MEDTECH PROFESSIONAL CERTIFICATE IN QUALITY ASSURANCE (10 DAYS)

Course description / objective:

The Medtech Professional Certificate in Quality Assurance aims to enhance the knowledge and skills of current employees in quality management system. They will learn how to ensure compliance with the latest US FDA Quality Management System Regulation (QMSR) and EU Medical Device Regulation (EUMDR), develop proper risk management documentation, address and handle non-conformances and product complaint, perform effective investigation to get to the root cause of a problem & manage incoming and outgoing inspection using acceptance sampling method.

Target participants:

This course aims to train quality assurance professionals.

Course outline:

Training Topics & Scope	Duration
1) Medical Device Quality System: ISO 13485:2016 & US FDA Quality Management System Regulation ➢ Interpretation of the ISO 13485:2016 and QMSR requirements ➢ FDA inspection – The expectation and preparation	2 days
2) EU Medical Device Regulation (EU MDR 2017/745) ➢ Classification rules of medical devices ➢ Technical documentation (Annex II & III of EU MDR) ➢ Conformity assessment procedures	2 days
3) Risk Management for Medical Devices (ISO 14971:2019 / EN ISO 14971:2019/A11:2021) ➢ EN ISO 14971:2019/A11:2021 requirements ➢ Risk management tools	2 days
4) NCR / CAPA / Complaint Handling ➢ Standard & regulatory perspective on NCR, CAPA & complaint handling ➢ Step-by-step process to address non-conformance, CAPA and complaint	2 days
5) Effective Root Cause Analysis ➢ Principles and techniques of effective root cause analysis ➢ Common barriers to root cause analysis and techniques to overcome it	1 day
6) Acceptance Sampling Method ➢ Selection of a suitable acceptance sampling plan ➢ Designing a sampling plan	1 day
Total	**10 days**

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Delivery mode: Choose either **online training** or **physical class**.

Training Schedule:
Batch: #1 (QA-Penang-1)

Training Topics	No. of Days	Date	Training Platform
Medical Device Quality System: ISO 13485:2016 & US FDA Quality Management System Regulation	2	31 Mar & 1 Apr 2026	Iconic Marjorie Hotel
Risk Management for Medical Devices (ISO 14971:2019 / EN ISO 14971:2019/A11:2021)	2	20 & 21 Apr 2026	Iconic Marjorie Hotel
Acceptance Sampling Method	1	6 May 2026	Iconic Marjorie Hotel
EU Medical Device Regulation (EU MDR 2017/745)	2	20 & 21 May 2026	Iconic Marjorie Hotel
NCR/ CAPA/ Complaint Handling	2	8 & 9 June 2026	Iconic Marjorie Hotel
Effective Root Cause Analysis	1	22 June 2026	Iconic Marjorie Hotel
Exam		26 June 2026	Online (Zoom)

Batch: #2 (QA-Online-2)

Training Topics	No. of Days	Date	Training Platform
Medical Device Quality System: ISO 13485:2016 & US FDA Quality Management System Regulation	2	20 & 21 July 2026	Online (Zoom)
EU Medical Device Regulation (EU MDR 2017/745)	2	5 & 6 Aug 2026	Online (Zoom)
Risk Management for Medical Devices (ISO 14971:2019 / EN ISO 14971:2019/A11:2021)	2	17 & 18 Aug 2026	Online (Zoom)
NCR/ CAPA/ Complaint Handling	2	7 & 8 Sep 2026	Online (Zoom)
Effective Root Cause Analysis	1	21 Sep 2026	Online (Zoom)
Acceptance Sampling Method	1	22 Sep 2026	Online (Zoom)
Exam		2 Oct 2026	Online (Zoom)

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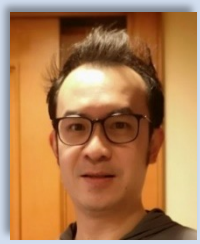
Trainer's profile:

WONG HON MENG (HARRY WONG)

Harry Wong has over 26 years of professional working experience in Quality Assurance for medical device, ceramic former, metal stamping and printing industries supporting healthcare, electrical, electronics and automotive sectors. Currently serving as a Principal Consultant, Harry provides comprehensive consultation and training services exclusively tailored for the medical device industry.

In his prior role as an Associate Director, Global Quality Assurance for Ansell, Harry served as a subject matter expert for risk management. After this role, he advanced to become Director of Operation Excellence and Strategy. His responsibilities includes providing guidance, direction and training to risk management personnel across global sites, spearheading global improvement initiatives, nurturing talent development, conducting corporate quality assessments, and ensuring compliance with ISO standards and regulatory requirements. He has extensive involvement in mock audits for global sites preparing for CCC, ANVISA, SEI and FDA.

Harry Wong is a HRD Corp Accredited Trainer, Certified Lean Sigma Black Belt, FMM & ASQ Certified Quality Engineer, and Lead Auditor for ISO 9001:2015 and ISO 13485:2016.



KENNY CHONG KHIN KHEN

Mr Kenny Chong has been involved in the Medical Device Industry for the past 20 years, working with Straits Orthopaedics, Symmetry Medical, Neville-Clarke as well as BSI Services. In this time, his experience throughout the entire product lifecycle and all 3 medical device regulatory stages has enabled him to gain qualification on all medical device technology scopes.

He is a trained CQI & IRCA Lead Auditor of ISO 13485:2016, ISO 9001:2015, ISO 14001:2015, and OHSAS 18001:2007. Kenny holds a Master's Degree in Biotechnology. Currently, Kenny Chong is a Principal Consultant, where his role also includes maintaining top quality training, consultancy and coaching service for Medical Device & other regulated industries.

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Trainer's profile:

LIM LIP KHOON (LK LIM)

LK Lim is a Six Sigma Master Black Belt. He has a Bachelor of Science in Mechanical Engineering and a Master of Business Administration. He has over 30 years of working experience in Operations, Process, Quality System and Business Process Improvement in a variety of industries, including medical device industry. He has worked with and at senior management level to improve process efficiency, implement practical Lean manufacturing systems and improve profitability.

Together with the University of Auckland, LK Lim has presented the Lean Six Sigma methodology and mentored candidates from industries such as telecommunication, banking, infrastructure, manufacturing, and others. Beyond the University of Auckland, he had also delivered Six Sigma training for Melbourne University (Australia) and Telkom University (Indonesia).

LK Lim is also a pioneer in Motorola University in the APAC region. He played a significant role in developing, enhancing, and customizing the Lean Six Sigma program for Motorola University. He has coached and consulted Motorola University's clients on the Lean Six Sigma Business Improvement Campaign. In addition to consulting, he has trained Six Sigma and Lean Green and Black Belts candidates in Australia, New Zealand, Peoples Republic of China, India, Malaysia, Singapore, Indonesia, and Thailand. He is currently also serving as an advisor to senior leadership for companies in a variety of industries, some of which are multinationals (MNC) and medical device manufacturing company.

PATSY CHAN PENG HONG

Patsy Chan Peng Hong is a Motorola University's Certified Six Sigma Black Belt. She has many years of experience in Operations Management working as Operations Manager for a multinational company. Her consulting and coaching experience include over 20 years of experience in Process, Quality System and Business Process Improvement in variety industries, including medical device industry.

While working with Motorola University, she has coached and completed over 100 Lean Six Sigma projects and achieving significant savings and revenues. She has trained Six Sigma, Lean Six Sigma and Lean candidates in Malaysia, Thailand, Japan and China. In addition to coaching and training, Patsy has successfully led a team of executives in turning around an operations in a multinational manufacturing facilities in less than 24 months.