AMMI
ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES
PERSATUAN INDUSTRI PERUBATAN MALAYSIA

MEDTECH® MALAYSIA

GLOBAL EXPERT SEMINAR

10 September 2026, 9:00 am – 5:00 pm
Olive Tree Hotel Penang

Navigating European Market Access with CE Marking & Clinical Evaluation

Speaker

Mr Richard Holborow
Global Head of Clinical Compliance, BSI

HRDCORP CLAIMABLE

Navigating European Market Access with CE Marking & Clinical Evaluation

INTRODUCTION

As the European MedTech regulatory landscape continues to evolve, staying informed on the latest regulatory developments and clinical evidence requirements is essential for manufacturers seeking access to the European market.

This seminar features two focused sessions. The first provides an overview of the latest EU regulatory updates impacting CE marking, highlighting key regulatory developments and their implications for market access. The second explores Clinical Evaluation and provides an overview of ISO 14155, covering key concepts and current expectations.

Whether you work in regulatory affairs, clinical affairs, quality assurance, research and development, or product management, this seminar offers practical insights to help you stay up to date with evolving regulatory requirements and support your organization's European market access journey.

COURSE OBJECTIVES

After participating in the seminar, you will be able to:

- Understand the latest EU regulatory updates related to CE marking.
- Gain an overview of ISO 14155 and clinical evaluation under the EU MDR.
- Learn the key elements of a clinical evaluation report (CER).
- Understand the Notified Body expectations for clinical evidence.

COURSE OUTLINE

1. EU Regulatory Updates for CE Marking
2. Clinical Evaluation & ISO 14155 Overview
3. Clinical Evaluation under EU MDR
4. Clinical Evaluation Report (CER)
5. MDR Notified Body Expectations for Clinical Evidence

DURATION

One (1) full day

MODE OF SEMINAR

Classroom / Face-to-face

Navigating European Market Access with CE Marking & Clinical Evaluation

COURSE AGENDA

Time	Details
9.00 am – 11.00 am	EU Regulatory Updates for CE Marking
11.00 am – 12.30 pm	Clinical Evaluation & ISO 14155 Overview
12.30 pm – 1.30 pm	Lunch break
1.30 pm – 4.00 pm	Clinical Evaluation under EU MDR Clinical Evaluation Report (CER) MDR Notified Body Expectations for Clinical Evidence
4.00 pm – 5.00 pm	Q&A session

CONTACT

For enquiries, please email to AMMI

Email: learning@ammi.com.my

Tel: +6012 539 4194