

New Programme (Major Award) External Validation Report

Section A

Report of the External Review Panel

Programme Reference Number:	
Faculty/School(s):	Faculty of Science and Computing
Department(s):	Analytical, Biopharmaceutical and Medicinal Sciences

Details of Programme(s) Reviewed

Title:	Master of Science in End-to-End Sterility Assurance
Type of Award:	Major
NFQ (National Framework of Qualifications) Level:	9
ECTS:	90
ISCED:	
Duration:	2 Years Part-time
Proposed Student Intake:	20
Proposed Start Date:	January 2024
Delivery Mode(s):	Part-time, <i>Blended</i>

Title:	Postgraduate Diploma in End-to-End Sterility Assurance
Type of Award:	Exit
NFQ Level:	9
ECTS:	60
ISCED:	
Duration:	2 Years Part-time
Proposed Student Intake:	20
Proposed Start Date:	January 2024
Delivery Mode(s):	Part-time, <i>Blended</i>

Date of Review:	06 November 2023
------------------------	------------------

Review Panel

Panellist Role	Title	Name	Organisation	Job Title
Chair	Dr	Derek O'Byrne	SETU	Vice President for Academic Affairs and Registrar
External Academic Discipline Expert	Dr	Damien Brady	SETU	Lecturer in Microbiology
External Academic Discipline Expert	Ms	Siobhan Curtin	TUS	Lecturer in Analytical Science, Quality and Regulatory Affairs
Industry/ Community Representative	Mr	Phillip Cogdill	Medtronic	VP Global Sterility Assurance
Student Representative	Mr	Agni Paul	ATU	Student
Vice President for Academic Affairs and Registrar (VPAAR) Nominee (Academic Secretary)	Mr	Hugh McBride	ATU	Senior Lecturer, Business Studies, Mayo Campus
Recording Secretary	Ms	Claire Healy	ATU	

All external members of the panel have declared that they are independent of ATU (Atlantic Technological University), and all have declared that they have no conflict of interest.

Programme Design Team

The panel met the staff listed below during the review process.

Dr Eugene McCarthy	Mary McMahan
Dr Lisa Ryan	Eilis McNulty
Orla Colleran	Marilla Keating
Fiona Cregg	Meghann Drury-Grogan
Margaret O'Halloran (VISIE)	Caroline Walsh (QARA)
Ann O'Connell (extern)	

Introduction

The Irish MedTech Skillnet recently conducted a competition for the development, accreditation, and delivery of training programme in end-to-end sterility assurance. This was in response to the specific request of industry to address the skill shortage within the sector. The proposed Master of Science in End-to-End Sterility Assurance programme is aimed at graduates who have a cognate qualification in science or engineering who are aiming to build their knowledge in end-to-end sterility assurance and associated emerging technologies. The programme will also develop learner's leadership skills and knowledge of methodologies managing both innovation and teams to drive business growth. ATU has collaborated with members of the Medical Technologies Sterility Assurance working group to develop this programme which will equip graduates with proficiencies to address the identified skills shortages in industrial sterilisation and industrial microbiology. Learners will cover key areas such as sterilisation, quality management, regulatory affairs, and biocompatibility. Other key areas covered include leadership and teams, managing innovation, global sterilisation trends, cleanroom technology, GMP and water systems.

The proposed MSc programme builds on the recently validated Postgraduate Certificate in End-to-End Sterility Assurance. It has the support of a large number of indigenous and multinational-based companies and will be delivered through a flexible *blended* approach. The proposal incorporates offering a Postgraduate Diploma in Science in End-to-End Sterility Assurance as an exit award.

See Appendix for Entry Requirements, Programme Learning Outcomes (PLOs) and Approved Programme Schedule (APS).

