Ollscoil Teicneolaíochta an Atlantaigh
Atlantic Technological University

PROGRAMME VALIDATION PANEL REPORT FORM

Date of Evaluation	22nd Mar. 2023

Proposed Programmes Title(s)	MSc in Validation and Digitalisation Technologies Level 9 PG Dip in Validation and Digitalisation Technologies Level 9 Postgraduate Diploma in Science in BioPharmaceutical Validation and Digitalisation Level 9 Master of Science in Commissioning, Qualification and Validation CQV for Biologics Manufacturing Level 9 Master of Science in BioIndustry 4.0 Level 9
Proposed Award Title(s):	Master of Science in Validation and Digitalisation Technologies Postgraduate Diploma in Science in Validation and Digitalisation Technologies Postgraduate Diploma in Science in BioPharmaceutical Validation and Digitalisation Master of Science in Commissioning, Qualification and Validation CQV for Biologics Manufacturing Master of Science in BioIndustry 4.0
Programme Code(s)	SG_SVALI_M09 SG_SVALI_O09 SG_SVALD_O09 SG_SCQVC_M09 SG_SBIOI_M09
NFQ Level	All Level 9
ECTS credits	PG Dip 60 ECTS Master of Science 90 ECTS

Evaluation Panel Member:

Name & title	Job title & place of work	Role on panel
Yvonne Kavanagh	Assistant Registrar, SETU	Chairperson
Dr Olivia McDermott	Assistant Professor, University of Galway	Academic Panel Member

Prof James Houghton	Emeritus Professor of Microbiology, NUIG	Academic Panel Member
Mr Bertie Daly	Manufacturing Head Cell Therapy at Takeda, Takeda	Industry Expert Panel Member*
Dr Aodhmar Cadogan	Assistant Registrar, ATU Sligo	Recording Secretary

* Conducted an off line review of the technical content of the programme, due to sudden issue prevented attendance. As the majority of the modules are currently running and approved, this was agreed as appropriate by the panel.

Declaration Regarding Any Conflicts of Interest: The members of the Panel signed a form confirming that they did not have any conflict of interest.

Meeting groups

Institute Management: Dr Jeremy Bird - Head of School, Dr Neville McClenaghan – Head of Department of Life Sciences, Mary Butler – Programme Development, Melissa Hoare - NIBRT

Programme development team: Lead, Mary Butler

Persons met by validation panel

Name & title	Role in Institute	Rationale for presence at validation.
Dr Jeremy Bird	Head of Faculty of Science	Head of Faculty
Dr Neville McClenaghan	Head of Department	Head of Department of Business
Mary Butler	Lecturer	Programme Development Lead
Melissa Hoare	NIBRT	Collaborative partner
Jean Gilligan	Head of Business Development and Operations	Online Learning Development
Dan O' Mahony	External Lecturer, NIBRT	Programme team member
Dave Clarke	External Lecturer, NIBRT	Programme team member
MacDara Bodeker	Lecturer	Programme team member
Margaret Doherty	Lecturer	Programme team member
Yvonne Lang	Lecturer	Programme team member
Ailish Breen	Lecturer	Programme team member

Note: In the context of this report, a condition indicates an action or amendment which in the view of the validation panel must be undertaken prior to the commencement of the new (or revised) programme. Conditions are mandatory for Approval of the Programme(s). A recommendation indicates an action or amendment which in the view of the panel should be given serious consideration by the programme development team for implementation.

Validation criteria	Sufficient evidence
Rationale for the programme • Philosophy underpinning the programme e.g. market for programme in the region and its relevance to the region • Graduate profile and employment opportunities for graduates • Rationale for the programme e.g. School's/Institute's strengths/opportunities • Programme Aims and Objectives • Expected intellectual development and Programme learning outcomes • Related existing programmes.	Sufficient evidence provided Demand for the programme was clearly articulated. Recent recruitment in Pharma, Biopharma, Biomedical area will cover the resourcing requirements for the Research supervision.
Commendations: 1. The panel commends the thoroughness of the documentation and the substantial effort made by the development team in writing the submission. 2. The panel commends the team responding and applying for the Funding HCI call. 3. The panel commends the relevance of the five programmes, the agility with which they have responded and the focus on the real needs of this sector of the Biopharma / Healthcare industry. 4. The panel commends the strong link the department has with NIBRT for the roll out of these programmes.	
Programme structure • Delivery type (semesterised or stage-based) • Proposed mode of delivery (i.e., in-class, on-line, blended, full time and/or part time) • Planned intake numbers (over the full duration of the programme) • Role of placement	The Research methods module was discussed in the context of the MSc in Validation and Digitalisation Technologies and the MSc in Commissioning, Qualification and Validation CQV for Biologics Manufacturing and MSc in Bioindustry 4.0. See condition 1
Resources (over the full duration of the programme) • Facilities and human and material resources available to mount the programme • Clarification of any staffing requirements	The academic supervision hours / student contact needs to be set out in the two dissertation modules, see condition 2.

