

Failure Mode Effects Analysis (FMEA) in Medical Device Manufacturing



INTRODUCTION

This course is designed for participants who are interested 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.

DELIVERY METHOD

Course will be delivered in a Workshop environment, adopting the Action Learning Methodology to increase the rate of transferring from knowledge acquisition to skill application. The emphasis is on learning by doing, and not learning by listening. Participants will experience a simulated process at the beginning of the course. Progressively, they will Learn, and Apply the tools to improve the simulated process.

COURSE OBJECTIVES

This course will enable you to **differentiate between Design and Process FMEA**, practise live Process and Design FMEA in class, assess risk in a systematic manner, quantify and prioritize risks with **Criticality Analysis (CA)**, improve process within own department (point kaizen), contribute to cross functional process improvement (flow-kaizen) and map your current "As Is" business process.

It will also enable you to engage staff through systematic analysis and improvement, while generating solutions to eliminate or reduce failure risks - all of which will lead to improved cost, delivery and quality.

COURSE OUTLINE

- ✓ Types of FMEA: Design and Process FMEA
- ✓ System and SIPOC diagrams
- ✓ Traditional and updated FMEA template
- ✓ Key components of FMEA: Rating scales, Risk Priority Number (RPN) & CA
- ✓ Planning for FMEA
- ✓ Executing Process FMEA
- ✓ Executing Design FMEA
- ✓ Evaluate solutions
- ✓ Monitor and continuously improve the solutions

TARGET AUDIENCE

Anyone who wants to learn a proactive method to manage and to continuously improve work processes, and to improve overall work effectiveness and efficiency

PRE-REQUISITE

There is no prerequisite for this course.

TRAINER'S PROFILE

Mr LK Lim is a director of NexMU Sdn. Bhd. and a Certified Six Sigma Master Black Belt. He is a professional engineer with a Bachelor of Science in Mechanical Engineering and a Master of Business Administration. He has over 20 years of working experience in Operations Management, Process, Quality System and Business Process Improvement in variety of industries including medical device industry. He has worked with and at senior management level to improve process efficiency, implement effective Lean manufacturing systems and improve profitability.

He has over 6 years of presenting experience with reputable universities such as the University of Melbourne in Australia and the University of Auckland in New Zealand. He coached and consulted for Motorola University's clients which have embarked 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, People Republic of China, India, Malaysia, Singapore, Indonesia and Thailand. He is currently also serving as advisor to senior leadership for companies in variety of industries, some of which are multinationals (MNC) and medical device manufacturing company.

COURSE REGISTRATION DETAILS

Course fees, payment details and online registration log-in will be provided once the course is open for registration.

CONTACT

For enquiries, please email to admin@medsociate.com

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