informed diagnosis and treatment plans. ISO 15189 process entails the application of a QMS with quality guidelines, such as personnel qualifications, operating protocols, and a documented approach to continuous improvement.
  - ISO 15189 Quality and Competence Training is aimed at helping candidates acquire the necessary expertise and competencies to establish a Quality Management System (QMS) for medical testing laboratories. The training program ventures into areas such as resource and infrastructure needs, process management, technical competence, quality control, and internal auditing practices that are in line with other standards.

### **ELIGIBILITY CRITERIA**

Aspirants need not meet any requirements to pursue ISO 15189 Quality and Competence Training Course.
However, having prior knowledge of the ISO standard is beneficial.

#### WHO SHOULD ATTEND

Individuals who want to learn about the Requirements for Quality and Competence can attend ISO 15189 Certification Course. UNICHRONE

#### ISO 15189 REQUIREMENTS FOR QUALITY AND COMPETENCE CERTIFICATION ADVANTAGES



#### Syllabus of ISO 15189 Requirements For Quality And Competence Training

<b>Lesson 01 –</b> Introduction to ISO 15189	
1.	Scope
2.	Terms and Definitions

**Lesson 02 –** General Requirements

- **1.** Impartiality
- 2. Confidentiality
- 3. Requirements Regarding Patients

#### Syllabus of ISO 15189 Requirements For Quality And Competence Training

Lesson 03 – Structural and Governance Requirements		
1.	Legal Entity	
2.	Laboratory Director	
3.	Laboratory Activities	
4.	Structure and Authority	
5.	Objectives and Policies	
6.	Risk Management	

#### **Lesson 04 –** Resource Requirements 1. General 2. Personnel Facilities and Environmental Conditions 3. Equipment 4. Equipment Calibration and Metrological Traceability 5. Reagents and Consumables 6. Service Agreements 7. Externally Provided Products and Services 8.

#### Syllabus of ISO 15189 Requirements For Quality And Competence Training

<b>Lesson 05 –</b> Process Requirements		
1.	Pre-Examination Processes	
2.	Examination Processes	
3.	Post Examination Processes	
4.	Nonconforming Work	
5.	Control of Data and Information Management	
6.	Complaints	
7.	Continuity and Emergency Preparedness Planning	

<b>Lesson 06 –</b> Management System Requirements		
1.	General Requirements and Options	
2.	Management System Documentation	
3.	Control of Management System Documents	
4.	Control of Records	
5.	Action to Address Risks and Opportunities	
6.	Improvement	
7.	Corrective Action	
8.	Evaluations	
9.	Management Reviews	

#### Exam Format of ISO 15189 Requirements For Quality And Competence Certification

<b>Examination Format</b>				
Exam Name	ISO 15189 Requirements For Quality And Competence exam			
Exam Format	Multiple Choice			
Total Questions & Duration	30 Questions, 1 Hour			
Passing Score	Minimum passing score of 70%			
Exam Cost	Included in training fee			

To get you fully prepared with the knowledge and skills for the ISO 15189 Requirements For Quality And Competence, a training session at Unichrone gives immense importance to mock questions at the end of every module and problemsolving exercises within the session. Prepared by certified ISO faculty, the practice tests are a true simulation of ISO 15189 Requirements For Quality And Competence exam.

# Contact Us

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