

# VALIDATION REPORT



1.	<b>Title of Programme(s):</b> (incl. Award Type and Specify Embedded Exit Awards)	Certificate in End-to-End Sterility Assurance
2.	<b>NFQ Level(s)/</b> <b>No. ECTS:</b>	NFQ Level 9 30 ECTS
3.	<b>Duration:</b>	1 Year
4.	<b>ISCED Code:</b>	0510 – Biological and Related Science
5.	<b>School / Centre:</b>	School of Science & Computing
6.	<b>Department:</b>	Analytical, Biopharmaceutical and Medical Science
7.	<b>Type of Review:</b>	New Programme
8.	<b>Date of Review:</b>	19/12/2022
9.	<b>Delivery Mode:</b>	Part Time, Blended
10.	<b>Panel Members:</b>	Dr David Denieffe, Vice President for Academic Affairs and Registrar, SETU Carlow Dr Damien Brady, Lecturer in Microbiology, SETU Carlow Dr Siobhan Curtin, Lecturer in Quality and Regulatory Affairs, TUS Dr Sean Hanley, Boston Scientific, Sterility Field  Dr Sean Duignan (ATU, Secretary to the panel)
11.	<b>Proposing Staff:</b>	Dr Des Foley Dr Eugene McCarthy Dr Mary McMahan
12.	<b>Programme Rationale:</b>	The Postgraduate Certificate in Science in Sterility is a 30 credit NFQ Level 9 award based on need to provide a skilled workforce to implement and support the medical device sector. This programme aims to develop learners: <ul style="list-style-type: none"> <li>• Understanding of sterility methodologies for medical technologies in a range of contexts.</li> </ul>

		<ul style="list-style-type: none"> <li>• Knowledge of innovation in sterility practises for medical technologies, including new techniques and global trends in technology and sustainability.</li> <li>• Ability to interpret and comply with regulations and standards for conformity, including the ability to handle common regulatory challenges.</li> <li>• A systematic understanding of industrial microbiology in controlled settings.</li> <li>• Understanding of the principles of biocompatibility and biological evaluations for sterility assurance.</li> <li>• Report writing, analytical, and problem-solving skills for a lifelong career in sterility.</li> </ul> <p>The programme is designed for persons currently employed in the Life Science sector wishing to up-skill in sterility assurance.</p> <p>These aims and objectives will be achieved using a blended learning approach with 5/6 contact hours on a weekly basis over 2 semesters resulting in 30 ECTS.</p>
13.	<b>Proposed Student Intake:</b>	16 – 20
14.	<b>Stakeholder Engagement:</b>	<p>The Irish MedTech Skillnet set up the Sterility Assurance Industry Working Group in order to address the skill shortage in the area of sterility assurance. One of the first actions completed by the Working Group was to conduct a consultation across the sector of the skills needs through a detailed questionnaire. There were 36 responses received from 22 companies across the MedTech sector, with multiple responses received from Abbott, Alcon, Avery Dennison Medical Ltd. Boston Scientific, Creganna Medical, Medtronic, Merit Medical, Natus Manufacturing Limited., Phenox, Stryker NV Cork, Teleflex Medical (Limerick), VistaMed, WhiteSwell and Zimmer Biomet.</p> <p>Thirty-four out of thirty-six respondents to the questionnaire agreed that sterility was important to their organisation, with 95% of the respondents to the questionnaire agreed that there is a need for a programme in end-to-end sterility assurance.</p>
15.	<b>Graduate Demand/Employment:</b>	<p>The proposed programme will equip graduates with necessary skills to ensure that future needs of the Medical Technologies sector in the West are met to further enhance the region's continued reputation as a recognised Life Sciences cluster, a strategic objective of the West Regional Enterprise Plan to 2024. Data collated from the Working Group expect graduates to fill roles in:</p> <ul style="list-style-type: none"> <li>• Sterility Assurance Specialist</li> </ul>