Rationale for the Programme

The European medical technology industry is made up of 32,000+ companies, with 95% classified as small to medium-sized enterprises, employing directly more than 730,000 people (MedTech Europe, National Associations survey 2019). Ireland is one of the top five emerging global hubs for medical technologies in the world, contributing to over €12 billion in exports annually. Ireland has the highest number of medical technology employees per capita in Europe with over 450 companies operating in this sector nationally employing directly 40,000+ people in 2019 (MedTech Europe, National Associations Survey).

It is expected that both global and domestic drivers will continue to impact on the skills demand for the MedTech sector. These include the challenges around achieving innovation and operational excellence, maintaining global standards of product and process compliance, and delivering on the specific skills required for manufacturing and sterility assurance. The Irish MedTech Skillnet highlighted the sector's concerns around skills deficits in the areas of sterility assurance and responded by issuing a call for proposals to develop the proposed programme, which ATU responded to. End-to-End Sterility Assurance is critical component of the manufacture of medical technologies and involves a range of tests to determine the acceptability of products labelled as sterile for patient use.

The proposed MSc programme will meet this growing demand and exceed these requirements due to industry feedback relating to course content and the geographical location of ATU. The programme will equip learners employed within the sector with the required skills, and at the same time enable learners who are currently unemployed, or employed in other industry sectors, to pivot towards careers in the medical technologies sector.

External Validation Panel Overall Findings and Recommendations

Overall, the Panel is supportive of what they consider to be a very strong programme proposal.

The Panel consider: that the programme concept is valid; that the rationale for the programme is solidly grounded and well-researched; that there will be a demand for the programme and for its graduates; that the programme will meet genuine education and training needs; that the programme is highly relevant in the contemporary environment and addresses a significant gap in education provision nationally and internationally; that it will be a valuable contribution to the enhancement of industry capacity in a critical area of operation with significant current skills shortage.

The Panel recommend approval of the proposed programme subject to the conditions and recommendations outlined below.

The Panel commend the programme team for their initiative in collaborating with the medical technologies industry to develop the proposal, and for the open and constructive nature of their engagement with the Panel.

Validation Criteria

ATU's Developing and Validating New Taught Programmes Policy specifies that new programmes must comply with the following criteria for validation:

1. The programme aims and learning outcomes are clear and aligned with the proposed award title.

The Panel is satisfied that the proposed programme meets this criterion subject to addressing the condition below.

The Panel consider that the aims and Programme Learning Outcomes (PLOs) of the MSc are clearly stated and aligned with the proposed award title. The award title is valid and fit-for-purpose of informing prospective learners, employers, and other stakeholders. The PLOs accord with the requirements of the Science Award Standards at Level 9.

The aims of the PGD are also clear and aligned with the proposed award title. However, the Panel is not satisfied that the PLOs of the PGD are consistent and aligned with the MSc learning outcomes, or indicative of the staged logic of progression in intended learning from the embedded Postgraduate Certificate through to the MSc.

The Panel require that the PLOs for the PGD be reviewed and revised, and that a Table be included in the MSc programme document comparing the PLOs for each of the awards (Certificate, Diploma, Masters), indicating their consistency and alignment, and tracing the intended logic of progression in student learning outcomes.

Condition of Validation 1

That the programme team review and revise the PLOs for the proposed PGD and include a Table in the MSc programme document comparing the PLOs for the embedded Certificate, the PGD and the MSc.

The Panel note an editing error in the proposed award title in the programme documents (including on the cover page). Some other ‘typos’ were referenced by the Panel during the validation meeting. The programme document should also clarify that the PGD is an exit award (including in section 8.4).

Recommendation 1

That the programme team review and revise the programme document to ensure that the award titles are correctly stated, that the PGD is identified as an exit award, and to amend any other ‘typos’, errors or omissions.

2. *The rationale for the programme is well informed and justified.*

The Panel is satisfied that the proposed programme meets this criterion.

End-to-End Sterility Assurance is a critical component of the manufacture of medical technologies. The programme addresses a significant gap in education provision as there are few (if any) similar offerings at present in Ireland or internationally. The proposed programme was developed in close consultation and collaboration with the medical technologies industry and will meet genuine education and training needs in a critical area of operation with significant current skills shortage.

