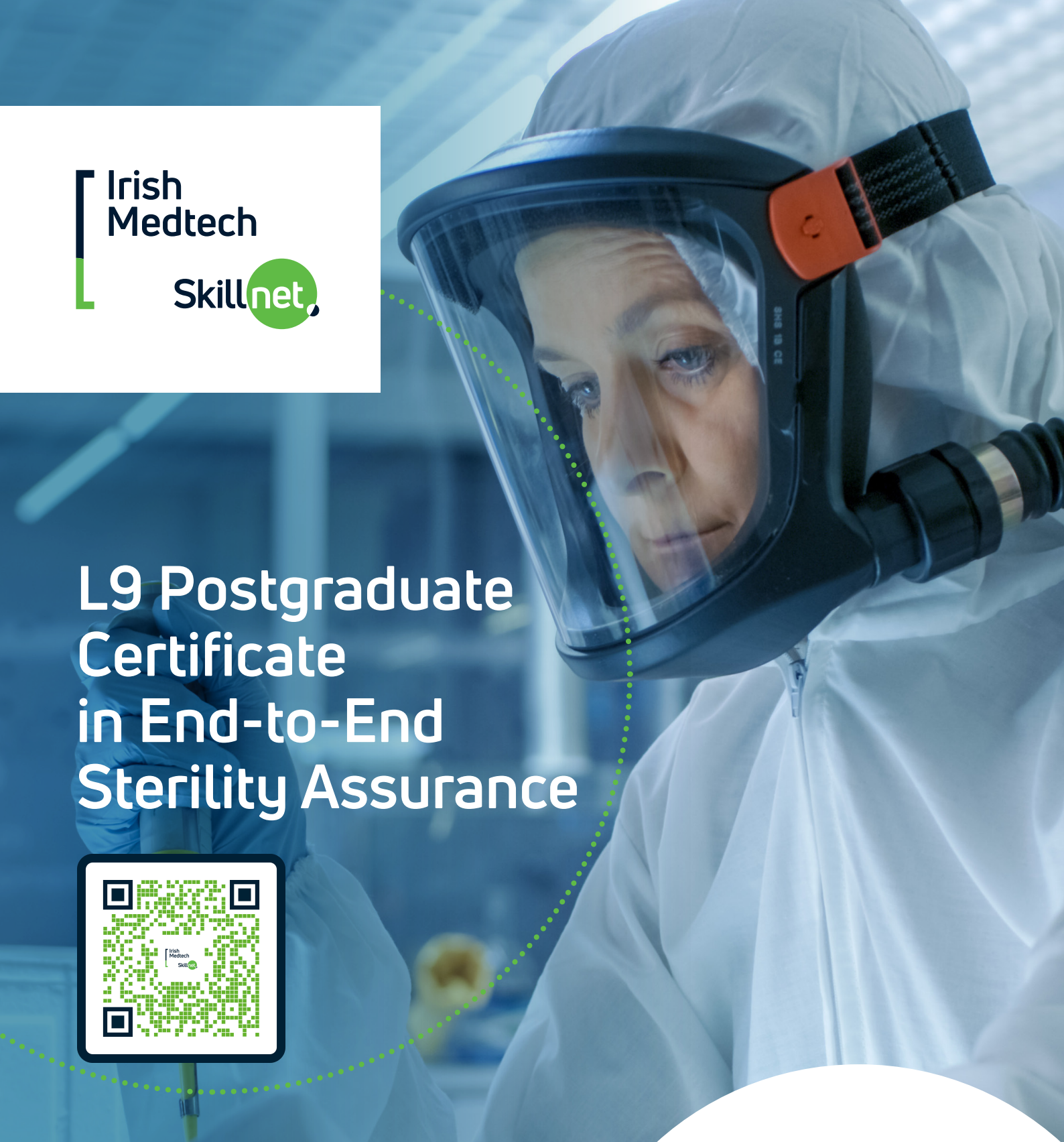
Irish Medtech Skillnet

L9 Postgraduate Certificate in End-to-End Sterility Assurance



Ollscoil Teicneolaíochta an Atlantaigh

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IRISH MEDTECH SKILLNET

POSTGRADUATE CERTIFICATE IN END-TO-END STERILITY ASSURANCE

The Irish Medtech Skillnet and contracting organisation, the Irish Medtech Association, the Ibec group that represents the Medical Technology sector and ATU Galway in collaboration with the Sterility Forum are delighted to present the new L9 Postgraduate Certificate in End-to-End Sterility Assurance. The first of its kind in Ireland and in Europe.

