New Programme Validation External Review Panel Report

Programme Reference Number:	S021
Faculty/School(s):	Faculty of Science
Department(s):	Department of Life Science
Type of Review:	SPA Validation

Details of Programme(s) Reviewed:

Title:	Award Type:	NFQ Level:	ECTS:	Duration:	Delivery Mode:	Proposed Student Intake:	Proposed Start Date:
Certificate in Advanced Therapy Medicinal Products (ATMP) Development and Manufacturing	SPA	9	5	1 Sem	Blended	40	Sept. 2025
Certificate in Data Analytics in BioPharmaceutical Manufacturing	SPA	6	5	1 Sem	Blended	40	Sept. 2025
Certificate in Advanced Data Analytics for Biopharmaceutical Manufacturing	SPA	9	5	1 Sem	Blended	40	Sept. 2025
Certificate in Good Manufacturing Practice for BioPharmaceutical Manufacturing	SPA	6	5	1 Sem	Blended	40	Sept. 2025
Certificate in Introduction to Quality Control Lab Skills for BioPharmaceuticals	SPA	6	5	1 Sem	Blended	40	Sept. 2025
Certificate in Regulatory Training for Advanced Therapy Medicinal Products (ATMPs): Understanding Manufacturing and Inspection Practices	SPA	9	5	1 Sem	Blended	40	Sept. 2025

Date of Review:	26 May 2025

Review Panel

Panellist Role	Title	Name	Organisation	Job Title
Chair	Dr	David Mulligan	ATU	Head of Department of Mechatronic Engineering
Academic Discipline Expert	Dr	Olivia McDermott	University of Galway, Ireland	Associate Professor in Regulatory Affairs and Operational Excellence, UoG.
Industry/ Community Representative	Dr	Timothy Golden	AbbVie	Director Aseptics, Abbvie Westport
Student Representative	Mr	Pranavsingh Dhunnoo	ATU	Student Representative
Vice President for Academic Affairs and Registrar (VPAAR) Nominee (Academic Secretary) and Recording Secretary	Dr	Aodhmar Cadogan	ATU	Assistant Registrar

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.

Prof Neville McClenaghan	Head of Department of Life Sciences
Mary Butler	Programme development Team Lead
Dr Melissa Hoare	NIBRT, programme development team.

Introduction

Certificate in Advanced Therapy Medicinal Products (ATMP) Development and Manufacturing
This module aims to equip the learners with a well-rounded understanding of ATMP development and manufacturing.

This blended course of 5 days of theory and NIBRT onsite practicals combines theoretical sessions blending comprehensive regulatory knowledge with hands-on technical experience, to ensure it equips the attendees with the skills and insights required to excel in ATMP production and compliance. The course emphasises regulatory frameworks, quality systems, risk management and cleanroom operations, ensuring learners gain both theoretical and practical expertise.

Certificate in Data Analytics in BioPharmaceutical Manufacturing
This module aims to provide the student with essential skills for effectively handling and interpreting bioprocessing data.

This blended course of 2 mornings online theory and 2 days NIBRT onsite practicals introduces the basic statistical and visualisation principles applied to the biopharmaceutical manufacturing industry. The hands-on practical days in

NIBRT compliment the theory with practical sessions covering bioprocess data summarisation and visualisation using software tools.

Certificate in Advanced Data Analytics for Biopharmaceutical Manufacturing
This programme is designed to equip students with the knowledge and skills necessary to process, analyse and collaborate on biomanufacturing data and derive actionable insights for GxP operation.

This blended course of 3 days of theory and NIBRT onsite practicals combines theoretical sessions with hands-on practical training. This course introduces advanced statistical principles applied to the biopharmaceutical manufacturing industry. Practical, hands-on sessions on bioprocess case studies are incorporated in this module to reflect the end-to-end workflow from development to commercial manufacturing.

