Course Code: TMD2

Medical Devices-Quality Management System ISO 13485:2016

Overview

COURSE CONTENT

- Introducing Medical Device & ISO 13485 :2016
- Interpretation on the requirements and implementation of ISO 13485:2016
- Interpretation of key ISO 13485:2016 clauses

OBJECTIVE

- To understand the concept behind and application of the standards
- To introduce ISO 13485 :2016 requirements

WHO SHOULD ATTEND?

- Person in charge of establishing and Implementing ISO 13485
- Management Representatives
- Person is seeking for learning essential knowledge in quality management control in medical device industry
- Medical Device professionals interested in conducting first-party, second-party, and/or third-party audits

GENERAL INFORMATION

Venue: ACI Training Venue

Duration: 1 day

Methodology:

Presentation, workgroup discussion and experience sharing

Certificate:

Certificate of Successful Completion will be awarded to delegates who have attended full course

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課程編號: TMD2

醫療器械 - 質量管理系統
ISO 13485:2016

概要

培訓內容

- 介紹醫療器械與ISO 13485:2016
- 解釋ISO 13485:2016的要求和實行
- 解釋ISO 13485:2016所有條款

培訓目的

- 瞭解該標準的概念和應用
- 介紹 ISO 13485:2016的支持技術

培訓對象

- 涉及負責建立和實施ISO13485系統的人員
- 負責社會企業責任的人員
- 希望學習醫療器械-質量管理基本知識的人員
- 對第一方、第二方和/或協力廠商審核感興趣的醫療器械專業人員

培訓詳情

地點: ACI 訓練中心

時間: 一天

上課模式:

講解、工作小組討論與經驗分享

證書:

高出席率之學員將獲頒發證書乙張

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