		<ul style="list-style-type: none"> <li>• Microbiology and Sterility Assurance Specialist</li> <li>• Sterility Assurance Scientist</li> <li>• Quality Assurance Operations Specialist</li> <li>• Quality Engineer in Sterility Assurance</li> <li>• Quality Control Microbiologist</li> </ul> <p>The competition for professionals has been extremely high for the past number of years and as the National Skills Bulletin 2025 report outlined the strong presence of research and innovation activities in Ireland means demand is expected to continue long into the future. Industry stakeholders have also indicated the proposed programme would enable people for leadership roles in Quality Assurance and Operations. The programme will offer (non-mandatory) an online careers module which will be available on the VLP for students to engage with. This module will focus on students developing their self-knowledge and realising their career potential. It aims to support students in following a process of self-discovery leading to developing a successful career plan. The material provided in this online module will offer structure and support for navigation of the current Recruitment and Selection process, which is vital in terms of the students' future career success.</p>
16.	<p><b>Entry Requirements, Access, Transfer &amp; Progression:</b></p>	<p><u>Minimum Entry Requirements</u> A H2.2 Bachelor degree at level 8 or equivalent in life science or engineering, or cognate discipline, is the minimum entry requirement for this programme.</p> <p><u>English Language Requirements</u> English Language Requirements will be as determined by ATU and as published in the Access, Transfer and Progression code.</p> <p><u>Alternative Admission Routes</u> ATU is committed to the principles of transparency, equity and fairness in recognition of prior learning (RPL) and to the principle of valuing all learning regardless of the mode or place of its acquisition. For applicants without this qualification, the RPL process of ATU will be used to determine admission to the programme. The universities Academic Code of Practice outlines the policies and procedures for the Recognition of Prior Learning and guidance for applicants is provided on myexperience.ie</p> <p>Selection of applicants will be based on level of qualification (including award classification) and relevant industry expertise of the candidate.</p>
17.	<p><b>Programme Structure:</b></p>	<p>The modules for this programme have been designed with stakeholder input, tailoring the programme to identified needs and aligned to subject-matter expert capabilities within ATU and the Sterility Assurance Working Group. The Postgraduate Certificate in End-to-End Sterility Assurance is a 30-credit, 1 year</p>

		<p>part-time programme, delivered across two academic semesters and will include the following:</p> <ul style="list-style-type: none"> <li>• Cleanroom Technology, GMP &amp; Water Systems module (5 ECTS)</li> <li>• Global Trends in Sterilisation module (5 ECTS)</li> <li>• Industrial Microbiology (5 ECTS)</li> <li>• Industrial Sterilisation (10 ECTS)</li> <li>• Quality Management, Regulatory Affairs and Biocompatibility (5 ECTS)</li> </ul> <p>For each module industry speakers will outline current practises and 1-2 site visits across the academic year (limited at the end of each semester) to ensure that students are familiar with industry practises in sterility assurance. Case studies and problem-based learning will be used as part of the teaching and learning strategy.</p> <p>To successfully complete the programme, all modules must be passed. The programme is blended with flexible, user-friendly delivery. Module lecturers (come from current academic staff within ATU and members of the Sterility Assurance Industry Working Group. The average weekly contact hours for the proposed programme is 7 hours. It is envisaged that lectures delivered online are recorded by the lecturer so that students can access the recorded version for study in their own time. This flexibility will allow students on the programme to manage their studies, work, and other commitments.</p>
18.	<p><b>Learning, Teaching &amp; Assessment Strategies:</b></p>	<p><u>Teaching &amp; Learning</u></p> <p>Learners will reach programme learning outcomes in one academic year through the combination of programme design, content, delivery, engagement with the learning material and performance at assessment. The programme learning outcomes are defined in accordance with QQI L9 Science award standards. The volume of learning (30 ECTS) is typical of part-time programmes of 1 academic year in duration. Learners are required to have a cognate Level 8 or equivalent as described on admission. Module learning outcomes also reflect the QQI L9 award standards and the teaching and assessment strategies that enable and confirm achievement of the learning outcomes are appropriate. Student centred teaching strategies will maximise problem-based learning focussed on real-world scenarios relevant to the discipline. A variety of teaching modalities fit to the content of a course will be used: Blended learning: Lectures (live online and recorded): provided by academics &amp; leading industry experts. Seminars/workshops/networking events: a session in which a specific topic fitting the scope of the course is discussed by an expert in the field. Student-centred teaching strategies will maximise the use of problem-based learning methods focussed on real-world scenarios relevant to the discipline.</p>