Certificate in Good Manufacturing Practice for BioPharmaceutical Manufacturing
This programme aims to equip the learners with the fundamental theoretical and practical skills that are required to work in a GMP-compliant manufacturing environment.

This blended course of 4 days (including 2 days NIBRT onsite and 2 days online) includes interactive theory and practical hands-on training to equip participants with the essential knowledge and skills needed to operate in a GMP-compliant manufacturing environment.

Certificate in Introduction to Quality Control Lab Skills for BioPharmaceuticals
This programme aims to equip the learners with the fundamental theoretical and practical laboratory skills that are required to work in a biopharmaceutical quality control environment.

This blended course of 4 days of theory and NIBRT onsite practicals combines theoretical sessions with hands-on practical training to ensure attendees have a comprehensive understanding of the key lab equipment used in biopharma QC labs and gain the key skills required to work safely and accurately in a laboratory setting.

Certificate in Regulatory Training for Advanced Therapy Medicinal Products (ATMPs): Understanding Manufacturing and Inspection Practices
This programme aims to equip the learners with a comprehensive understanding of ATMP manufacturing workflows and the critical points to assess during facility inspections.

This blended course of 2 days of theory and NIBRT onsite practicals/workshops combines theoretical sessions blending comprehensive knowledge of ATMP production processes, aseptic procedures, equipment, and QC practices with hands-on practical sessions and mock inspections to prepare participants to identify regulatory compliance issue effectively and ensure product safety and quality within ATMP facilities.

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 micro-credentials for BioPharma training are an opportunity for skills enhancement. The EGFSN report also highlights there is a significant requirement for both science and engineering personnel with ATMP development and manufacturing knowledge. In addition to this, NIBRT consulted extensively with biopharmaceutical regional/national employers to determine skills/training needs requirements in this area, where all reported employee shortages emerging in certain areas such as ATMPs, automation engineers, artificial intelligence specialists, data analytics experts and automation experts.

NIBRT have approached ATU to develop some of their practical NIBRT short courses as special purpose awards whereby students could still avail of the practical training in core techniques in NIBRT but develop this further into a special purpose award afterwards by engagement with ATU.

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. (see condition 1 below)
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)	**X**
Rejected	

Reason for Overall Finding

The six proposed special purpose awards meet the requirements for validation subject to meeting the conditions and recommendations below.

Commendations

The Validation Panel advises Academic Council of the following commendations.

The choice of these topics for SPA awards are well considered, it is important to the Biopharmaceutical Industry in Ireland to build the skills and knowledge of those employed in the sector.

Conditions

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

1. Review the three L9 modules BIOL09003 Regulatory Training for ATMP etc, BIOL09002 ATMP Development and Manufacturing and BIOL09004 Advanced Data Analytics for Biopharmaceutical Manufacturing and revise the Learning Outcome verbs to ensure they are appropriate to Level 9 on the Bloom's taxonomy.
2. Complete all fields on the title page of each SPA submission, example Classified award (No), Work Placement Credits(No) etc.
3. In the Certificate in Introduction to Quality Control Lab Skills for Bio Pharmaceuticals, include Data integrity use of Data standards for Handling Out of Specification results in the indicative syllabus.
4. Review the reading lists in module BIOL06060 Good Manufacturing Practice for Biopharmaceutical Manufacturing and BIOL06059 Introduction to Quality Control Lab Skills for Biopharmaceuticals and update to a newer reference in each case from the current 2013 reference.

Recommendations

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

1. In section 5.1, of each of the six submission documents, review the information relating to the fees payable from the student perspective and ensure they are clear.
2. Include a reflection on the application of the learning in relation to their own employment context in the reflective log for the three L9 modules
3. Review the reading lists on all modules and move the references from 'Required Reading' to 'Recommended Reading' or refer to sections of the reading material as appropriate.
4. In the Teaching and Learning Strategy, reiterate that the laptops and software are provided by NIBRT/ATU in the Data Analytics modules BIOL06058 and BIOL09007.
5. As there are significant additional student numbers anticipated with these programmes, in addition to those recently recruited for the previous suite of ATU/NIBRT programmes, review the resourcing requirement for to provide a sufficient administrative support to administer the collaborative programmes.

