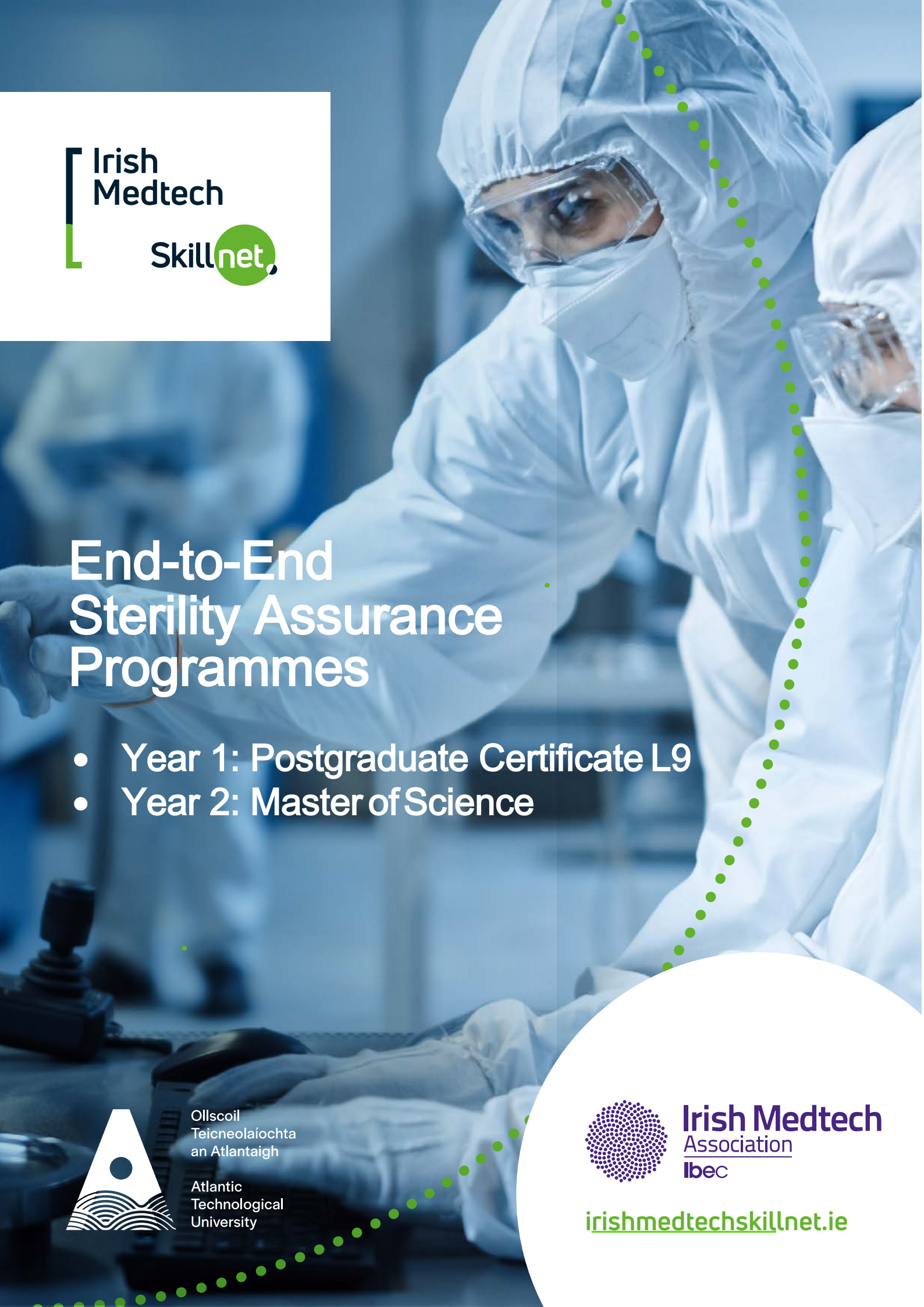

Irish Medtech Skillnet

End-to-End Sterility Assurance Programmes

- Year 1: Postgraduate Certificate L9
- Year 2: Master of Science

Ollscoil Teicneolaíochta an Atlantaigh

Atlantic Technological University

Irish Medtech Association

Ibec

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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

POSTGRADUATE CERTIFICATE IN END-TO-END STERILITY ASSURANCE

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.

