MEDTECH PROFESSIONAL CERTIFICATE IN MANUFACTURING EXCELLENCE (10 DAYS)

Course description / objective:

The Medtech Professional Certificate in Manufacturing Excellence aims to enhance the knowledge and skills of current employees in medical device manufacturing operation. They will learn about product life cycle management and how to improve the operation system by eliminating waste, improve current process through process mapping, comply with process validation requirements, use statistics to validate assumptions and root causes, identify process instability and develop improvement strategies, evaluate the quality of measurement systems, determine the relationship between factors affecting a process & address non-conformances and product complaint.

Target participants:

This course aims to train manufacturing professionals.

Course outline:

Training Topics & Scope	Duration
1) Lean Manufacturing ➢ The operational 'waste' (The 7 lean wastes) ➢ Lean best practices	2 days
2) Process Mapping ➢ Process mapping tools and process analysis tools ➢ Strategies to improve current 'as is' process	1 day
3) Medical Device Manufacturing Process Validation ➢ Validation Master Plan ➢ IQ , OQ & PQ	2 days
4) Hypothesis Testing ➢ Hypothesis testing with comparative methods ➢ Correlation and regression analysis	1 day
5) Statistical Process Control and Capability Analysis ➢ Control charts ➢ Methods to determine the current process capability	1 day
6) Measurement System Analysis ➢ Gage repeatability and reproducibility ➢ Attribute agreement analysis	1 day
7) Design of Experiments ➢ Factorial design and analysis for experimentation ➢ Process model for process prediction and simulation	1 day
8) NCR / CAPA / Complaint Handling ➢ Standard and regulatory perspective ➢ Step-by-step process to address non-conformance, CAPA and complaint	1 day
Total	**10 days**

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

Training Schedule:
Batch: #3 (ME-Hybrid-3)

Training Topics	No. of Days	Date	Training Platform
Process Mapping	1	22 Oct 2026	Iconic Marjorie Hotel
Lean Manufacturing	2	2 & 3 Nov 2026	Eastin Hotel
Hypothesis Testing	1	16 Nov 2026	Iconic Marjorie Hotel
Statistical Process Control & Capability Analysis	1	17 Nov 2026	Iconic Marjorie Hotel
Medical Device Manufacturing Process Validation	2	30 Nov & 1 Dec 2026	Iconic Marjorie Hotel
Measurement System Analysis	1	9 Dec 2026	Iconic Marjorie Hotel
Design of Experiments	1	10 Dec 2026	Iconic Marjorie Hotel
NCR/ CAPA/ Complaint Handling	1	21 Dec 2026	Iconic Marjorie Hotel
Exam		To be confirmed	Online (Zoom)

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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.

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Trainer's profile:

GOBU DEVARAJAN

Mr Gobu Devarajan has more than twenty-five years of working experience and extensive knowledge in the fields of quality engineering, statistical analysis, and quality system requirements. Mr Gobu Devarajan retired as the QA/RA Director, APAC from Ansell in May 2025. Prior to his role at Ansell, Mr Gobu served as a Senior QA Manager (Operation) at Teleflex from 2010 to 2016.

He is a subject matter expert in the US FDA 21 CFR Part 820, Good Manufacturing Practices (GMP), Medical Device Regulation EU MDR 2017/745, ISO 13485, Japan's Pharmaceutical Affairs Law (JPAL), ISO 9001 and ISO/TS 16949 Quality Management Systems.

Mr Gobu holds a Master's Degree in Electrical and Electronic Engineering. He is a Certified Manager of Quality/Organizational Excellence (CMQ/OE) and Certified Quality Auditor (CQA) from the American Society of Quality (ASQ). He has the credential of a Certified Six Sigma Green Belt. He is also the Lead Assessor for the Department of Standard Malaysia (DSM).

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.