Report Approval

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

Signed: David Mulligan Name Dr David Mulligan Validation Panel Chair.	Date: 26 May 2025

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Atlantic Technological University

SG_SNBMD_S06
Certificate in Data Analytics in BioPharmaceutical Manufacturing

Programme Overview

Type of Award	Special Purpose Award
Programme Title	Certificate in Data Analytics in BioPharmaceutical Manufacturing
Proposed Commencement Date	2025

Status	Approved by School	**Programme Code**	SG_SNBMD_S06
Framework Level	06	**Number of ECTS**	5 ECTS
Delivered By	Semester	**Minimum Duration**	1
Minimum Course Grade	40	**Classified Award**	No
Primary Award Standard	Science	**Secondary Award Standard**	
ISCED Code	0511 - Biology	**RGAM Code**	1 - Non Laboratory

Proposed Delivery Mode(s)	Blended		
Contains Work Placement	No	**Work Placement Credits**	
Contains Work-based Project	No	**Work-based Project Credits**	
PSRB Recognition Planned		**Garda Vetting Required**	
Fitness to Practice Applies		**Interim List of Eligble Programmes ILEP**	
Department	Life Sciences	**Campus**	ATU Sligo

Programme Authors
Neville McClenaghan, Mary Butler

Entry Requirements and Access Routes

Leaving Certificate or equivalent award.

Applicants with other qualifications and with relevant work experience may also be considered through ATU Sligo's Recognised Prior Learning (RPL) process. RPL is a process that may allow you to gain admission to a programme or to receive exemptions / credit from some parts of a programme based on demonstrated learning that you may have achieved through another programme of study or through your work and career. Further information is available through www.atu.ie/recognition-of-prior-learning which our dedicated RPL portal or by contacting our admissions team at admissions.sligo@atu.ie

RPL can be applied for Students who may have previously completed the practical element between Jan 2024 - Jan 2025 to allow them to take the remaining assessment elements to complete the modules. This type of RPL situation can be explained in the reflective report assignment."

Applicants can apply directly to the University through admissions.

A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the Special Purpose Award.

Programme Learning Outcomes

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

PLO	Programme Learning Outcome
PLO 1	Outline the basics of statistics, the concept of probability and the measures of central tendency.
PLO 2	Describe the Normal distribution and understand the concept of handling outliers effectively.
PLO 3	Implement data visualisation of both discrete and continuous data using graphical software

Approved Programme Schedule - SG_SNBMD_S06 Certificate in Data Analytics in BioPharmaceutical Manufacturing

Stage 1

Delivery	Code	Module Title	Level	Credit	M/E	BL	BL IL	CA	PJ	PC	FE	Total
SEM 1	BIOL06058	Data Analytics in BioPharmaceutical Manufacturing	06	05	M	2.60	4.50	30	30	40	0	100
		Credit Total		5								

Area Effective Term	Credits Required	Award Classification Percentage
202500	5	100 %

Stage / Semester Average Weekly Contact Hours	BL
Semester 1	2.60
Stage Total Average Weekly Contact Hours	2.60

Note: The duration listed for each module on the Approved Programme Schedule includes module delivery, revision and assessment

Note: Average weekly hours for programmes with more than two semesters per stage and which have year-long modules may not calculate correctly

Special Regulation
For this special purpose award, students are required to attend two days in NIBRT at their state-of-the-art facilities in Dublin. This represents week 1. A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU. Students can access this SPA any time in either semester 1 or semester 2 and the results will be brought to the next available exam board.

