Course Code:TMD4

Medical Devices-Quality Management System

ISO 13485:2016

Internal Auditor

COURSE CONTENT

- ISO 13485:2016 standard review
- Understand ISO 13485:2016 Medical Device – Quality Management System audit and regulatory requirements
- Internal auditing (including audit planning, auditing methodology, auditing skills, reporting and CAPA follow up

OBJECTIVE

- To understand the application of Medical Device – Quality Management System.
- To understand the importance of internal auditing and the responsibilities of internal auditors
- To plan and organize an internal audit

WHO SHOULD ATTEND?

- Person in charge of establishing and implementing ISO 13485:2016
- Management Representatives
- Person wishes be trained as ISO 13485:2016 internal auditors
- 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: 2 day

Methodology:

Presentation, workshop and case study

Certificate:

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

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課程編號: TMD4

醫療器械 - 質量管理系統
ISO 13485:2016
內部審核培訓

培訓目的

- 瞭解醫療器械 - 質量管理系統標準的應用
- 瞭解內部審核的重要性和責任
- 計劃和組織內部審核

培訓內容

- ISO 13485:2016 文檔記錄概述
- 了解 ISO 13485:2016醫療器械 - 質量管理系統審核和監管規定
- 內部審核(包括審核計劃，審核方法，審核技巧，報告和CAPA跟進)

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
- 希望取得內審員資格的人員
- 與體系建立維護相關的質量管理人員
- 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: 二天

上課模式:

講解、工作坊及個案分析

證書:

高出席率之學員將獲頒發證書乙張

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