This programme has been designed to meet the growing demands of companies in filling sterility assurance scientist and quality assurance operational roles. The impetus for the development of this specialist programme emerged from industry needs and the content has been developed in conjunction with a Sterility focus group comprised of industry sterility experts from Irish Medtech Association's Sterility Forum.

The Postgraduate Certificate in Science in End-to-End Sterility Assurance will provide students with a detailed understanding of sterilisation methodologies applied to medical technologies in a range of contexts. The programme will cover topics such as industrial microbiology, biocompatibility and cleanroom operations. In addition to current practices, the programme will include content on global trends in new sterilization methods. Learners will also develop detailed knowledge of the regulatory requirements for sterilisation and the ability to source, interpret and apply standards for conformity. The programme will be delivered by both academics and key industry experts through a flexible blended approach, with lectures on-line and practical demonstrations to be delivered at the later stages of the programme.

Upon successful completion of the programme, participants receive a level 9 Postgraduate Certificate (30 ECTS) in Science in End-to-End Sterility Assurance

ABOUT IRISH MEDTECH SKILLNET

Irish Medtech Skillnet is a business network operating in the Medtech and Manufacturing Sector, proactively nurturing technical and non-technical skills and talent development, and driving best practice knowledge sharing to its network, in enhancing Ireland's position as an emerging global Medtech hub.

The Skillnet is promoted through the Irish Medtech Association, an Ibec business association and our skills support to business in funded through Skillnet Ireland. The Irish Medtech Skillnet ecosystem is vast and multi-layered from the Skillnet's Steering Committee, and it's directly engaged staff, to all its stakeholders, partners and existing or potential collaborators.

ABOUT IRISH MEDTECH ASSOCIATION

The Irish Medtech Association is the business association within Ibec representing the medical technology sector. The Irish Medtech Association has more than 250 members, located throughout the island of Ireland. The Irish Medtech Association is led by a Board of CEOs and Chief Representatives, it implements its strategy through working groups and taskforces.

The sterility assurance forum provides a platform for industry to input into developing and revising international standards relating to sterilisation methods and associated test methods utilised in the industry.

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Topics include:

- sharing sterility assurance best practice
- product bioburden (human handlings)
- auditing trends in sterilisation
- clean room set up and more

Phillips Medisize a molex company

Boston Scientific

Teleflex

Medtronic

MERITMEDICAL

Aerogen

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ENTRY REQUIREMENTS

Open to students who have obtained a Level 8 primary degree in a science/engineering subject, related to the life sciences. Previous or current experience in sterility (minimum two years) will be considered in assessing entry qualifications for candidates with a relevant Level 7 qualification with appropriate experience. Candidates who have completed modules in cognate programme areas may also enter the programme and gain exemptions as determined by the Programme Committee in accordance with the partner Institutions' guidelines. Cases will be assessed on an individual basis by the Programme Committee. Students applying on the basis of formal qualifications and supplementary accredited prior learning (APL) for core pre-requisites will be required to submit full details and references to the Programme Board for consideration of educational equivalencies. Prior experiential learning will be assessed using guidelines recommended by the Academic Council of ATU Galway.

DELIVERY

The programme will employ a blended learning approach involving synchronous and asynchronous online lectures. Lectures are delivered on a weekly basis to students using Microsoft Teams. Students who cannot attend the live lectures may view the recorded lectures anytime, with links to the recordings placed on the Moodle page for the respective subject. Moodle acts as the virtual learning environment (VLE) whereby students enrol on a VLE page for a respective subject and lecturers provide learning materials, notes and handouts to them via the VLE. The blended delivery format proposed for this programme includes online (synchronous and asynchronous learning), as well as workshops, group project work, case studies and variety of other teaching and learning tools. Practical components include site visits to industry facilities and are confined to the final week of each semester.

