

New Programme (Major Award) External Validation Report

Section A

Report of the External Review Panel

Programme Reference Number:	
Faculty/School(s):	Science
Department(s):	Dept. of Analytical, Biopharmaceutical and Medical Sciences

Details of Programme(s) Reviewed

Title:	Master of Science in Entrepreneurship and	
	Biopharmaceutical Manufacturing	
Type of Award:	Taught Masters	
NFQ (National Framework of	9	
Qualifications) Level:		
ECTS:	90	
ISCED:	0510	
Duration:	2 Years	
Proposed Student Intake:	25	
Proposed Start Date:	January 2024	
Delivery Mode(s):	Full-time Blended, Part-time Blended	

Title:	Postgraduate Diploma in Entrepreneurship and	
	Biopharmaceutical Manufacturing	
Type of Award:	Postgraduate Diploma	
NFQ Level:	9	
ECTS:	60	
ISCED:	0510	
Duration:	1 year	
Proposed Student Intake:	25	
Proposed Start Date:	January 2024	
Delivery Mode(s):	Full-time Blended, Part-time Blended	

Title:	Postgraduate Certificate in Entrepreneurship and		
	Biopharmaceutical Manufacturing		
Type of Award:	Postgraduate Certificate		
NFQ Level:	9		
ECTS:	30		

ISCED:	0510
Duration:	0.5 year
Proposed Student Intake:	25
Proposed Start Date:	January 2024
Delivery Mode(s):	Full-time Blended, Part-time Blended
Date of Review:	21 st November 2024

Review Panel

Panellist Role	Title	Name	Organisation	Job Title
Chair	Dr	Brendan Ryder	Dundalk	Head of Academic
			Institute of	Planning and Quality
			Technology	Assurance
External Academic Discipline	Prof	Brendan Duffy	Technological	Research Hub Lead
Expert			University	
			Dublin	
External Academic Discipline	Prof	Tewfik Soulimane	University of	Full Professor,
Expert			Limerick	Industrial
				Biochemistry
Industry/ Community	Ms	Caroline Walsh	Aerogen	Senior Director of
Representative				QARA
Industry/ Community	Dr	Greg Williams	Curia Global	Senior Scientist
Representative				
Student Representative	Mr	Pranavsingh	ATU	Student Rep
		Dhunnoo		
Vice President for Academic	Ms	Carmel Brennan	ATU	Assistant Registrar
Affairs and Registrar (VPAAR)				
Nominee (Academic				
Secretary)				

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	Dr Meghann Drury-Grogan
Joaquin Penide	Orla Colleran
Eilis McNulty	Mary McCormack
Yannick Casamayou	Dr Trish O'Connell
Rita Woodings	Teresa Hanley
Orla Slattery	

Introduction

EU Strategic Plan for Education, Youth, Sport, and Culture 2020-2024 aims to develop a knowledge-based Europe to support a thriving competitive economy and an inclusive society underpinned by competitive research and innovation. This objective is also reflected in Irelands 'National Smart Specialisation Strategy for Innovation 2022-27' vision to become a global leader driving a strong sustainable economy through excellent research in strategically important areas and developing a renowned pool of talent both in Ireland's research system. Europe and indeed Irelands future growth depends on innovation and future innovation depends on people. Ireland's high proportion of young people, relative to other EU countries, presents us with a unique opportunity. However, in order to deliver on this ambition highly trained researchers and innovators are required. European policy highlights the need to develop in partnership with enterprise, state-of-the-art, innovative training schemes, consistent with the highly competitive and increasingly inter-disciplinary requirements of research and innovation in order to equip researchers with the cross-cutting innovation and entrepreneurial skills demanded by the jobs of tomorrow.

