CERTIFICATE IN MEDICAL TECHNOLOGY REGULATORY AFFAIRS & QUALITY

(LEVEL 8; PART-TIME ONLINE; 30 ECTS CREDITS)

Course Overview

NUI Galway and IT Sligo in collaboration with ulearning Skillnet are pleased to announce a new programme designed in consultation with the MedTech industry to address skills shortages in the MedTech sector in the areas of Quality and Regulatory Affairs. The Level 8 Certificate in Medical Technology Regulatory Affairs and Quality, a one year part-time online programme, is designed for those in employment and job-seekers.

The Level 8 Certificate in Medical Technologies Regulatory Affairs and Quality provides students with an introduction to the core elements of the product development lifecycle and the associated role of a Medical Technology Regulatory Affairs and/or Quality professional. The programme ensures that students acquire a good, fundamental understanding of all applicable regulations and skills to address the ever-changing environment of Medical Technologies Regulatory Affairs and Quality.

Programme Benefits:

- Provides a fundamental grounding in medical device regulatory requirements.

- Upskills medical technology professionals in the regulatory framework in their existing roles

- Specialised training for Medical Technologies employees and job-seekers with life sciences qualifications to transition into quality assurance and/or regulatory affairs functions

- Develops skills to work with appropriate autonomy and communicate effectively

Entry Requirements

- Students with a Level 7 or higher qualification in Science or Engineering are eligible for the proposed Level 8 programme.

- Students with a Level 7 or higher qualification in a non-technical subject area but who hold a minimum of 5 years relevant MedTech industrial experience in regulatory affairs or quality are eligible for the Level 8 programme.

Start Date	Duration	Delivery Format
September 2017	1 year part-time	Online, Distance-Learning
Standard Fee	**ulearning Member Fee**	**ulearning Non-Member Fee**
€4,500 per year	€1,350 per semester *	€2,025 per semester **

* *Subject to confirmation of ulearning Skillnet funding support for semester 2.*

** *Companies who do not qualify under the ulearning criteria may still enrol on the course at the Non-Member rate by contacting ulearning Skillnet.*

See ulearning Skillnet qualifying criteria at http://ulearning.ie/upcoming-training/certificate-in-medical-technology-regulatory-affairs-and-quality-online/

Course Outline

• One year part-time Level 8 Certificate in Medical Technology Regulatory Affairs and Quality (30 ECTS credits)

• The programme is also available for students to take in a modular format, enabling students to select any individual module or combination of modules, up to a maximum of 3 modules per semester

• A Level 8 Higher Diploma award of 60 ECTS (12 modules) will be offered from September 2018, combining the Year 1 Cert and a further 30 ECTS over a second year

• The educational elements are provided by IT Sligo, and NUI Galway staff. Additional lecturing is provided by industry specialists and practitioners.

Semester 1 Modules (All modules 5 ECTS)

1. Introduction to Quality Management Systems

2. Fundamentals of EU Medical Device Regulations

3. Auditing and Compliance

Semester 2 Modules (All modules 5 ECTS)

4. Fundamentals of US Medical Device Regulations

5. Risk Assessment

6. Validation and Calibration

Career Opportunities

The Certificate will equip graduates with essential knowledge and skills to work in a Regulatory Affairs or Quality environment within the highly successful and growing Irish Medical Technology industry sector, with over 30,000 people employed.

The programme is specifically designed to meet the growing requirements of medical technology companies in filling regulatory and quality assurance roles. The impetus for the development of this specialist programme emerged from industry needs and the content has been developed in conjunction with a taskforce comprised of regulatory experts from industry, industry practitioners.

The Irish Medtech Association (IMA) Skillnet invited senior MedTech industry executives to identify the current number of employees required to meet current skills demand, as well as forecasted number of employees required in MedTech organisations up to 2020. The IMA report (2017) has estimated that 4,000 additional Medical Technologies jobs will be added by 2020, with a 43% increase in staff numbers in the regulatory affairs functions and 17% in Quality roles.

FIND OUT MORE!

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