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For those who:

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

Are Quality Engineers or Regulatory Affairs professionals.

Are manufacturers, importers or distributors

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:

Quality Manager 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 18 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 100 hours 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 PRQ002

Module title	Lectures	Description
Introduction to ISO 13485 (clause by clause)	3	An introduction to the Plan, Do, Check, Act cycle for Management Systems and a systematic walk through the ISO 13485 standard.
Internal auditor for Quality Management Systems	5	The principles of process auditing and the types of audit. How to plan and conduct an audit. Writing an audit report and conducting audit follow-up.
Development of procedures for ISO 13485 and regulatory compliance	3	Writing Quality Management System procedures to meet ISO 13485 and the requirements of the Saudi Medical Device Regulation.
Verification and Validation of Medical Devices	2	Techniques for meeting the essential principles and implementing standards. Installation Qualification. Operational Qualification. Performance Qualification. Use of external laboratories, internal testing and demonstrating sufficient evidence.
Post-Market Surveillance and Vigilance of Medical Devices	2	Procedures for 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