

Failure Modes, Effects and Criticality Analysis (FMECA) for Medical Device Manufacturing

Training Brochure



INTRODUCTION

FMECA is a proactive risk assessment, quality and cost improvement method. It is useful in pre-empting failure risks, and driving process improvement without having to deal with Statistical Tools. Participants will learn to systematically identify potential failure risks, quantify and prioritize these risks, and to work effectively in team to identify solutions to these risks.

COURSE OBJECTIVES

The course is design for the participants to:

- Differentiate between Design and Process FMECA.
- Assess risks in a systematic manner.
- Quantify and prioritize risks.
- Improve process within own department (point-kaizen).
- Contribute to cross functional process improvement (flow-kaizen).
- Engage staff through systematic analysis and improvement.

COURSE OUTLINE

- ISO 13485 and FMEA
- Overview of Change and Risks
- Introduction to FMECA
- FMECA Overview
- Failure Modes and Effects Analysis (FMEA)
- FMEA Terminologies, Tools and Method
- Criticality Analysis (CA)
- FMEA Key Success Factors
- Introduction to Process FMECA
- The Five (5) Phases of Conducting FMEA
- FMECA Tools.
- Application Examples of FMEA

DURATION: 8 Hours

MODE OF TRAINING

Remote Online Training

TARGET AUDIENCE

This programme is designed for operations and design staffs who wants to learn a proactive method to manage and to continuously improve work processes, and to improve overall work effectiveness and efficiency.

TRAINER'S PROFILE

Lim Lip Khoo (LK) is an engineer and a Six Sigma Master Black Belt. He has a Bachelor of Science in Mechanical Engineering and a Master of Business Administration. He has over 10 years of Operations Management experience at senior leadership level in manufacturing sector. He also has over 30 years of working experience in Operations, Process, Quality System and Business Process Improvement in a variety of industries in Australia, New Zealand, Malaysia, Singapore, China, Indonesia, and Thailand. 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, he 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, LK had also delivered Six Sigma training for Melbourne University (Australia) and Telkom University (Indonesia).

Apart from being a principal of NexMU Sdn. Bhd., he 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. Also, 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).

PAYMENT AND CONFIRMATION OF REGISTRATION

Option 1: HRDCorp Claim under SBL-Khas Scheme

A quotation together with course outlines and course agenda will be sent to you for HRDCorp grant application upon confirmation of the training. Please send us the grant application number for our record upon submission.

Option 2: Self-paying

2a) Direct Bank-in or via E-Banking

An invoice will be sent to you within 3 working days upon your registration. Please note that any Early Bird Discounts (for registration within validity period) will be reflected in the invoice. Please email us (admin@medsociate.com) the bank-in slip / remittance slip once the payment is made.

Please refer the following bank account details:

Beneficiary Name: Medsociate Sdn Bhd

Bank Account Number: 230-302-078-2

Bank: UOB Bank

Swift Code: UOVBMKYL

For Government Sector - A Local Order (LO) or letter of approval to participate must be submitted before your registration can be confirmed.

2b) Direct Online Payment

You may choose to make credit card payment via Paypal. An invoice with payment link will be sent to your email address separately when you choose this option.

CANCELLATION / REFUND POLICY

The organisers, AMMI/ Medsociate Sdn Bhd reserves the right to cancel or postpone any training or event but with due notice to the registered participants / company(s). Any payment made will be refunded in full if the cancellation is made by AMMI/ Medsociate Sdn Bhd. No shows and cancellations made by participants/ companies within the specified period will incur the specified costs as per below schedule.

Prior to Training Date	Cancellation Charges
30 days or more	No charges
15-29 days	25% of training course fee
8 - 14 days	50% of training course fee
0 - 7 days	100% of training course fee

SUBSTITUTION

Replacement of participant is allowed at no additional cost if you are unable to attend. Please inform us of the replacement in writing at least 3 working days before the training date.

CONTACT

For enquiries, please email to Medsociate Sdn Bhd

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