

# LABORATORY TRAINING COURSE

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This course is specifically designed for medical device manufacturers seeking to enhance their understanding of laboratory processes and regulatory requirements for medical devices. You will gain insights into quality management principles aligned with ISO/IEC 17025, explore laboratory practices and the considerations of ISO 14971 in relation to laboratory operations.

**DURATION:** 1 Day

**LANGUAGE:** English

### COURSE CONTENT:

#### Introduction

- Laboratory accreditation in the USA, the UK and the EU
- Laboratory relationship to notified bodies
- Guidance documents for laboratories in the USA, the UK and the EU

#### Quality Management According to ISO/IEC 17025

- Overview of ISO 17025 and its applicability
- **Clauses covered:**
  - Technical competence
  - Impartiality and confidentiality
  - Metrological traceability
  - Selection, verification, and validation of methods
- Significance of ISO 17025 for laboratories and their customers
- Process for obtaining accreditation

#### Good Laboratory Practice (GLP)

- Definition of GLP and its history
- Applicability of GLP to various researchers and studies
- The meaning of GLP to laboratories and their customers
- Process for obtaining accreditation

#### Considerations in-line with ISO 14971

- Necessary information for laboratory submissions (the minimum viable information to be included in the sample submission form, as utilized in the report)
- Biological evaluation report and plan for biocompatibility assessments (ISO 10993)
- Laboratory requirements in alignment with safety standards IEC 61010 and IEC 60601

### TARGET AUDIENCE:

This course is suitable for participants with no prior knowledge of laboratory processes, ISO/IEC 17025 and ISO 14971 standards or can be customized for a more experienced audience.

### FURTHER INFORMATION:

The training takes place either online or live. The duration of the training is 8 hours (including a 30 minute lunch break and 2 shorter breaks). On request we grant a discount for group bookings.



We are happy to work with your organization to develop **customized and cost-effective training** that meets your requirements in terms of date, timing and content.

### PLEASE CONTACT US FOR YOUR BOOKING OR ENQUIRY:

info@lorit-consultancy.com  
+44 7708 360023

info@testlabsuk.com  
+44 2038 130969