Medical Device Authority Malaysia

PIHAK BERKUASA PERANTI PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA

THE TRAINING OF

ISO 13485 : 2016

Quality Management System for Medical Device

5 November 2024
09:00 AM - 05.00 PM

Bilik Mesyuarat Meranti Aras 6, Pejabat MDA, Cyberjaya

TRAINING FEE
RM1000
PER PAX

WHAT IS YOUR 'TAKE AWAY' FROM THIS COURSE?

- ✔ Understand the scope and the structure of ISO 13485:2016, the type of Organizations that can get certified to this International Standard.
- ✔ Recognize the value of ISO 13485:2016 certification and its contribution to Medical Device Quality and Regulatory Compliance.
- ✔ Learn about quality management principles and their use in the medical devices sector
- ✔ To have an Awareness on the various clauses of the ISO 13485:2016 and its requirements.
- ✔ To have an Awareness on Risk Management, Process Validation, required Documentation and Maintenance of Records in the context of ISO 13485:2016 requirements.
- ✔ To have an Understanding of the basics of maintaining product quality and safety, navigating supplier management, traceability, and post-market surveillance for medical devices in the context of ISO 13485:2016
- ✔ To have an Awareness of recent innovations and sources of regulatory changes affecting the medical devices sector.

Target Audience

- ✔ Senior Management
- ✔ Regulatory Affairs Manager
- ✔ Quality Assurance Manager
- ✔ QRMS Internal and External Auditors
- ✔ Department & Section Head involved in the implementation of the ISO 13485:2016 Standard.
- ✔ Interested Individuals

SCAN NOW TO REGISTER

CLOSING DATE: 25 OCTOBER 2024

Upon acceptance of the registration, an invoice (for payment purposes) together with details of the payment methods will be issued accordingly)

Contact us at: Trainingpackage@mda.gov.my

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Training Outline

8:30AM - 9:00AM	Registration & Briefing
9:00AM - 10:00AM	• Overview of Quality Regulatory Management Systems (QRMS) • Overview of ISO 13485:2016 – Familiarization of the Standards • Medical Device Regulators Demands - Relationship with Jurisdictions
10:00AM - 10:30AM	• The relation between ISO 9001:2015 to ISO 13485:2016 • Cross-referencing to ISO 14971:2019 (Application of Risk Management to Medical Devices)
10:30AM - 10:45PM	**Short Break**
10:45 AM - 12:30 PM	• Navigating and Interpreting the ISO 13485:2016 • Introduction to **Clause 0, 1, 2,** • **Clause 3** – Terms & Definition
12:30 PM - 02:00 PM	**Lunch Break**
02:00 PM - 03:30 PM	• **Clause 4** – Quality Management System • **Clause 5** – Management Responsibility • **Clause 6** – Resource Management
03:30 PM - 03:45 PM	**Tea Break**
03:45 PM - 05:00 PM	• **Clause 7 – Product Realization** • **Clause 8 – Measurement, Analysis and Improvement** • **Q & A Session**
05:00 PM	**End of Program**

**** This training Outline is Subject to Change**

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