The biopharmaceutical Industry is expanding globally with an estimation of global biologics sales of \$380 billion dollars by 2024 from \$240 billion dollars in 2017 with Biologics contributing to 52% of the top 100 product sales in the world by 2024. As more biopharmaceutical products received commercial approval each year, the overall requirements needed to meet commercial product demand increased from 13 metric tons in 2014 to nearly 40 metric tons in 2020 globally. The landscape in Ireland with regard to the biopharmaceutical industry is that there are 75+ companies with operations in Ireland with the 10 top global biopharmaceutical companies having a presence in Ireland. The Biopharma industry is regionally based, with main operations located in the South-West, Dublin, Mid-East, and West regions. The Western Region has a globally recognised cluster of biopharma life science indigenous and multinational companies including Allergan, Regeneron, MeriaGTx and Abbvie. The Biopharma industry is of significant economic importance with it making a capital investment of approximately \$10 billion in new facilities in Ireland since 2009. This represents close to the biggest wave of investment in new BioTech facilities anywhere in the world. In 2018, the Irish Biopharma industry exported products to the value of €73bn. €1.8bn was invested in Ireland in 2017 in manufacturing processes and R&D and the motive for this level of investments in Ireland is because of its excellence in the manufacture of drug product.

This programme Entrepreneurship and Biopharmaceutical Manufacturing is aimed at graduates who have either a science or bioengineering background and are aiming to develop their careers in biopharmaceutical manufacturing. Learners will develop in-depth knowledge of biologics manufacturing including advanced skills in research and entrepreneurship.

See Appendix for Entry Requirements, Programme Learning Outcomes and Approved Programme Schedule post the validation response.

Rationale for Programme(s)

In the most recent Future Skills Needs of the Biopharma Industry in Ireland report, an estimated >30,000 people were directly engaged in the Biopharma industry and 25,000 indirectly. At a recent IBEC seminar on the future of work in the biopharma sector it is expected that between 8,000-10,000 jobs will be created within this sector over the next five years. Further consultation with companies (Boston Scientific; Aerogen; Merit Medical; Regeneron; PPD; ONK Therapeutics; Alkermes; Janssen

Science Ireland; MSD Biotech; Alexion; BioPharmaChem Skillnet; Regional Skillnet) further substantiated the need for graduates with the ability to combine a knowledge of biopharmaceutical manufacturing with a knowledge of entrepreneurship/leadership skills are highly sought after in Life Science industries.

This programme ensures that future needs of the life science sector in the west of Ireland are met to ensure the region's continued reputation as a recognised Life Sciences cluster, a strategic objective of the West and North/West Regional Enterprise Plans. The Postgraduate Diploma in Entrepreneurship and Biopharmaceutical Manufacturing (embedded award) successfully secured funding (€320,000) from the recent Human Capital initiative call, further substantiating the need for the proposed programme. The programme board expect that the intake each year for the proposed programme will be approximately 25 students. The proposed programme is in line with ATU's strategic plan to support regional growth. Participation in initiatives such as Springboard, ICT Skills and the Human Capital Initiative delivers on several of these strategic goals identified by the School and the University as a whole. The proposed programme will diversify ATU's cohort of learners, enhances industry engagement, and delivers on regional and national policy developments in higher education.

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.
- 2. The rationale for the programme is well informed and justified.
- 3. The design of the programme is suitably structured and fit for purpose.
- 4. The design of the programme ensures that students can successfully achieve the Programme Learning Outcomes.
- 5. The teaching, learning and assessment strategy is well planned and appropriate for the discipline area and type of award.
- 6. Assessment techniques are fair, valid, reliable, consistent and a credible measure of the academic standard attained by students.
- 7. The planned resources, including staff, physical, online, library and student supports, sufficiently support the teaching, learning and assessment strategy for the programme.
- 8. The programme facilitates lifelong learning for a diverse student population by setting out appropriate entry requirements and opportunities for access, transfer, and progression.
- 9. There is demand for potential graduates from the programme.
- 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.
- 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.

Findings

Overall Finding

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

Reason for Overall Finding

The panel were satisfied that subject to meeting the conditions outlined below that the programme meets ATU's validation criteria, and are satisfied that there is a strong rationale and need for the programme. They have outlined a number of recommendations which will enhance the programmes.

Commendations

The Validation Panel advises Academic Council of the following commendations.

