New Programme Validation Report

Report of the External Review Panel

Programme Reference Number:	MC056-MC059
Faculty/School(s):	Science
Department(s):	Life Sciences
Type of Review:	SPA Awards - Validation Panel

Details of Programme(s) Reviewed:

Title:	Award Type:	NFQ Level:	ECTS:	Duration:	Delivery Mode:	Proposed Student Intake:	Proposed Start Date:
Certificate in Downstream	Micro credential	6	5	1 Sem	Online	20	Jan. & Sep. 2025
Certificate in Upstream Processing	Micro credential	6	5	1 Sem	Online	20	Jan. & Sep. 2025
Certificate in Fill Finish Operations	Micro credential	6	5	1 Sem	Online	20	Jan. & Sep. 2025
Certificate in Cleanroom Behaviour in Biopharmaceutical Manufacturing	Micro credential	6	5	1 Sem	Online	20	Jan. & Sep. 2025

Date of Review:	20th Nov. 2024

Review Panel

Panellist Role	Name	Role and Organisation
Co - Chairs	David Mulligan Dr Aodhmar Cadogan	Head of Department of Mechatronics, ATU Sligo. Assistant Registrar, ATU Sligo.
Academic Discipline Expert	Dr Olivia McDermott	Associate Professor in Operational Excellence, CSSBB, CMBE, School of Biological & Chemical Sciences, University of Galway.

Industry Representative	Lesley Ann Armstrong	HR, Abbvie, Sligo.
Student Representative	Ali Usama	PhD(Computing), ATU Donegal.
Vice President for Academic Affairs and Registrar (VPAAR) Nominee (Academic Secretary)	Dr Aodhmar Cadogan Gemma Lyons	Assistant Registrar, ATU Sligo. Quality Office, ATU Sligo.

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 Neville McClenaghan	Head of department of Life Sciences, ATU Sligo.
Dr Mary Butler	Lecturer in Life Sciences, ATU Sligo
John Milne	NIBRT

Introduction

Certificate in Downstream Processing: This course in NIBRT is designed to deliver an introduction to the typical downstream operations used in a biopharmaceutical production process. This course includes both hands-on practical and lecture components covering topics such as harvest, ultrafiltration/diafiltration, viral clearance and chromatography.

This module aims to provide the student with a fundamental understanding of both the theory and practical aspects of protein purification processing as it pertains to the manufacture of modern biopharmaceutical products.

Certificate in Upstream Processing:

This module aims to provide the student with a fundamental understanding of both the theory and practical aspects of cell culture processing as it pertains to the manufacture of modern biopharmaceutical products

This course delivers online theory covering cell culture, upstream processing, and bioreactor control for biopharmaceutical manufacture. The hands-on practical days in NIBRT compliment this theory with practical sessions covering cell culture and aseptic technique, operation of disposable rocking and stirred-tank reactors, and stainless-steel reactors. These sessions will be utilised to reflect upstream operations in biopharmaceutical manufacturing processes.

Certificate in Fill Finish Operations:

This module provides students with a general knowledge and understanding of the critical aspects of aseptic/sterile technique as it relates to filling operations for the biologics Industry.

This course delivers online theory covering aseptic processing, fill finish process overview including lyophilisation, barrier systems, decontamination methods, aseptic process simulations as well as QC in fill finish. The hands-on practical days in NIBRT compliment this theory with practical sessions covering an overview of a filling line, aseptic gowning, filter integrity testing, aseptic process simulations and filling line troubleshooting scenarios.

Certificate in Cleanroom Behaviour in Biopharmaceutical Manufacturing:

This course includes both hands-on practical and lecture components covering topics such as cleanroom classification, contamination control, gowning, behaviour and best practices.

During this course trainees will be introduced to the basics of cleanroom gowning and entry, gloving, environmental monitoring and sampling in a theory session before building on this knowledge and performing these operations using a practical component and practical scenarios to troubleshoot.

Rationale for Programme(s)

A new report from the Expert Group on Future Skills Needs forecasts that 21,000 additional jobs are likely to be created in the Biopharma sector in Ireland by 2027. The report, entitled Skills for Biopharma – Researching and forecasting the current and future skills needs of the Biopharma sector in Ireland to 2027 shows the strong growth in employment in the Biopharma sector in both manufacturing and services subsectors in Ireland since 2016, and highlights the specific skills needed to support this dynamic and strategically important sector for Ireland's economy.

This report highlights that microcredentials for BioPharma training are an opportunity for skills enhancement.

NIBRT have approached ATU at our recent quarterly training meeting and again at the NIBRT Global Partners strategy meeting to partner with them to develop some of their practical NIBRT short courses as microcredentials whereby students could still avail of the practical training in core techniques in NIBRT but develop this further into a microcredential afterwards by engagement with ATU. This is one of NIBRTs key training objectives for the year ahead. Upstream processing, Downstream Processing and Formulation, Fill Finish short courses at NIBRT are some of their key training areas of most demand providing learning in the core areas for the growing BioPharma industry in Ireland and internationally with global partners.

Individuals who complete the microcredential can demonstrate accredited learning to their employer or consider stacking other related microcredentials to build a future larger award, as applicable.

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 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 intended learning Outcomes.
5. The teaching, learning and assessment strategy is well planned and appropriate for the discipline area and type of award. See recommendation 2.
6. Assessment techniques are fair, valid, reliable, consistent and a credible measure of the academic standard attained by students. See recommendation 2
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. See condition 1

The panel is satisfied that the proposed micro credentials meet all the requirements above.

Findings

Overall Finding

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

Reason for Overall Finding

Commendations

The Validation Panel advises Academic Council of the following commendations.

- The validation panel team felt that the modules presented for validation were well written with clear learning outcomes and an indicative syllabus that was understandable for students at all levels.
- The panel agreed that the module content satisfied an industry need that would be suitable to be taken as part of employee upskilling and development initiatives.
- The panel commended the rationale and could clearly see that there was an industry demand for the content.

- From a student perspective the content was found to be clearly laid out and the practical elements were particularly welcomed.

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. Students who have previously completed the practical element will be able to complete the remaining assessment elements to complete the modules. This should be limited to students who completed the practical element between Jan 2024 - Jan 2025. Update the entry requirements in all module/programmes to reflect this.

Recommendations

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

1. Review and revise each of the module descriptions. They should start with the aims, keeping in mind the potential students and their perspective.
2. Update the module Teaching and Learning strategy section in each module to set out clearly for the student the mandatory three days consecutive attendance in NIBRT and the timing of the assessment elements in week 2 etc, that are timed to follow the practical attendance.
3. Update the delivery section to change from 2 hours supervision to 1-hour online tutorial/directed learning in each module.

Report Approval

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

Signed: Validation Panel Chair David Mulligan Dr Aodhmar Cadogan	David Mulligan Date: 25 Nov. 24