Check our website for current funded pricing, upcoming commencement dates, and to book your place.

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)

POSTGRADUATE CERTIFICATE IN END-TO-END STERILITY ASSURANCE

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.

POSTGRADUATE CERTIFICATE IN END-TO-END STERILITY ASSURANCE

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.

POSTGRADUATE CERTIFICATE IN END-TO-END STERILITY ASSURANCE

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)

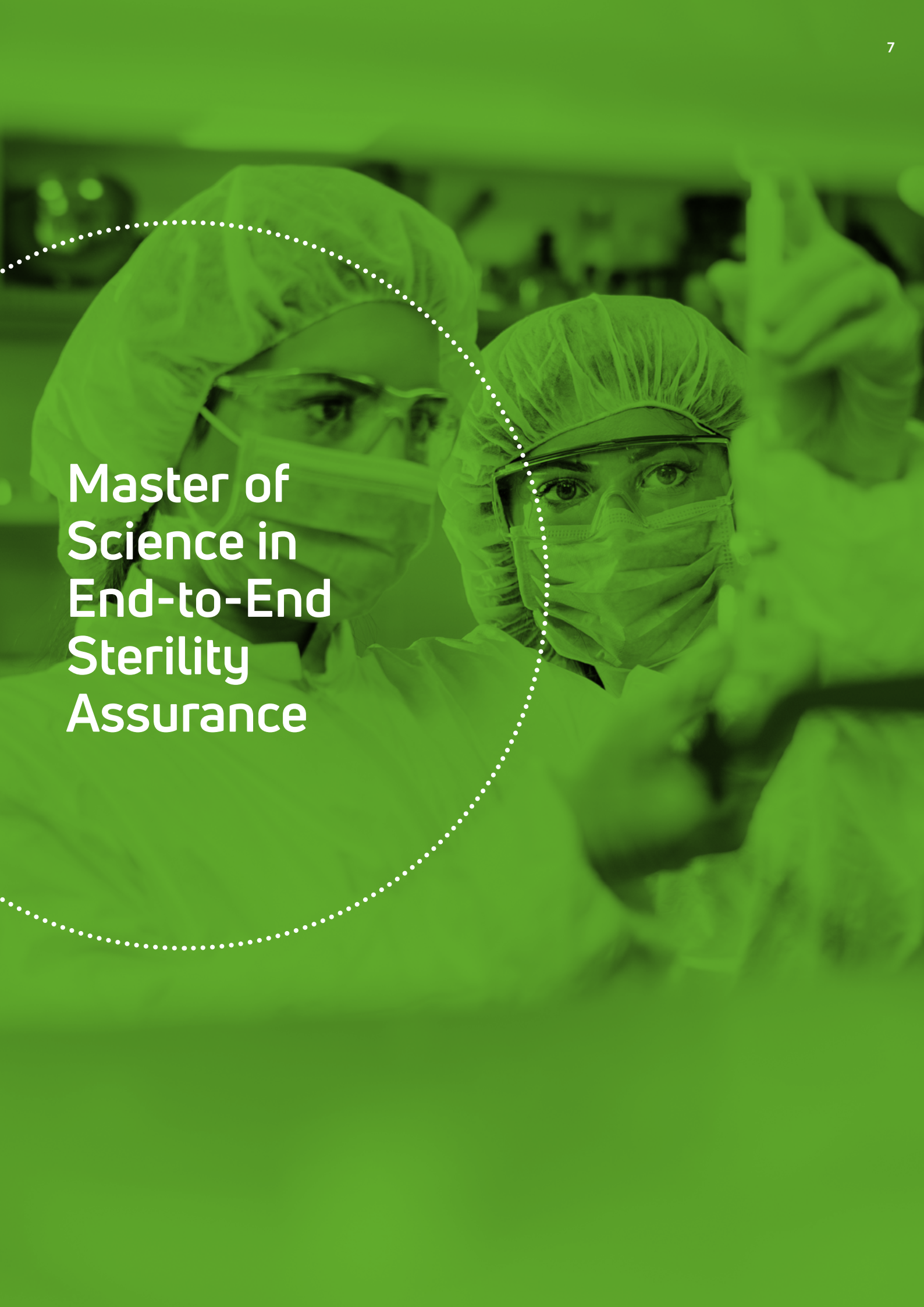
MODULE DESCRIPTOR:

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.



