

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 Manager for Medical Devices



Course Highlights

- This is a live on-line course.
- Each lecture is two and a half hours.
- The course comprises 36 lectures spread over the course of 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 250 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.



Module title	Lectures	Description
The Saudi Regulation for Medical Devices and IVDs	3	An introduction to the basic requirements of the law.
Procedures for 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.
Sterilisation of Medical Devices	3	Sterile medical devices and packaging.
Biocompatibility of Medical Devices	2	Meeting the biological safety requirements of ISO 10993
Combination Products	2	Meeting the additional requirements of medicinal and biological combination products.
The Risk Analysis of Medical Devices	3	Meeting the requirements of ISO 14971 and the law.
Clinical Evaluation of Medical Devices	2	Understanding the requirements and techniques for writing a Clinical Evaluation report.
Performance Evaluation of In Vitro Medical Devices	2	Understanding the requirements and techniques for writing a Performance Evaluation report.
Clinical Investigation	3	How to conduct an ethical Clinical Investigation to meet the law.
Global Regulations for Medical Devices	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.