

# THE TRAINING OF ISO 13485 : 2016 Quality Management System for Medical Device



5 November 2024  
09:00 AM - 05.00 PM



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Pejabat MDA, Cyberjaya



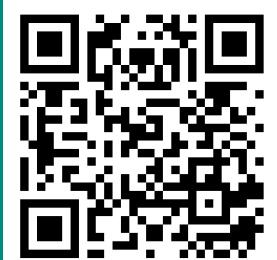
## WHAT IS YOUR 'TAKE AWAY' FROM THIS COURSE?

- ✓ 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.

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TO REGISTER**



## 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

**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](mailto:Trainingpackage@mda.gov.my)

# Training Outline

8:30AM - 9:00AM	Registration & Briefing
9:00AM - 10:00AM	<ul style="list-style-type: none"> <li>• Overview of Quality Regulatory Management Systems (QRMS)</li> <li>• Overview of ISO 13485:2016 – Familiarization of the Standards</li> <li>• Medical Device Regulators Demands - Relationship with Jurisdictions</li> </ul>
10:00AM - 10:30AM	<ul style="list-style-type: none"> <li>• The relation between ISO 9001:2015 to ISO 13485:2016</li> <li>• Cross-referencing to ISO 14971:2019 (Application of Risk Management to Medical Devices)</li> </ul>
10:30AM - 10:45PM	Short Break
10:45 AM - 12:30 PM	<ul style="list-style-type: none"> <li>• Navigating and Interpreting the ISO 13485:2016</li> <li>• Introduction to <b>Clause 0, 1, 2,</b></li> <li>• <b>Clause 3</b> – Terms &amp; Definition</li> </ul>
12:30 PM - 02:00 PM	Lunch Break
02:00 PM - 03:30 PM	<ul style="list-style-type: none"> <li>• <b>Clause 4</b> – Quality Management System</li> <li>• <b>Clause 5</b> – Management Responsibility</li> <li>• <b>Clause 6</b> – Resource Management</li> </ul>
03:30 PM - 03:45 PM	Tea Break
03:45 PM - 05:00 PM	<ul style="list-style-type: none"> <li>• <b>Clause 7</b> – Product Realization</li> <li>• <b>Clause 8</b> – Measurement, Analysis and Improvement</li> <li>• Q &amp; A Session</li> </ul>
05:00 PM	End of Program

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

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