Master of Science in End-to-End Sterility Assurance

MASTER OF SCIENCE 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 Master of Science in End-to-End Sterility Assurance, the first of its kind in Ireland and in Europe.

The Master of Science in End-to-End Sterility Assurance programme is aimed at graduates who have either a science or bioengineering background and are aiming to develop their careers in sterility assurance. The programme aims to develop an in-depth knowledge/ understanding of Sterility assurance methodologies for medical technologies in a range of contexts. Innovation in sterility assurance for medical technologies, including new techniques and global trends in technology and sustainability. Concepts of industrial microbiology in controlled settings. Principles of biocompatibility and biological evaluations for sterility assurance. Report writing, analytical, and problem-solving skills for a lifelong career in sterility assurance. Executive leadership strategies and advanced methodologies for managing innovation to drive business growth. Learners will develop advanced skills in research and the ability to interpret and implement regulations and quality standards for conformity within the Medtech sector. This programme builds on the recently developed Postgraduate Certificate in Sterility Assurance and has the support of a large number of indigenous and multinational-based companies and will be delivered through a flexible blended approach.

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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

MASTER OF SCIENCE IN END-TO-END STERILITY ASSURANCE

ENTRY REQUIREMENTS

Open to students who have obtained a L9 Postgraduate Certificate in End-to-End Sterility Assurance.

DELIVERY

Induction will take place onsite at ATU Galway and there after 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.

PROPOSED STUDENT ENGAGEMENT

Students will study 4 modules per semester. Students will typically have 6 to 7 1-hour live recorded lectures per week. 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 4 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 in conjunction with submission of the applied research project at the end of the year.

Check our website for current funded pricing, upcoming commencement dates and to book your place.

ASSESSMENT GRADING SYSTEM

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. This is to ensure that the students can assign the appropriate level of commitment and energy to any given assessment.

PROGRAMME TEAM

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.

THIS PROGRAMME WILL BE DELIVERED OVER ONE ACADEMIC YEAR:

SEMESTER 1:

- Medical Device Product life-cycle (10 ECTS – year long)
- Design of Experiments & Analysis (5 ECTS)
- Research Methods (5 ECTS)
- Research Project (30 ECTS – year long)

SEMESTER 2:

- Leadership and Teams (5 EXTS)
- Managing Innovation (5 ECTS)
- Medical Device Product Life Cycle (10 ECTS – year long)
- Applied Research Project (30 ECTS – year long)

MASTER OF SCIENCE IN END-TO-END STERILITY ASSURANCE

SEMESTER 1

MODULE CONTENT:

Design of Experiments and Analysis (5 ECTS)

MODULE DESCRIPTOR:

This module provides the student with the design of experiments concepts, tools and techniques for optimising products and processes. The student will learn to build empirical models of a process and assess their validity. The R statistical software or equivalent will be used extensively for data analysis and interpretation.

LEARNING OUTCOMES:

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

1. Demonstrate principles of statistical design, hypothesis testing and model diagnostics
2. Plan, conduct and analyse experiments using completely randomised design (CRD) and randomised block design
3. Design, analyse and interpret the results of the factorial, fractional factorial and repeated measures design
4. Analyse and interpret data from experiments involving latin square design, split plots and response surface design
5. Review concepts of statistical power and sample size and their implications for design and analysis of experiments

MODULE CONTENT:

Research Methods (5 ECTS)

MODULE DESCRIPTOR:

Research methodology is an integral part of any Master course. The aim of this module is to ensure that students will be fully competent to devise, run and present research in a professional manner.

LEARNING OUTCOMES:

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

1. Systematically review and evaluate current literature, using appropriate tools and techniques.
2. Identify, analyse and evaluate appropriate research methods for research project proposal development.
3. Demonstrate the synthesis and integration of knowledge.
4. Draft a research proposal appropriate to their career stage and aligned with their research interests.
5. Create an appropriate data management structure.
6. Communicate research in various formats including written and oral presentation methods.

MASTER OF SCIENCE IN END-TO-END STERILITY ASSURANCE

SEMESTER 1 AND 2 (YEAR-LONG)

MODULE CONTENT:

Applied Research Project (10 ECTS)

MODULE DESCRIPTOR:

Students will undertake an approved research project under the direction of an internal supervisor and, if appropriate, a supervisor from a relevant external organisation. Design of the project should be produced by the learner with the advice of the supervisors and may also be of relevance to an organisation such as an employer.

