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For those who are:

Meeting the requirements within ISO 13485:2016.

Implementing a Risk Analysis to ISO 14971:2019.

Involved in ensuring a Risk Analysis meets the requirements of the Saudi Medical Device Regulation.

Quality Engineers or Regulatory Affairs professionals.

Benefits of the Course

Highly skilled tutor with Notified Body (CE) and Competent Authority (SFDA) experience.

Practical, to incite discussion and accelerate learning.

Provides an open forum to air concerns and ask questions.

Offers the opportunity to compare notes and interact with industry peers.

A full set of course notes and guidance documents for post-course referral.

Five x 2½ hour modules held live in an on-line lecture theatre

The Risk Analysis of Medical Devices

Academy Centre

Goals of the Course

1. Introduction

ISO 14971 Structure.
Definitions.
Regulatory Requirements.
Risk / Benefit Analysis.

2. Plan

Risk Management Plan.
Risk Management Procedure.
Use of the Regulation.
Hazard Analysis.

3. Analysis

Determination of Probability & Severity.
FMEA.
Fault Tree Analysis.
Links to ISO 13485.

4. PMS

PMCF.
PMS by Complexity.
Tying Severity and Occurrence to PMS.

5. Vigilance

Conducting Vigilance.
Setting Limits & Trigger Points.
Compilation of a Risk Analysis Report.
The SSCP and the PSUR.

Courses

Public course dates available.

All private courses tailored to the client's individual devices.

Hotel and parking at special rates.

The Academy Centre
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المؤسسة العامة للتدريب التقني والمهني
Technical and Vocational Training Corporation

Course code
OC1105