PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

HRDCORP CLAIMABLE

TRAINING ON
MEDICAL DEVICE STERILISATION
METHODS, VALIDATION & REGULATING COMPLIANCE

TRAINING OVERVIEW

Medical device sterilisation is essential for ensuring products are safe for patient use while maintaining their quality and performance. This course provides a practical overview of sterilisation methods, process validation, sterile packaging, and regulatory requirements.

Participants will learn how to validate and control sterilisation processes, meet ISO standards and Malaysian regulatory requirements, prepare technical documentation, and identify compliance gaps through practical case studies and interactive discussions.

TRAINING OBJECTIVE

Upon completion of this training, participants will be able to:

- Understand the fundamentals of medical device sterilisation and key regulatory requirements.
- Describe different sterilisation methods and their applications.
- Explain sterilisation process validation and routine process control requirements.
- Understand sterile barrier system validation and packaging considerations.
- Interpret applicable regulatory requirements and relevant ISO standards.
- Identify compliance gaps through practical case studies and document reviews.

DATE
6 August 2026
(Thursday)

TIME
8:30 am – 5:00 pm

VENUE
Seminar Room,
Medical Device Authority,
Cyberjaya

EARLY REGISTRATION RECOMMENDED
RM 1000 / PARTICIPANT
(Fee Included: Comprehensive Training, E-certificate, Training materials and Meals)

Upon submission of your registration, an invoice for payment, along with the payment method details, will be issued within 2–3 working days.

This program is claimable under the SBL Scheme. Please refer here for the SBL Scheme terms and conditions

TRAINING TENTATIVE

TIME	CONTENT
08.30 AM - 09.00 AM	**Registration and Briefing**
09.00 AM - 10.30 AM	**Session 1: Fundamentals of Medical Device Sterilisation.** • Sterility assurance level, bioburden, endotoxin and basic regulatory requirements.
10.30 AM - 10.45 AM	**Morning Break**
10.45 AM - 11.45 AM	**Session 2: Medical Device Sterilisation Methods** • Ethylene oxide, radiation, moist heat, dry heat and low-temperature sterilisation methods.
11.45 AM - 12.45 PM	**Session 3: Sterilisation Process Validation** • Process development, IQ, OQ, PQ, routine monitoring, revalidation and change control.
12.45 PM - 02.00 PM	**Lunch Break**
02.00 PM - 03.00 PM	**Session 4: Sterile Barrier System and Routine Control** • Packaging validation, batch release, process monitoring, shelf life and handling of deviations.
03.00 PM - 04.00 PM	**Session 5: Regulatory Compliance and Applicable Standards** • Technical documentation, labelling, risk management and key ISO standards.
04.00 PM - 04.15 PM	**Tea Break**
04.15 PM - 05.00 PM	**Session 6: Case Study and Group Discussion** • Review of sterilisation validation documents and identification of compliance gaps.
05.00 PM	**Session End**

SCAN TO REGISTER!

Registration open until :
31 July 2026

LIMITED SEATS!
REGISTER NOW!