• Location of the delivery • Specific s requirements: lecture rooms, laboratories, library, Information technology and other student supports • Confirmation regarding any new facilities and staffing requirements • Special requirements (e.g. remote access for distance learners)	
Access, Transfer and Progression Criteria • Student admission requirements • Progression criteria from one stage to the next and to higher levels on the NFQ • Non-standard entry (e.g. mature candidates and candidates with experiential learning) • Transfer policy into the programme and onto other programmes	Sufficient evidence provided In the Progression Pathways for the submission in relation to the PGDip in Biopharmacetuical, Validation and Digitalisation, the potential pathways to a Masters level qualification should be more clearly articulated. See recommendation 2
Curriculum • A matrix exhibiting the academic pathway and the relationship between modules • The consistency between the programme content, teaching methods and the programme learning outcomes • Balance between the depth and breadth of the programme • Rigour of the academic standard in the final stage of the programme • Student workload • Practice: the role and management of placement or work-based projects.	Sufficient evidence provided. Revision is required of the programme learning outcomes for all programmes, particularly for the two PG Dip programmes, see condition 4
Assessment • The appropriateness of the modes of assessment to be used	Sufficient evidence provided. Review the Two thesis modules and correct the grading to numerical, see condition 3 and recommendation 3 and 4.

• The balance between the marks awarded for different assessment modes (e.g. continuous assessment, projects, reports, sit-down examination) • Confirmation that all of the programme learning outcomes are appropriately and adequately assessed within the set of module assessments.	
Staffing • Quality and specialities of staff available to support the programme • Technical and administrative support • Staff development • Industrial/commercial profile of staff • Research and publications	Staffing for supervision of thesis was discussed in detail. Sufficient evidence provided for support for the programmes. The Thesis / Project will be assigned an academic supervisor in addition to an industrial mentor. See recommendation 1.
Programme Administration and Quality Assurance • Procedure for managing programme • Student support student counselling and tutorial arrangements • Aspects of programme which highlight and foster study skills, independent learning and the inculcation of individual responsibility in students • EU and international aspects if appropriate • Feedback mechanisms e.g. use of surveys, focus groups and follow-up actions.	Sufficient evidence provided. See recommendation 5.
Overall Summary.	
Conditions 1. The Research Methods Biopharma BIO09051 module must be mandatory on the MSc in CQV Commissioning, Qualification and Validation for Biologics Manufacturing, the MSc in Validation and Digitalisation Technologies and the Master of Science in BioIndustry 4.0. 2. The academic supervisor contact hours for an individual student must be listed clearly in the Biopharmaceutical Dissertation module DISS09002 and Bioprocessing Thesis module BIO09075.	

3. Thesis / dissertation module(s) DISS09002 and BIO09075, both of the module are indicated to be Pass / Fail. However, as the thesis is graded both of these need to be changed to numerical and not Pass / Fail in order to comply with the requirements for classification of a structured Masters as per the Draft Marks and Standards Ver 2.0 Effective from academic year 2023-2024.
4. Review the Programme Learning outcomes and articulate clearly the progression from PG Dip to Master level for the two programmes in the Validation and Digitalisation Technologies area. Also review the Programme Learning outcomes for the PG Dip in BioPharmaceutical Validation and Digitalisation to ensure learning outcomes are scaled to the level of a PG Dip and the verbs used are appropriate to L9 learning outcomes.

Recommendations

1. The guidelines, training and support for industry mentors, needs to be in place in order to ensure that the project is achievable, agreed with the company, is the right standard, is achievable. Articulate these clearly in the programme documents for the Master programmes and the Postgraduate diploma where required.
2. In the Progression Pathways for the submission in relation to the PGDip in Biopharmacetuical, Validation and Digitalisation, the potential pathways to a Masters level qualification should be more clearly articulated.
3. The thesis / dissertation module(s) DISS09002 and BIO09075. The articulation of the type of work expected for both these thesis modules in terms of the learning outcomes and the dept and nature of the thesis, was clearly articulated by the panel, but this needs to be clearly differentiated in the two modules.
4. Recommend that the word requirement for the 30 credit thesis module would be reviewed in comparison to the requirement in the 60 credit thesis module and reduced to a lower range for example 15 – 20 thousand or maximum 20 thousand words.
5. In the New Work Practice and Placement module SCI09010, the pathway to the, NIBRT supported placement for those who are not in employment or between employments in not outlined in the module.
6. The panel recommended the removal the failed element of 50% in the Work practice / placement module SCI09010 and the use of an appropriate rubric instead.
7. The placement element could consider connecting students to industry staff for specific learning in GMP(Good Manufacturing Practice)