3. *The design of the programme is suitably structured and fit for purpose.*

The Panel is satisfied that the proposed programme meets this criterion subject to addressing the condition below.

The Panel is satisfied that the programme curriculum is fit-for-purpose. The curriculum design is coherent, integrated, balanced and well-structured, and it accords with employer expectations for Level 9 graduates in the area.

However, the Panel consider that there is a need to articulate with greater clarity a quality assurance framework for the Applied Research Project (30 ECTS) module, including to address the management of implementation in the context of the potentially complex challenge of meeting the needs of different student cohorts (refer criterion 4 below) and of remote supervision. This may be best achieved through the preparation of a Project Handbook as a supplement to the module descriptor. Consideration should be given to identifying partner companies offering project opportunities, and giving examples of potential projects, in the Handbook.

The Panel also consider that the Applied Research Project module descriptor should provide greater clarity in specifying the requirement that all students undertake a work-based project, and that the School commits to arranging project placements for students who require such support (including for students not employed in the sector or unemployed). The word count for the ‘scientific paper’ option should be specified and examples given of the internationally regarded journals referred to as format and standard guides. The nature of the ‘business report’ option and expectations in this regard are unclear and require elucidation. The reference to ‘failed elements’ in the assessment strategy and the approach to repeat assessment is also unclear.

Condition of Validation 2

That the programme team review and revise the Applied Research Project module descriptor and prepare a Project Handbook.

4. *The design of the programme ensures that students can successfully achieve the Programme Learning Outcomes.*

The Panel is satisfied that the proposed programme meets this criterion subject to addressing the condition below.

The programme team have identified a variety of cohorts of target learners, including: employees already working in a sterility assurance role in medical technology companies, nationally and internationally, who wish to upskill; employees of companies working in various roles and sectors, nationally and internationally, who wish to reskill to move into a sterility assurance role; qualified applicants from a range of backgrounds and experience who are currently unemployed; recent Irish and international graduates with relevant qualifications but limited work experience. These various cohorts should be clearly profiled in section 5 of the programme document.

This diversity in prospective learner background, qualifications and experience presents a challenge in ensuring that all students can successfully achieve the PLOs. The nature and complexity of the challenge for each entry cohort should be articulated, and the approaches to be taken by the programme team in addressing these challenges outlined in the programme document.

Condition of Validation 3

That the programme document identifies and profiles the various target learner cohorts, articulates the challenge faced by each in achieving the PLOs, and outlines the intended approaches to addressing these challenges.

5. *The teaching, learning and assessment strategy is well planned and appropriate for the discipline area and type of award.*

The Panel is satisfied that the proposed programme meets this criterion subject to addressing the condition below.

Lectures and tutorials will be delivered online and will be recorded. This will provide students with the flexibility to manage their studies, work, and other commitments. There is no requirement for on-site face-to-face delivery. The Panel agree that that this approach is appropriate and necessary for the target learner cohorts. However, the Panel consider this mode of delivery to be 'online' rather than 'blended' as described throughout the document. The Panel require that the document be amended accordingly.

Condition of Validation 4

That the programme document be amended to specify the delivery mode as 'online' rather than 'blended'.

The programme team intend to hold an initial induction session for students on-site, and a second on-site workshop and networking event during each semester. The Panel agree that such on-site events will enrich the student experience and commend the team for the

initiative. However, the practicalities are such that it will be difficult for many students to attend, and as such attendance will be encouraged but will not be a requirement.

6. *Assessment techniques are fair, valid, reliable, consistent and a credible measure of the academic standard attained by students.*

The Panel is satisfied that the proposed programme meets this criterion.

There is no reference in the programme document to the challenge of embedding Academic Integrity in the programme, particularly in the context of recent developments in artificial intelligence capabilities (including ChatGPT). For example, to outline the approaches intended to be taken to address academic misconduct.

