

Course Overview

ISO 14155:2026 provides a structured framework for the design, conduct, recording, and reporting of clinical investigations involving medical devices. It ensures that studies are conducted in accordance with Good Clinical Practice, protecting the rights, safety, and well-being of participants while generating reliable and robust clinical data.

This course introduces the key principles of clinical investigations, including study design, the Clinical Investigation Plan, risk management integration, informed consent, safety reporting, data integrity, and sponsor oversight. It also highlights how clinical investigations support regulatory compliance and the demonstration of device safety and performance.

By applying these principles, organisations can ensure that clinical investigations are ethically conducted, scientifically sound, and compliant with regulatory expectations, ultimately supporting the development of safe and effective medical devices.

Learning Objectives

Understand the key requirements of ISO 14155:2026 and how they apply to the design, conduct, and oversight of medical device clinical investigations .

Explain the roles, responsibilities, and processes involved in ensuring participant safety, data integrity, and regulatory compliance throughout the clinical investigation lifecycle.

Module One:

- Introduction to ISO 14155:2026
- Key Terms and Definitions
- Good Clinical Practice (GCP) Principles
- Ethical Considerations
- Informed Consent
- Clinical Investigation Planning
- Risk Management in Clinical Investigations
- Roles and Responsibilities
- Data Management and Documentation
- Safety Reporting
- Audits, Inspections and Quality Oversight
- Suspension, Termination, Close-out and Reporting
- Governance and Oversight
- Practical Tips for Applying ISO 14155:2026
- ISO 14155:2026 Annexes

Duration: Approx. 3 hours

As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.



