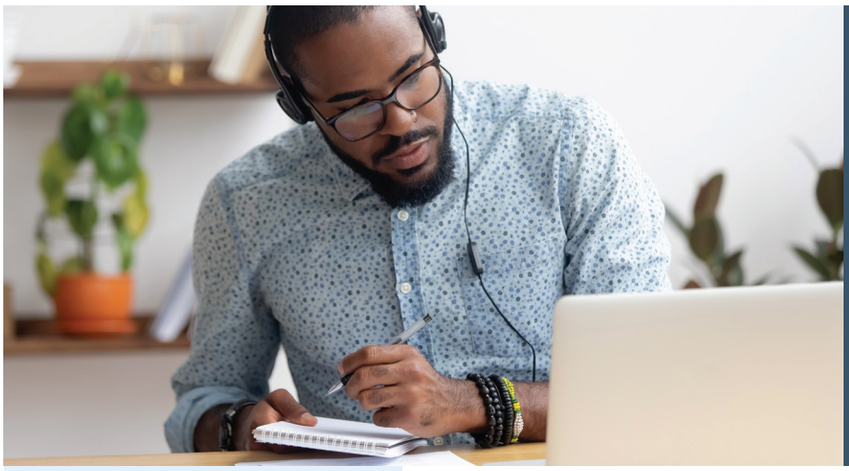
POSTGRADUATE CPD CERTIFICATE

Implementing Regulatory Requirements for Medical Devices

SGS, the world's leading testing, inspection and certification company and Notified Body under Medical Device Regulation (EU) 2017/745 has developed a 10-week online postgraduate CPD programme in Implementing Regulatory Requirements for Medical Devices.

SGS is delighted to partner with TU Dublin, who are accrediting the programme, to support Ireland's dynamic and highly innovative medical device sector in meeting the challenges of achieving regulatory compliance, notably, the European MDR.

SGS



COST: €1475

COMMENCING:
SEPTEMBER 2022

REGISTER INTEREST:
IREACADEMY@SGS.COM

KEY FEATURES:

- 10-week course
- 100% online
- Accredited by TU Dublin
- Led by experienced lecturers with guest lecturers from SGS's global team of auditors
- Provides comprehensive knowledge of the requirements for regulatory compliance

SYLLABUS AWARD

Final award is a CPD Certificate in Regulatory Requirements for Medical Devices. The award is at NFQ level 9 and will be awarded without classification, accredited by TU Dublin.

WHO IS THIS COURSE FOR?

This course is aimed at graduates* and existing employees in the Medical Device sector looking to upskill and develop their competence in supporting their businesses in preparing for full compliance with regulation in this increasingly complex sector, including and most specifically, MDR.

APPLICATION PROCESS

To request a registration of interest form contact ireacademy@sgs.com

Following receipt your application will be reviewed and if required, further information sought.

Once your registration is accepted, you will receive an application form with details for payment and complete registration with SGS and TU Dublin.

LEARNING OUTCOMES

At the end of this programme, participants will have established a foundation in Medical Device quality assurance demonstrated by being able to:

- Describe ISO 13485 and its application in Medical Device certification, in particular the EU Medical Device Regulation
- Interpret risk management as applied to Medical Device certification, with particular use of ISO 14971
- Structure and critique product technical documentation
- Examine the quality requirements for sterilisation, labelling, biocompatibility and process validation
- Describe clinical evaluation and how this links into the product risk assessment
- Evaluate work conducted by a manufacturer after launching a product to maintain state of the art
- Contrast the regulatory requirements in Europe with those from other parts of the world
- Synthesise the module material and develop an action plan to implement the regulatory requirement.

ABOUT SGS

We are SGS – the world's leading testing, inspection and certification company.

We are recognized as the global benchmark for quality and integrity. Our 96,000 employees operate a network of 2,600 offices and laboratories, working together to enable a better, safer and more interconnected world.

Wherever you are, whatever your industry, our experts worldwide provide specialised solutions to make your business faster, simpler and more efficient.

**Those who do not have a primary degree in science or engineering but have the relevant experience in the Medical Device sector may be considered. Request the registration form for details.*

Partners of SGS

DUBLIN TECHNOLOGICAL UNIVERSITY DUBLIN — OLLSCOIL TEICNEOLAÍOCHTA BHAILE ÁTHA CLIATH

CONVENE transforming *university-enterprise* engagement

WHEN YOU NEED TO BE SURE

SGS