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For those who are:

Writing or involved in implementing a Clinical Evaluation.

Checking a Clinical Evaluation meets requirements of CE and SFDA.

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 Performance Evaluation of In Vitro Medical Devices

Academy Centre

Goals of the Course

1. Introduction

Regulation.
Definitions.
The state of the art.
Classification.

2. Plan

Intended purpose.
The General Safety and Performance Requirements.
Risk versus benefit.
Objectives.
Pre-clinical data.

3. Data

Literature review.
Exploring data sources.
Appraisal of data.
Weighting evidence.
Writing a critique.

4. Investigation and PMS

Clinical investigations.
PMS plan & PMPF plan.
Justifying the level of PMS/PMPF.
Tying severity and occurrence to PMS.
Writing a PSUR & SSP.

5. Vigilance

Conducting vigilance and setting limits and trigger points.
Additional Quality Procedures.
Compilation of a PER.

Courses

Public course dates available.

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

Hotel and parking at special rates.

The Academy Centre
info@academycenters.com

المؤسسة العامة للتدريب التقني والمهني
Technical and Vocational Training Corporation

Course code
OC0905