MS ISO 13485:2016 MEDICAL DEVICES UNDERSTANDING & IMPLEMENTING

Duration: 2 Days

PROGRAM OVERVIEW

Most medical devices are used globally. The safety, performance and consistent quality of medical devices are an internationally public health interest. Thus standard is utmost important to provide guidance for those who participate in manufacture, servicing, trading or distributing including regulating act in medical device. This course is designed to provide an understanding on the fundamental principles, objectives and requirements of ISO 13485 Standards and its importance in conformity assessment which has become essential in compliance to the medical device regulation. It is beneficial to organization in planning to develop a quality management system for medical device in the company to be capable for certification to the standard's requirement.

COURSE CONTENTS

- What is Medical Device and its classification.
- Medical Device Regulation.
- Introduction to ISO 13485 & its History.
- ISO 13485 standard requirements.
- ISO 13485 Implementation & Certification Process.

OBJECTIVES

- Provide understanding on what is medical device and its classification.
- To gain knowledge on related medical device regulation and the affect to industry.
- Provide an understanding of the ISO 13485 registration process.
- Be able to understand the concept and requirements of ISO 13485.
- To assist organization to implement steps towards ISO 13485.

WHO SHOULD ATTEND?

Manager, executives, engineers, professionals and employees involved in manufacturing, servicing and distribution that is related to the quality and efficiency of medical device.

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