		<p><u>Assessment</u></p> <p>The Programme Assessment Strategy is consistent with ATU Marks and Standards and has been designed to determine whether students have achieved the module learning outcomes and, ultimately, the programme learning outcomes. Assessment methodologies and the assessment schedule are made to fit to the learning outcomes of each element of the curriculum. Assessment methodologies are published before the beginning of all modules on the programme website. The variety of assessment methods employed will ensure that students with a wide range of learning styles will be facilitated. Assessment methods will be designed to be authentic in nature and include case studies, written reports/assignments and oral presentations. Formative assessment will be ongoing in each module and the use of rubric based assessments will support student learning. Assessment methods will be designed to ensure that students are not "over-assessed" and to ensure that students are not over assessed', co-assessment of modules will be employed at the end of each semester thus reducing the number of assessments. An assessment schedule will also be drawn up by the programme board at the start of the semester to ensure a balanced workload for students over the entire semester. This assessment schedule will be distributed to the students at the start of the semester. Where appropriate, integrated assessments will be used between modules. Feedback on performance in assessments will be provided to students in a timely manner.</p> <p>Repeat Assessment: Students that have been deemed to have met the module learning outcomes will pass the module. Failure to meet the specified learning outcomes will require repeat assessment. Repeat assessment will be accommodated in accordance with ATU regulations. The repeat assessment type will be linked to the achievement of the learning outcomes and will be appropriate to demonstrating achievement of these outcomes.</p>
19.	<b>Resource Implications:</b>	None
20.	<b>Synergies with Existing Programmes:</b>	None
21.	<b>Findings and Recommendations:</b>	<p><b>Commendations:</b></p> <p>The proposing team are commended for the development of this highly innovative programme to address a significant skills shortage in the MedTech Sector.</p> <p>Additionally, the team are commended for the high quality of the documentation (content, structure and layout) provided to the review panel.</p>

		<p>The proposing team are commended for the rich discourse and engagement that took place over the duration of the validation meeting, and for the evident synergies that have developed between the industry and academic partners as a result of this collaboration.</p>
		<p><b>Conditions:</b> None</p>
		<p><b>Recommendations:</b></p> <p>The panel recommend including “sterilisation” in the introductory section of the programme document (<i>“Learners will cover key areas such as quality management etc.... -- include “sterilisation” in this sentence.)</i>)</p> <p>The panel recommend that the proposing team articulate how access may be facilitated for level 7 graduates through recognition of prior learning (RPL).</p> <p>The panel recommend that the online induction to the programme includes detail on the use of tools and platforms that will be used throughout the programme.</p> <p>The panel recommend facilitating site visits in tandem with programme and module delivery, where feasible.</p> <p>The panel recommend re-titling the module ‘Industrial Microbiology’ to ‘Industrial Microbiology for MedTech’ (or similar).</p> <p>The panel recommend that minor typographical errors throughout the document be addressed (some of which were noted and highlighted during the meeting). Likewise, the final programme document should use numbering schemes consistently (<i>e.g.</i>, decimal numbers or Roman numerals).</p> <p>In respect of module learning outcomes, the panel recommend that modules avoid using “understand” as a learning outcome and that all learning outcomes lead with an active verb, where appropriate (for example, LOs for the ‘Cleanroom Technology, GMP &amp; Water Systems’ module would</p>

		<p>benefit from this suggested revision).</p> <p>In respect of assessment, the panel recommend confirming whether it is 12- week or 13-week teaching terms, and to revise programmes assessment schedule accordingly, if necessary. Additionally, consider whether 2 x 40% MCQ is appropriate for the 'Cleanroom Technology, GMP &amp; Water Systems' at NFQ level 9.</p> <p>In respect of the book of modules, some 'required reading lists' are unreasonably long, and should be shortened.</p>	
22.	FAO: Academic Council:	Approved:	
		Approved subject to recommended changes:	Yes
		Not approved at this time:	
	Signed:		
		Chair	Secretary