Learners enrolled are expected to develop the knowledge, know-how and skills, and competencies required to successfully research, develop, scope the project and present and project implementation plan. Learners are expected to either individually or as part of a team develop research, problem analysis, project planning and communication skills at masters level. Projects may be drawn from any discipline within the course or from an area of expertise of the supervisors.

LEARNING OUTCOMES:

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

1. Identify and choose a research project topic and plan the delivery of that research project.
2. Select and synthesise information available in scientific literature (and in some cases other literature) in order to establish the need for,and potential scope and context of, the research project.
3. Develop creative ways of solving new research problems.
4. Collect and analyse data qualitatively and quantitatively, including an assessment of the statistical validity of the research results.
5. Manage resources allocated to completing a research project.
6. Communicate research results in written and oral forms, demonstrating critical analysis, synthesis and organisation of knowledge, and the construction of a rational and lucid scientific argument.

MODULE CONTENT:

Medical Device Product Life Cycle (10 ECTS)

MODULE DESCRIPTOR:

This module is designed to give learners an understanding of the life cycle of a medical device. It will provide learners with the information and skills to enable them to have a thorough understanding of the design and development of medical devices from initial evaluation to regulatory approval. It will also enable learners to have fundamental understanding of pre and post -marketing authorisation requirements for medical devices. The leaner 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 the lifecycle 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. Critically review the medical device life cycle from design & development, design verification and validation and post market activities as they apply to sterility assurance.
2. Compare and contrast the regulatory submission activities for the US and Europe and other key global markets and become a competent business partner to the regulatory affairs department and be capable of preparing for regulatory submissions and addressing questions.
3. Demonstrate detailed knowledge and systematic understanding of packaging validation requirements for medical devices.
4. Evaluate and show a detailed knowledge of the reprocessing requirements for medical devices.
5. Critically analyse how supplier management chain functions in a medical device manufacturing environment and be a competent business partner to the supplier management and procurement teams.

MASTER OF SCIENCE IN END-TO-END STERILITY ASSURANCE

SEMESTER 2

MODULE CONTENT:

Leadership and Teams (5 ECTS)

MODULE DESCRIPTOR:

Effective leadership is needed to understand, predict, plan and communicate the nature of organisational change and manage the response. This module explores various opportunities and challenges associated with leading and managing organisational change. Through the learning outcomes mentioned below, learners will be equipped with the knowledge, skills and attitudes necessary to effectively lead and collaborate with teams in a variety of organisational settings. It fosters collaborative engagement through the understanding of cross-functional teams within an organisation.

LEARNING OUTCOMES:

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

1. Demonstrate an understanding of leadership theories and concepts.
2. Develop essential and ethical leadership skills/ practices, while enhancing personal leadership development
3. Apply leadership strategies to diverse/challenging situations
4. Foster effective team dynamics, by identifying and leveraging the strengths of team members to achieve collective goals.
5. Apply effective strategies for team building and employee engagement.

MODULE CONTENT:

Managing Innovation (5 ECTS)

MODULE DESCRIPTOR:

Innovation is a key element in successfully growing business and competing in an ever-changing global environment. This module provides learners with an understanding of innovation at individual and firm level. An appreciation of the ever-changing macro and micro environments and stakeholder interest for contemporary organisations will be integral to the module.

Learners will appraise different approaches to innovation. A key focus will be the drive for business growth in today's rapidly changing business landscape. The development of effective organisation-wide strategies in the successful management of innovation in any industry.

LEARNING OUTCOMES:

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

1. Demonstrate Demonstrate the economics of innovation and implications of the macro environment and stakeholder interests in successfully driving business growth.
2. Appraise effective approaches to innovation.
3. Establish and implement organisation-wide strategies in the management of innovation.
4. Explore approaches for enhancing organisational creativity.
5. Assess the importance of people, culture and organisation in the effective management of innovation.


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Irish Medtech Skillnet is co-funded by Skillnet Ireland and network companies. Skillnet Ireland is funded from the National Training Fund through the Department of Further and Higher Education, Research, Innovation and Science.

Skillnet IRELAND

An Roinn Breisoideachais agus Ardoideachais, Taighde, Nuálaíochta agus Eolaíochta
Department of Further and Higher Education, Research, Innovation and Science

Co-funded by the European Union