Key
M/E - Mandatory/Elective, BL - Blended Hours, IL - Independent Learning Hours, CA - Coursework Assessment, PJ - Project, PC - Practical, FE - Final Exam,

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Atlantic Technological University

SG_SNBMA_S09
Certificate in Advanced Therapy Medicinal Products (ATMP) Development and Manufacturing

Programme Overview

Type of Award	Special Purpose Award		
Programme Title	Certificate in Advanced Therapy Medicinal Products (ATMP) Development and Manufacturing		
Proposed Commencement Date	2025		
Status	Approved by School	**Programme Code**	SG_SNBMA_S09
Framework Level	09	**Number of ECTS**	5 ECTS
Delivered By	Semester	**Minimum Duration**	1
Minimum Course Grade	40	**Classified Award**	No
Primary Award Standard	Science	**Secondary Award Standard**	
ISCED Code	0511 - Biology	**RGAM Code**	1 - Non Laboratory
Proposed Delivery Mode(s)	Blended		
Contains Work Placement	No	**Work Placement Credits**	
Contains Work-based Project	No	**Work-based Project Credits**	
PSRB Recognition Planned		**Garda Vetting Required**	
Fitness to Practice Applies		**Interim List of Eligble Programmes ILEP**	
Department	Life Sciences	**Campus**	ATU Sligo

Programme Authors
Neville McClenaghan, Mary Butler

Entry Requirements and Access Routes

The programme is open to students who have completed a minimum of a 2.2 Honours Level 8 degree in a Science or Engineering subject related to the life sciences.

Other candidates with alternative honours degrees and experience in the BioPharma industry may apply for consideration (typically 5 years duration in a GMP environment). The entry requirements will encompass recognition of prior accredited learning in other third level institutions, in accordance with ATU procedures.

Applicants can apply directly to the University through admissions.

A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the special purpose award.

Programme Learning Outcomes

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

PLO	Programme Learning Outcome
PLO 1	Critically evaluate and apply ATMP manufacturing principles in compliance with relevant regulatory frameworks, including EU GMP Annex 1, FDA guidelines, and ATMP-specific regulations.
PLO 2	Implement GxP principles, draft and evaluate GMP compliant SOPs and conduct risk assessments effectively.
PLO 3	Critically apply contamination control strategies and advanced aseptic techniques within cleanroom environments, demonstrating mastery of industry best practices.

PLO 4	Assess and implement appropriate QC techniques, including sterility, endotoxin testing, and flow cytometry, to ensure product integrity and regulatory compliance.
PLO 5	Troubleshoot issues within manufacturing processes with confidence and develop teamwork, critical thinking, problem-solving and troubleshooting skills in real-world scenarios.

Approved Programme Schedule - SG_SNBMA_S09 Certificate in Advanced Therapy Medicinal Products (ATMP) Development and Manufacturing

Stage 1

Delivery	Code	Module Title	Level	Credit	M/E	BL	BL IL	CA	PJ	PC	FE	Total
SEM 1	BIOL09002	Advanced Therapy Medicinal Products (ATMP) Development and Manufacturing	09	05	M	3.03	4.50	30	30	40	0	100
		Credit Total		5								

Area Effective Term	Credits Required	Award Classification Percentage
202500	5	100 %

Stage / Semester Average Weekly Contact Hours	BL
Semester 1	3.03
Stage Total Average Weekly Contact Hours	3.03

Note: The duration listed for each module on the Approved Programme Schedule includes module delivery, revision and assessment

Note: Average weekly hours for programmes with more than two semesters per stage and which have year-long modules may not calculate correctly

Special Regulation
For this special purpose award, students are required to attend five days in NIBRT at their state-of-the-art facilities in Dublin. This represents week 1. A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the special purpose award. Students can access this SPA any time in either semester 1 or semester 2 and the results will be brought to the next available exam board.

