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For those who:

Are implementing the Saudi Regulation on Medical Devices and IVDs.

Are involved in writing Technical Files or Quality Systems for the Saudi Regulation on Medical Devices and IVDs.

Are Quality Engineers or Regulatory Affairs professionals.

Require a TVTC accredited certificate.

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 are available for post-course referral from the student portal.

Professional Regulatory Qualification for:

Regulatory Specialist for Medical Devices

Academy Centre

Course Highlights

- This is a live on-line course.
- Each lecture is two and a half hours.
- The course comprises 23 lectures spread over a year.
- Lectures include exercises conducted in groups, in pairs or individually.
- All students have access to the Academy student portal.
- Students are expected to commit to a minimum of 150 hours study for this course.
- A tutorial is held each month during the course.
- At the conclusion of each module a tutor marked assessment is given.
- Students are continuously graded and these grades count towards the final mark.
- The course concludes with a three hour exam.

المؤسسة العامة للتدريب التقني والمهني
Technical and Vocational Training Corporation

Course Description

Course code PRQ003

Module title	Lectures	Description
The Saudi Regulation for Medical Devices and IVDs	3	An introduction to the basic requirements of the law.
Development of procedures for ISO 13485 and regulatory compliance	3	An introduction to quality management systems, the ISO 13485 standard and writing procedures to meet the law.
Verification and Validation of Medical Devices	2	Techniques for meeting the essential principles, and implementing standards.
The Risk Analysis of Medical Devices	3	Meeting the requirements of the ISO 14971 and the law.
The Clinical Evaluation of Medical Devices	2	Meeting the requirements of the law, writing a clinical evaluation report.
Introduction to global regulations.	4	An introduction to preparing technical documentation and selling to the larger territories around the world.
Introduction to USA regulations.	3	An introduction to preparing technical documentation and selling to the USA.
Post-Market Surveillance and Vigilance of Medical Devices	2	Gathering and using post-market intelligence and reporting to the SFDA.

The Academy Portal

All students registered with the academy are given a login id and password for entry to the student portal.

The student portal allows you to:

- ✓ Access the .pdfs of all the slides from the lectures.
- ✓ Access recordings if you miss a lecture.
- ✓ Leave questions for your tutors and pick up answers from them.
- ✓ Pick up and submit your homework.
- ✓ Sit your exam.

Entry Requirements

- Students must have:
  a recognised degree, or higher,
  OR at least 3 years experience in Regulatory Affairs.
- Students must be fluent in English, both spoken English and the written language.
- Students will be registered with the Academy Centre in Riyadh.

The Academy Centre

For more information, email:
info@academycenters.com