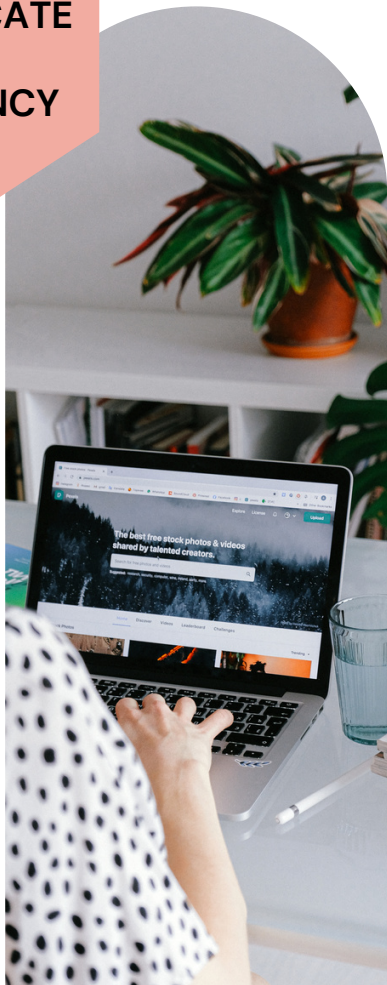


INCLUDES  
EXAMINATION  
& CERTIFICATE  
OF  
PROFICIENCY

# FIRST ANNOUNCEMENT



2022 ONLINE   
TRAINING BY  
THE AUTHORITY

## ISO 13485:2016 Quality Management System for Medical Devices

This two-day online training course is to provide an in-depth understanding of the Quality Management System for Medical Device for those involved in the development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support).

### OUR TRAINER



#### Dr Vincent Lam

Senior Product Specialist  
and Notified Body Auditor,  
TÜV SÜD Product Service

- has established and maintained device test programs for the assessment of specific medical devices to facilitate the review of pre-market regulatory requirements including the requirements of the European Notified Body conformity assessment scheme.
- has established test programs for devices such as medical examination and surgical gloves, condoms and wound care devices, and their sterilization methods
- has 20 years of experience as senior medical device lead auditor and reviewer of device technical documentation e.g. technical files and design dossiers in compliance with the Essential Principles of Safety and Performance of medical devices (EPSP).

9 & 10 AUGUST 2022  
TUESDAY & WEDNESDAY

8.30 AM - 5.00 PM

TRAINING SECRETARIAT  
(MDA-CoRE)

**03-8230 0240 /**  
**0355 / 0211 / 0395**  
**/ 0343**

[trainingpackage@mda.gov.my](mailto:trainingpackage@mda.gov.my)



# OBJECTIVES

- To provide an overview and interpretation of the clauses of ISO 13485:2016
- To understand the scope and use of ISO 13485:2016 in meeting the requirements of Medical Device Regulations
- To highlight the importance of ISO 13485:2016
- To improve the understanding of the requirements of ISO 13485:2016



## DAY 1

## DAY 2



Briefing

Overview of Quality Management System

Overview of ISO 13485

ISO 13485 Requirements

0. Introduction

1. Scope

Break

2. Normative References

3. Terms and Definitions

4. Quality Management System

Lunch Break

Part 5: Supply-chain & Device Specific

Break

5. Management Responsibility

6. Resource Management

Q&A Session

End of Day 1

Briefing

7. Product Realization

Break

8. Measurement, analysis and improvement

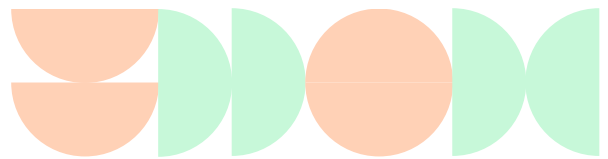
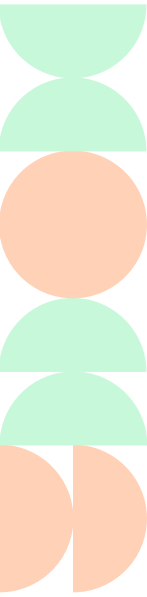
Q&A Session

Lunch Break

Briefing for Exams & Revision

Examination

End of Day 2



SCAN QR

CLICK OR



TO REGISTER

**CLOSE ON AUGUST 1, 2022**

**FEES RM2.000 PER PAX**