Key
M/E - Mandatory/Elective, BL - Blended Hours, IL - Independent Learning Hours, CA - Coursework Assessment, PJ - Project, PC - Practical, FE - Final Exam,

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Atlantic Technological University

SG_SNBMR_S09
Certificate in Regulatory Training for Advanced Therapy Medicinal Products (ATMPs): Understanding Manufacturing and Inspection Practices

Programme Overview

Type of Award	Special Purpose Award		
Programme Title	Certificate in Regulatory Training for Advanced Therapy Medicinal Products (ATMPs): Understanding Manufacturing and Inspection Practices		
Proposed Commencement Date	2025		
Status	Approved by School	**Programme Code**	SG_SNBMR_S09
Framework Level	09	**Number of ECTS**	5 ECTS
Delivered By	Semester	**Minimum Duration**	1
Minimum Course Grade	40	**Classified Award**	No
Primary Award Standard	Science	**Secondary Award Standard**	
ISCED Code	0511 - Biology	**RGAM Code**	1 - Non Laboratory
Proposed Delivery Mode(s)	Blended		
Contains Work Placement	No	**Work Placement Credits**	
Contains Work-based Project	No	**Work-based Project Credits**	
PSRB Recognition Planned		**Garda Vetting Required**	
Fitness to Practice Applies		**Interim List of Eligble Programmes ILEP**	
Department	Life Sciences	**Campus**	ATU Sligo

Programme Authors
Neville McClenaghan, Mary Butler

Entry Requirements and Access Routes

The programme is open to students who have completed a minimum of a 2.2 Honours Level 8 degree in a Science or Engineering subject related to the life sciences.

Other candidates with alternative honours degrees and experience in the BioPharma industry may apply for consideration (typically 5 years duration in a GMP environment). The entry requirements will encompass recognition of prior accredited learning in other third level institutions, in accordance with ATU procedures.

Applicants can apply directly to the University through admissions.

A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the Special Purpose Award.

Programme Learning Outcomes

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

PLO	Programme Learning Outcome
PLO 1	Analyse and assess the core components of ATMP development, including production workflows and equipment, while applying an advanced understanding of relevant GMP standards.
PLO 2	Apply knowledge of aseptic processing, transfer techniques, and cell culture operations to evaluate compliance.

PLO 3	Demonstrate critical insight into the selection and application of analytical and microbiological techniques used in the quality assurance of ATMPs.
PLO 4	Collate a structured aide memoire tailored to inspecting ATMP manufacturing facilities. Manage mock inspections effectively, focusing on identifying compliance gaps and ensuring adherence to regulatory standards.
PLO 5	Demonstrate expertise in navigating facility audits, inspections, and deviation handling, simulating real-world manufacturing challenges.

Approved Programme Schedule - SG_SNBMR_S09 Certificate in Regulatory Training for Advanced Therapy Medicinal Products (ATMPs): Understanding Manufacturing and Inspection Practices

Stage 1

Delivery	Code	Module Title	Level	Credit	M/E	BL	BL IL	CA	PJ	PC	FE	Total
SEM 1	BIOL09003	Regulatory Training for Advanced Therapy Medicinal Products (ATMPs): Understanding Ma	09	05	M	2.60	4.50	30	30	40	0	100
		Credit Total		5								

Area Effective Term	Credits Required	Award Classification Percentage
202500	5	100 %

Stage / Semester Average Weekly Contact Hours	BL
Semester 1	2.60
Stage Total Average Weekly Contact Hours	2.60

Note: The duration listed for each module on the Approved Programme Schedule includes module delivery, revision and assessment

Note: Average weekly hours for programmes with more than two semesters per stage and which have year-long modules may not calculate correctly

Special Regulation
For this Special Purpose Award students are required to attend two days in NIBRT at their state-of-the-art facilities in Dublin. This represents week 1. A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the Special Purpose Award. Students can access this SPA any time in either semester 1 or semester 2 and the results will be brought to the next available exam board.