COURSE FEES AND SCHEDULE

See our website for current course fees, funding and schedule.

PROPOSED STUDENT ENGAGEMENT

Students will study 3 modules per semester. The students will typically have a 1-hour, live recorded lecture per week on each of the three modules. A schedule of the lecture times and associated assessments/site-visits dates will be communicated to students at the beginning of each semester. Material delivered for each module will be supplemented by additional reading material (Book list; Journal Resources; On-line Resources). Students will engage up to 3 hours independent learning per module per week, which includes self-directed learning activities associated with assessments and assignments. Assessment of students will be based on 100% continuous assessment with assignments throughout the course.

ASSESSMENT GRADING SYSTEMS

All assessments are assigned a percentage of the total module marks and this is indicated to the students at the commencement of each module or module part. These percentages are also indicated in the assessment matrices.

PROGRAMME TEAM

The educational elements will be provided by academic staff from the Atlantic Technological University, Galway city campus and industry experts from the Medical Technology sector. Additional lecturing and workshop contributions, as required, will be provided by experts in the field.

THE PROGRAMME WILL BE DELIVERED OVER ONE ACADEMIC YEAR:

SEMESTER 1:

- Quality Management, Regulatory Affairs and Biocompatibility (5 ECTS)
- Industrial Microbiology for Medtech (5 ECTS)
- Terminal sterilisation for Medtech Industry (Year-long) (10 ECTS)

SEMESTER 2:

- Global Sterilisation Trends for Medtech Industry (5 ECTS)
- Cleanroom Technoogy, GMP & Water Systems (5 ECTS)
- Terminal sterilisation for Medtech Industry (Year-long) (10 ECTS)

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SEMESTER 1

MODULE CONTENT:

Quality Management, Regulatory Affairs and Biocompatibility (5 ECTS)

MODULE DESCRIPTOR:

The module is designed to give learners a clear understanding of the roles of Quality Management, Regulatory Affairs and Biocompatibility, particularly as applied to the medical device and healthcare sector. It will provide learners with the skills and information to enable them to interpret and understand the regulations and their associated standards in relation to sterilisation and biocompatibility practises for medical devices in Europe and the US with reference to other markets. It will also provide learners with the information and skills to enable them to recognise the roles quality, regulatory affairs and biocompatibility plays in the production of medical device products and to participate effectively as part of QA, RA and product development teams in the medical device Industry.

LEARNING OUTCOMES:

On completion of this module the learner will/should be able to:

1. Evaluate legislation and regulations as well as the roles of the various regulatory agencies in governing the use of medical devices in the US, EU and other major markets.
2. Analyse the way in which the regulations feed into the Quality Management System with respect to sterilisation, microbiological control, biocompatibility & clean-rooms.
3. Examine the ISO13485 and 21 CFR Part 820 Quality System requirements for medical devices with specific attention to patient safety, product quality and sterility.
4. Evaluate how to achieve and maintain Quality System compliance via risk management, validation, calibration and change control methodologies.
5. Critically review the driving principles behind European and international biocompatibility quality and regulatory requirements and demonstrate imp.

MODULE CONTENT:

Industrial Microbiology for Medtech (5 ECTS)

MODULE DESCRIPTOR:

This module is designed to give learners a clear understanding of the role of microbiological Quality Assurance (QA) and Quality Control (QC), particularly as applied to the medical device sector. It will provide learners with the information and skills to enable them to recognise the role of microbiology in the production of medical device products and to participate effectively as part of QA teams in the Medtech industry.

LEARNING OUTCOMES:

On completion of this module the learner will/should be able to:

1. Describe and illustrate the relevance of microbiology in terms of sterility assurance, cleanrooms, microbiological contamination control, risk assessments and cleaning.
2. Design, construct and apply appropriate microbiological QC testing protocols for bioburden, sterility testing, pyroburden and environmental monitoring.
3. Design, develop and establish environmental monitoring programmes for cleanroom validation and routine monitoring to include active microbial airborne testing, surface and contact testing, air particulate testing, humidity, temperature, compressed air and air moisture.
4. Critically review potential microbial contamination problems which would compromise the safety of medical device products and evaluate the effects of microorganism presence on products for patients.
5. Demonstrate the ability to analyse, trend, track and interpret laboratory test results and data to help identify potential drifts or seasonal excursions and utilise such data to determine suitable action and alert levels.

