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Medical Laboratory Accreditation Standard ISO 15189 Two Training Days (for 5 to 20 participants)

Course Objectives

Understand and interpret the requirements of ISO 15189, including its QMS. Identify required documents and records.

Target Organisations

This Training Course applies to medical laboratories and regulatory agencies seeking to specify ISO 15189 within their policies and regulations.

Course Participants

Pathologists, Microbiologists, Biochemists and Technicians working in Medical labs to understand ISO 15189 requirements

Training Process

This 2-day Training Course examines structural components of the standard. See the syllabus to the right. Quality system and technical requirements are grouped in a manner that makes them clear and understandable.

Technical considerations include traceability of measurement and estimations of uncertainty. Quality system discussions include easy-to-understand approaches (with sample forms provided) for continual improvement and handling of customer feedback.

The course contains extensive reference to common accreditation body interpretations and implementation guidance documents from ILAC and APAC.

Syllabus

Time Activities

Day 1

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| 08.45 | Registration |
| 09.00 | Introduction to the training course |
| 09.30 | Introduction to ISO 15189 – Scope- Definitions |
| 10.00 | Tea/Coffee Break |
| 10.15 | Management Requirements |
| 13.00 | Lunch Break |
| 13.30 | Management Requirements |
| 15.30 | Tea/Coffee Break |
| 15.45 | Implementation Exercises (Policy, Procedures, Records) |
| 17.00 | End of day 1 |

Day 2

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| 08.45 | Review of Day 1 |
| 09.00 | Technical Requirements |
| 11.00 | Tea/Coffee Break |
| 11.20 | Technical Requirements |
| 13.00 | Lunch Break |
| 13.30 | Technical Requirements |
| 15.30 | Tea Break |
| 15.45 | Documentation and Clause identification exercises |
| 17.00 | Feedback and close |