Key
M/E - Mandatory/Elective, BL - Blended Hours, IL - Independent Learning Hours, CA - Coursework Assessment, PJ - Project, PC - Practical, FE - Final Exam,

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Atlantic Technological University

SG_SNBMQ_S06
Certificate in Introduction to Quality Control Lab Skills for BioPharmaceuticals

Programme Overview

Type of Award	Special Purpose Award		
Programme Title	Certificate in Introduction to Quality Control Lab Skills for BioPharmaceuticals		
Proposed Commencement Date	2025		
Status	Approved by School	**Programme Code**	SG_SNBMQ_S06
Framework Level	06	**Number of ECTS**	5 ECTS
Delivered By	Semester	**Minimum Duration**	1
Minimum Course Grade	40	**Classified Award**	No
Primary Award Standard	Science	**Secondary Award Standard**	
ISCED Code	0511 - Biology	**RGAM Code**	1 - Non Laboratory
Proposed Delivery Mode(s)	Blended		
Contains Work Placement	No	**Work Placement Credits**	
Contains Work-based Project	No	**Work-based Project Credits**	
PSRB Recognition Planned		**Garda Vetting Required**	
Fitness to Practice Applies		**Interim List of Eligble Programmes ILEP**	
Department	Life Sciences	**Campus**	ATU Sligo

Programme Authors
Neville McClenaghan, Mary Butler

Entry Requirements and Access Routes

Leaving Certificate or equivalent award.

Applicants with other qualifications and with relevant work experience may also be considered through ATU Sligo's Recognised Prior Learning (RPL) process. RPL is a process that may allow you to gain admission to a programme or to receive exemptions / credit from some parts of a programme based on demonstrated learning that you may have achieved through another programme of study or through your work and career. Further information is available through www.atu.ie/recognition-of-prior-learning which our dedicated RPL portal or by contacting our admissions team at admissions.sligo@atu.ie

RPL can be applied for Students who may have previously completed the practical element between Jan 2024 - Jan 2025 to allow them to take the remaining assessment elements to complete the modules. This type of RPL situation can be explained in the reflective report assignment."

Applicants can apply directly to the University through admissions.

A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the Special Purpose Award.

Programme Learning Outcomes

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

PLO	Programme Learning Outcome
PLO 1	Describe the main stages involved in the production of a biopharmaceutical product.
PLO 2	Outline the main principles of Good Laboratory Practice
PLO 3	Participate in a range of laboratory practical sessions designed to impart basic lab skills for working in biopharma.

PLO 4	Demonstrate familiarity with crucial aspects of lab safety when working in a QC environment.

Approved Programme Schedule - SG_SNBMQ_S06 Certificate in Introduction to Quality Control Lab Skills for BioPharmaceuticals

Stage 1

Delivery	Code	Module Title	Level	Credit	M/E	BL	BL IL	CA	PJ	PC	FE	Total
SEM 1	BIOL06059	Introduction to Quality Control Lab Skills for BioPharmaceuticals	06	05	M	2.63	4.50	30	30	40	0	100
		Credit Total		5								

Area Effective Term	Credits Required	Award Classification Percentage
202500	5	100 %

Stage / Semester Average Weekly Contact Hours	BL
Semester 1	2.63
Stage Total Average Weekly Contact Hours	2.63

Note: The duration listed for each module on the Approved Programme Schedule includes module delivery, revision and assessment

Note: Average weekly hours for programmes with more than two semesters per stage and which have year-long modules may not calculate correctly

Special Regulation
For this Special Purpose Award, students are required to attend four days in NIBRT at their state-of-the-art facilities in Dublin. This represents week 1. A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the Special Purpose Award. Students can access this SPA any time in either semester 1 or semester 2 and the results will be brought to the next available exam board.

