



Medical Laboratories

ISO 15189 : 2012

What is ISO 15189?

ISO 15189:2012 is the International Standard for medical laboratories and determines the criteria laboratories require to develop a Quality Management System and appraise their competence. This globally accepted standard establishes a framework of individual requirements to construct a quality management system. Regulators, accreditation bodies, and customers also adopt the International Standard to confirm and acknowledge a laboratory's competence.

Who needs ISO 15189?

Any medical laboratory wanting to deliver clinically relevant results that meet the highest ethical standards should consider ISO 15189 accreditation. Medical laboratory services are crucial to patient care and require meeting the needs of all patients and the clinical personnel responsible for the support of those patients. Therefore, an increasing number of medical laboratories voluntarily undertake a pathway towards achieving ISO 15189 accreditation, to ensure practice and professional competence according to the Good Clinical Laboratory Practice principles and to increase confidence in laboratory testing by all stakeholders.

While ISO 15189 is intended for use throughout medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging and medical physics could also find ISO 15189 appropriate and valuable.

Benefits of ISO 15189

One of the main benefits of ISO 15189 accreditation is global acceptance and recognition. However, additional benefits are vast and sometimes unique to your particular business, but could include:

- Risk reduction by adhering to best practices
- Identifies and promotes the technical competence of staff
- Conveys trust and a level of recognition to stakeholders and decision-makers
- Avoids expenses associated with costly retesting
- Opens up new markets, both internationally and locally
- Improves staff motivation and reduces staff mistakes
- Ensures support in the event of a legal challenge
- Assures client results are technically valid
- Assures that clinical lab services are safe, reliable, and of good value
- Provides a tool for measuring quality improvements and supporting consistency

Related services and products



Beyond ISO 15189, IMSM can introduce your business to a range of management system standards designed to be compatible and integrated to help develop and grow a profitable company by delivering audit efficiency, consistency and continual improvement.

“We could not compete in our marketplace without ISO Certification. IMSM made it easy to implement and follow the system. The efficiency we gained keeps us competitive, the Certification opens the doors and keeps them open.”

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If you could improve your company's bottom line, increase revenue, reduce business risk and boost your competitive advantage - all at the same time, wouldn't you?

Take the next step:

Speak to one of our experts today.