Recommendation 2

That explicit reference be made in the programme document to embedding Academic Integrity in the programme.

7. *The planned resources, including staff, physical, online, library and student supports, sufficiently support the teaching, learning and assessment strategy for the programme.*

The Panel is satisfied that the proposed programme meets this criterion.

An additional staffing resource of 0.8 Assistant Lecturer will be required for programme delivery.

8. *The programme facilitates lifelong learning for a diverse student population by setting out appropriate entry requirements and opportunities for access, transfer, and progression.*

The Panel is satisfied that the proposed programme meets this criterion subject to addressing the condition below.

The programme document does not specify a provision for advanced entry, including for holders of the Postgraduate Certificate or equivalent. The Panel consider that this should be included in the document. In this context, the question of whether graduates of the Postgraduate Certificate will be entitled to progress onto the MSc should also be addressed.

Condition of Validation 5

That provision for advanced entry be specified in the programme document.

9. *There is demand for potential graduates from the programme.*

The Panel is satisfied that the proposed programme meets this criterion.

The programme was developed and designed in collaboration with industry to address identified and significant skills shortages in a critical area of industry operation. Potential graduate roles are identified in the programme document.

10. The learning environment and mode of delivery are consistent with the needs of the intended students of the programme and accessible and appropriate support services for students have been provided for.

The Panel is satisfied that the proposed programme meets this criterion.

11. Students will be well informed on the requirements of the programme, guided to relevant resources and supported in their studies in a caring environment.

The Panel is satisfied that the proposed programme meets this criterion.

Findings

Overall Finding

Validated without changes	
Validated subject to condition(s) and/or recommendation(s)	X
Rejected	

Reason for Overall Finding

The Panel consider: that the programme concept is valid; that the rationale for the programme is solidly grounded and well-researched; that there will be a demand for the programme and for its graduates; that the programme will meet genuine education and training needs; that the programme is highly relevant in the contemporary environment and addresses a significant gap in education provision nationally and internationally; that it will be a valuable contribution to the enhancement of industry capacity in a critical area of operation with significant current skills shortage.

The Panel are satisfied that the proposed programme satisfies the validation criteria, subject to the conditions and recommendations outlined below.

Panel recognition

Commendations

The Validation Panel advises Academic Council of the following commendations.

1. The Panel commend the programme team for their initiative and collaboration with industry in developing and designing the programme and awards.
2. The Panel commend the programme team for open and constructive nature of their engagement with the Panel.
3. The Panel commend the programme team for offering students the option of on-site induction, workshops, and networking opportunities, which will serve to enhance the student experience.

Conditions

The Validation Panel advises Academic Council that subject to satisfying any condition(s) detailed below, the panel is satisfied that the proposed programme(s) meets the validation criteria as set out in Atlantic Technological University's Developing and Validating New Programmes Policy.

1. That the programme team review and revise the PLOs for the proposed PGD and include a Table in the MSc programme document comparing the PLOs for the embedded Certificate, the PGD and the MSc.
2. That the programme team review and revise the Applied Research Project module descriptor and prepare a Project Handbook.

3. That the programme document identifies and profiles the various target learner cohorts, articulates the challenge faced by each in achieving the PLOs, and outlines the intended approaches to addressing these challenges.
4. That the programme document be amended to specify the delivery mode as ‘online’ rather than ‘blended’.
5. That provision for advanced entry be specified in the programme document.


Recommendations

The panel advises Academic Council that the Programme Development Team and/or the Department should take cognisance of any recommendations outlined below.

1. That the programme team review and revise the programme document to ensure that the award titles are correctly stated, that the PGD is identified as an exit award, and to amend any other ‘typos’, errors or omissions.
2. That explicit reference be made in the programme document to embedding Academic Integrity in the programme.

Report Approval

This report has been agreed by the review panel and is signed on their behalf by the chairperson.

<p>Signed: </p> <p>Name Dr. Derek O’Byrne Validation Panel Chair</p>	<p>Date 21st November 2023</p>
---	---