Key
M/E - Mandatory/Elective, BL - Blended Hours, IL - Independent Learning Hours, CA - Coursework Assessment, PJ - Project, PC - Practical, FE - Final Exam,

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Ollscoil Teicneolaíochta an Atlantaigh

Atlantic Technological University

SG_SNBMG_S06
Certificate in Good Manufacturing Practice for BioPharmaceutical Manufacturing

Programme Overview

Type of Award	Special Purpose Award		
Programme Title	Certificate in Good Manufacturing Practice for BioPharmaceutical Manufacturing		
Proposed Commencement Date	2025		
Status	Approved by School	**Programme Code**	SG_SNBMG_S06
Framework Level	06	**Number of ECTS**	5 ECTS
Delivered By	Semester	**Minimum Duration**	1
Minimum Course Grade	40	**Classified Award**	No
Primary Award Standard	Science	**Secondary Award Standard**	
ISCED Code	0511 - Biology	**RGAM Code**	1 - Non Laboratory
Proposed Delivery Mode(s)	Blended		
Contains Work Placement	No	**Work Placement Credits**	
Contains Work-based Project	No	**Work-based Project Credits**	
PSRB Recognition Planned		**Garda Vetting Required**	
Fitness to Practice Applies		**Interim List of Eligble Programmes ILEP**	
Department	Life Sciences	**Campus**	ATU Sligo

Programme Authors
Neville McClenaghan, Mary Butler

Entry Requirements and Access Routes

Leaving Certificate or equivalent award.

Applicants with other qualifications and with relevant work experience may also be considered through ATU Sligo's Recognised Prior Learning (RPL) process. RPL is a process that may allow you to gain admission to a programme or to receive exemptions / credit from some parts of a programme based on demonstrated learning that you may have achieved through another programme of study or through your work and career. Further information is available through www.atu.ie/recognition-of-prior-learning which our dedicated RPL portal or by contacting our admissions team at admissions.sligo@atu.ie

RPL can be applied for Students who may have previously completed the practical element between Jan 2024 - Jan 2025 to allow them to take the remaining assessment elements to complete the modules. This type of RPL situation can be explained in the reflective report assignment."

Applicants can apply directly to the University through admissions.

A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the Special Purpose Award.

Programme Learning Outcomes

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

PLO	Programme Learning Outcome
PLO 1	Demonstrate solid foundational understanding in Good Manufacturing Practice (GMP), its regulatory basis, and its essential role in ensuring that biopharmaceutical products are consistently produced to high-quality, safety, and efficacy.
PLO 2	Describe the role of global regulatory agencies, their impact on biopharmaceutical production and GMP, and the importance of quality systems within manufacturing facilities.

PLO 3	Describe effective contamination control strategies in a GMP environment, including proper gowning procedures, aseptic technique, equipment sanitisation, and environmental monitoring.
PLO 4	Participate in workshops to understand how to capture and analyse data from manufacturing processes, investigate and manage deviations, and implement corrective and preventative actions to ensure process adherence and continuous improvement.
PLO 5	Undergo a mock inspection process to understand the regulatory inspection process and gain skills for ensuring successful completion of such inspections as a manufacturing operator.

Approved Programme Schedule - SG_SNBMG_S06 Certificate in Good Manufacturing Practice for BioPharmaceutical Manufacturing

Stage 1

Delivery	Code	Module Title	Level	Credit	M/E	BL	BL IL	CA	PJ	PC	FE	Total
SEM 1	BIOL06060	Good Manufacturing Practice for BioPharmaceutical Manufacturing	06	05	M	2.63	4.50	30	30	40	0	100
		Credit Total		5								

Area Effective Term	Credits Required	Award Classification Percentage
202500	5	100 %

Stage / Semester Average Weekly Contact Hours	BL
Semester 1	2.63
Stage Total Average Weekly Contact Hours	2.63

Note: The duration listed for each module on the Approved Programme Schedule includes module delivery, revision and assessment

Note: Average weekly hours for programmes with more than two semesters per stage and which have year-long modules may not calculate correctly

Special Regulation
For this Special Purpose Award, students are required to attend two days in NIBRT at their state-of-the-art facilities in Dublin (Total of 4 days including 2 days NIBRT onsite and 2 days online). This represents week 1. A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the Special Purpose Award. Students can access this SPA any time in either semester 1 or semester 2 and the results will be brought to the next available exam board.