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SEMESTER 1 & 2 (YEAR-LONG)

MODULE CONTENT:

Terminal sterilisation for Medtech Industry
(10 ECTS – YEAR LONG)

MODULE DESCRIPTOR:

This module is designed to give learners a clear understanding of the role sterilization plays in the medical device and healthcare sector. It will provide learners with the fundamentals on sterilization technologies and methods, sterilization standards, regulatory requirements, and product release criteria. The learner will be able to determine how to select and implement an appropriate sterilisation process and how to identify the elements of a successful sterilisation validation. Learners will participate in the design of process validations for EO, Irradiation and other modalities.

LEARNING OUTCOMES:

On completion of this module the learner will/should be able to:

1. Define the principles of EO sterilisation, irradiation sterilization and other sterilization modalities such as moist heat, and aseptic processing.
2. Describe sterilization process development, process definition, validation, requalification, change management, and routine control.
3. Illustrate an in-depth knowledge of sterilization product validation, change management/control.
4. Appraise regulatory/standard requirements pertaining to sterilization validation and routine processing.
5. Critique the advantages and limitations with each sterilisation modality.
6. Demonstrate the ability to assess and evaluate out of specification results.

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SEMESTER 2

MODULE CONTENT:

Global Sterilisation Trends for Medtech Industry (5 ECTS)

MODULE DESCRIPTOR:

This module is designed to give learners an understanding of the global trends in sterilisation, particularly as applied to the medical device sector. It will provide learners with the information and skills to enable them to recognise emerging diverse novel & less frequently used sterilisation technologies (e.g., VHP, X ray, Chlorine Dioxide, Nitrogen dioxide, Liquid chemical & Dry heat) plus innovation and sustainability concerning these technologies. The learner will thus be able to participate effectively, as part of sterility assurance teams in the medical devices and Healthcare Industries. Learners will have gained sufficient knowledge of new and novel modalities for the sterilisation of medical devices and healthcare products to enable them to take up responsible positions in sterility assurance within Industry.

LEARNING OUTCOMES:

On completion of this module the learner will/should be able to:

1. Evualate and critique new and novel technologies for the sterilisation of medical devices and healthcare products.
2. Describe and design the validation and routine control of these novel technologies, the advantages of each method and their performance qualification.
3. Substantiate and compare global sterilisation technologies, innovation and alternatives to the standard sterilization processing techniques.
4. Critically appraise the role of sustainability, environmental health and safety and environmental considerations for all sterility modalities.

MODULE CONTENT:

Cleanroom Technoogy, GMP & Water Systems (5 ECTS)

MODULE DESCRIPTOR:

This module introduces learners to the use of cleanroom technology in the medical technologies industry. Learners will explore standards and guidelines and how they pertain to cleanrooms of different classification in industry. Cleanroom technology, design materials, HEPA systems and filtration, cleanroom practices and day-to-day operation, validation, control and monitoring, maintenance, cleaning, and housekeeping of cleanrooms will be examined to ensure adherence to these regulatory and GMP guidelines.

LEARNING OUTCOMES:

On completion of this module the learner will/should be able to:

1. Demonstrate they have detailed knowledge and understanding of the US FDA administrative and legislative tructure (FD&C Act) and requirements.
2. Source and interpret regulations and guidance documents currently applicable to medical device classification within the US and demonstrate ability to classify devices appropriately.
3. Critique FDA guidance documents, consensus standards, FDA forms etc.
4. Illustrate an understanding of the steps required to achieve market clearance/approval for a US destined medical device including all aspects and types of 510(k), PMA, IDE and De Novo applications.
5. Analyze requirements for device registration, device listing and establishment registration and post market surveillance requirements once a product is placed on the market.

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Irish Medtech is a business sector within Ibec

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Rialtas na hÉireann
Government of Ireland

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