- 1. Staff engagement and interaction with the panel during the virtual event and their clear enthusiasm for the programmes presented.
- 2. The programme development team's engagement with industry in developing the programmes and planned industry involvement in delivery.
- 3. The knowledge of staff relevant to the programme derived from their industrial experience.
- 4. The collaboration between the School of Science and Computing and the School of Business in providing level 9 programmes in pursuance of ATU's strategic objectives.
- 5. The receipt of funding for the delivery of the programmes which will benefit students and ultimately the two industries involved through the provision of appropriately knowledgeable graduates.
- 6. The student-centred teaching, learning and assessment strategies outlined in the document and discussed with the panel.
- 7. The clear incorporation of Sustainable Development Goals in the programme.
- 8. The quality of the documentation provided to the panel.

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. The approved programme schedule should show the programme as a single stage with no barriers to progression.
- 2. Ensure that the certificate programmes are correctly labelled as Postgraduate Certificates, and as minor awards of the Masters programmes.
- 3. Ensure the ATU's award standards are referenced as appropriate throughout the document.
- 4. Ensure that the total hours for modules, including independent learning hours, accurately reflect ECTS requirements in all instances i.e., 7-8 hours per week for a 5 ECTS module. Review the project supervision hours to ensure that they are aligned with university agreed norms for both project modules.
- 5. Ensure that it is correctly reflected in the documentation that the programmes will be delivered as blended on a full-time/part-time basis, and this delivery mode also applies to any future international cohorts who will have to be based onsite. The online element of the blended delivery must be recorded accurately in each module's delivery section.

Recommendations

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

- 1. Provide further detail on the entry requirements for each of the programme, in particular language requirements and RPL options including stipulating any modules where exemptions are not feasible. Ensure that the cognate disciplines required for entry are reflected consistently throughout the document. Be explicit about specific transfer or progression opportunities available, if any. Provide further detail on level 10 opportunities in ATU within this discipline area.
- 2. Contextualise the student supports available for this student cohort i.e., NFQ Level 9 students undertaking a blended programme. Students' requirements for academic and technical writing should be clear at entry, with relevant supports provided.
- 3. Articulate how group assessments will be managed and will account for individuals' contributions in the marking scheme.
- 4. Consider recording videos showing how equipment works so that students can have familiarity in advance of lectures thereby optimising use of class time.
- 5. In the absence of an attendance policy, remove 100% attendance requirement from modules.
- 6. The panel was satisfied through discussion with the Programme Development Team that three is appropriately skilled and knowledgeable staff to deliver this programme. However, it is suggested that in future staff CVs should be provided to panels in advance to help demonstrate the capacity available to deliver the programme and supervise at level nine.
- 7. Revise diagrams in the document, particularly those in the programme delivery section, ensuring that module names and hours are correct and correspond with the Approved Programme Schedule. If it intended to block deliver modules, a sample timetable should be provided.
- 8. Review the assessment strategy for each module to enhance the level of detail provided. It should be clear what is expected from students for each assessment component. Ensure that assessment is considered in the context of generative artificial intelligence. In particular, review the repeat assessment strategy ensuring that it is explicitly articulated in each module. Clarify which exams are online proctored examinations in the module descriptors.
- 9. In the future, after HCI funding ends, the structure of the programme in terms of duration and dispersal of modules should be considered in light of the likely target cohort.
- 10. Module specific recommendations:
 - ACCT09023 2023 Principles of Finance and Accounting Review the MLOs to ensure that
 they are appropriately written for a level 9 module. Ensure texts are displaying correctly
 on the module descriptor.
 - BIOL09061 2023 Research Project 1 Ensure that the output of this module is recorded at 6,000 words. Consider whether the weighting of the oral examination/presentation is too high in proportion to the thesis. Develop a project handbook to support students' completion of the project.
 - THES09011 2023 Commercialisation Project: Remove all references to 'Research Project
 2'. Insert a mid-way progress report instead of a poster presentation given potential
 commercial sensitivities. Develop a project handbook to support students' completion of
 the project outlining any industry input.
 - MANU09004 2021 Bioprocessing Technology: Consider including guest lecturers from HPRA.

Report Approval

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

Signed:

Dr Brendan Ryder, Validation Panel Chair

Date: 4th December 2023