Key
M/E - Mandatory/Elective, BL - Blended Hours, IL - Independent Learning Hours, CA - Coursework Assessment, PJ - Project, PC - Practical, FE - Final Exam,

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Ollscoil Teicneolaíochta an Atlantaigh

Atlantic Technological University

SG_SNBMD_S09
Certificate in Advanced Data Analytics for Biopharmaceutical Manufacturing

Programme Overview

Type of Award	Special Purpose Award		
Programme Title	Certificate in Advanced Data Analytics for Biopharmaceutical Manufacturing		
Proposed Commencement Date	2025		
Status	Approved by School	**Programme Code**	SG_SNBMD_S09
Framework Level	09	**Number of ECTS**	5 ECTS
Delivered By	Semester	**Minimum Duration**	1
Minimum Course Grade	40	**Classified Award**	No
Primary Award Standard	Science	**Secondary Award Standard**	
ISCED Code	0511 - Biology	**RGAM Code**	1 - Non Laboratory
Proposed Delivery Mode(s)	Blended		
Contains Work Placement	No	**Work Placement Credits**	
Contains Work-based Project	No	**Work-based Project Credits**	
PSRB Recognition Planned		**Garda Vetting Required**	
Fitness to Practice Applies		**Interim List of Eligble Programmes ILEP**	
Department	Life Sciences	**Campus**	ATU Sligo

Programme Authors
Neville McClenaghan, Mary Butler

Entry Requirements and Access Routes

The programme is open to students who have completed a minimum of a 2.2 Honours Level 8 degree in a Science or Engineering subject related to the life sciences.

Other candidates with alternative honours degrees and experience in the BioPharma industry may apply for consideration (typically 5 years duration in a GMP environment). The entry requirements will encompass recognition of prior accredited learning in other third level institutions, in accordance with ATU procedures.

Applicants can apply directly to the University through admissions.

A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the special purpose award.

Programme Learning Outcomes

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

PLO	Programme Learning Outcome
PLO 1	Evaluate and implement linear and non-linear regression techniques to model, interpret, and optimise complex bioprocessing systems.
PLO 2	Construct and justify data-efficient experimental designs tailored to fulfil regulatory requirements.
PLO 3	Optimise manufacturing processes through the application of process capability analysis, supporting data-driven quality improvement strategies.

Approved Programme Schedule - SG_SNBMD_S09 Certificate in Advanced Data Analytics for Biopharmaceutical Manufacturing

Stage 1

Delivery	Code	Module Title	Level	Credit	M/E	BL	BL IL	CA	PJ	PC	FE	Total
SEM 1	BIOL09004	Advanced Data Analytics for Biopharmaceutical Manufacturing	09	05	M	2.63	4.50	30	30	40	0	100
		Credit Total		5								

Area Effective Term	Credits Required	Award Classification Percentage
202500	5	100 %

Stage / Semester Average Weekly Contact Hours	BL
Semester 1	2.63
Stage Total Average Weekly Contact Hours	2.63

Note: The duration listed for each module on the Approved Programme Schedule includes module delivery, revision and assessment

Note: Average weekly hours for programmes with more than two semesters per stage and which have year-long modules may not calculate correctly

Special Regulation
For this special purpose award, students are required to attend three days in NIBRT at their state-of-the-art facilities in Dublin. This represents week 1. A time limit of 12 months is applied from NIBRT mandatory attendance until completion of additional learning online via ATU for the Special Purpose Award. Students can access this SPA any time in either semester 1 or semester 2 and the results will be brought to the next available exam board.

Key
M/E - Mandatory/Elective, BL - Blended Hours, IL - Independent Learning Hours, CA - Coursework Assessment, PJ - Project, PC - Practical, FE - Final Exam,