Overall decision of the panel	
Postgraduate Diploma in Science in Validation and Digitalisation Technologies Master of Science in Validation and Digitalisation Technologies Postgraduate Diploma in Science in BioPharmaceutical Validation and Digitalisation Master of Science in Commissioning, Qualification and Validation(CQV) for Biologics Manufacturing Master of Science in BioIndustry 4.0	

Chairperson: ___ Yvonne Kavanagh _____ Date: ____25/04/2023_____

Dr Yvonne Kavanagh, Assistant Registrar, SETU Carlow

Aodhmar Cadog
_____ Date: ____25/04/2023_____

Secretary: Dr Aodhmar Cadogan, Assistant Registrar, ATU Sligo Date: 29/3/2023

Programme Schedules *(table from AMM)*

SG_SVALI_M09 **Master of Science in Validation and Digitalisation Technologies**

SG_SVALI_M09

Module Code	Module Title	Stage	Semester	M/E	PT Hours	OL Hours	Credits	CA %	PRAC %	PROJ %
VALD09007	Biologics Manufacturing	Stage 5	Semester 9	Mandatory	2	0	5	50	0	50
BIO09012	FACILITY DESIGN AND OPERATION	Stage 5	Semester 9	Mandatory	2	0	5	60	0	40
REGU09022	Regulation, Risk and Compliance	Stage 5	Semester 9	Mandatory	2	0	5	40	0	60
VALD09006	Commissioning, Qualification & Validation	Stage 5	Semester 10	Mandatory	2	0	10	30	40	30
BIO09006	SCALE-UP AND TECHNOLOGY TRANSFER	Stage 5	Semester 10	Mandatory	2	0	5	60	0	40
BIO09093	Introduction to BioIndustry 4.0	Stage 6	Semester 11	Mandatory	2	0	5	50	0	50
BIO09094	Biologics Manufacturing: Current and Future	Stage 6	Semester 11	Mandatory	2	0	5	50	0	50
REGU09022	Regulation, Risk and Compliance	Stage 6	Semester 11	Elective	2	0	5	40	0	60
BIO09051	Research Methods Biopharma	Stage 6	Semester 11	Elective	2	0	5	100	0	0
BIO09095	Bio-Industry 4.0 Theory and Practice	Stage 6	Semester 12	Mandatory	4	0	10	50	0	50
BIO09096	Bio-Industry Data & Digital Technologies	Stage 6	Semester 12	Mandatory	2	0	5	50	0	50
DISS09002	BIOPHARMACEUTICAL DISSERTATION	Stage 7	Year Long	Mandatory	1	0	30	100	0	0

SG_SVALI_O09 **Postgraduate Diploma in Science in Validation and Digitalisation Technologies**

Module Code	Module Title	Stage	Semester	M/E	PT Hours	OL Hours	Credits	CA %	PRAC %	PROJ %
VALD09007	Biologics Manufacturing	Stage 5	Semester 9	Mandatory	2	0	5	50	0	50
BIO09012	FACILITY DESIGN AND OPERATION	Stage 5	Semester 9	Mandatory	2	0	5	60	0	40
REGU09022	Regulation, Risk and Compliance	Stage 5	Semester 9	Mandatory	2	0	5	40	0	60
VALD09006	Commissioning, Qualification & Validation	Stage 5	Semester 10	Mandatory	2	0	10	30	40	30
BIO09006	SCALE-UP AND TECHNOLOGY TRANSFER	Stage 5	Semester 10	Mandatory	2	0	5	60	0	40
BIO09093	Introduction to BioIndustry 4.0	Stage 6	Semester 11	Mandatory	2	0	5	50	0	50
BIO09094	Biologics Manufacturing: Current and Future	Stage 6	Semester 11	Mandatory	2	0	5	50	0	50
REGU09022	Regulation, Risk and Compliance	Stage 6	Semester 11	Elective	2	0	5	40	0	60
BIO09051	Research Methods Biopharma	Stage 6	Semester 11	Elective	2	0	5	100	0	0
BIO09095	Bio-Industry 4.0 Theory and Practice	Stage 6	Semester 12	Mandatory	4	0	10	50	0	50
BIO09096	Bio-Industry Data & Digital Technologies	Stage 6	Semester 12	Mandatory	2	0	5	50	0	50

SG_SVALD_O09 **Postgraduate Diploma in Science in BioPharmaceutical Validation and Digitalisation**

Module Code	Module Title	Stage	Semester	M/E	PT Hours	OL Hours	Credits	CA %	PRAC %	PROJ %
VALD09007	Biologics Manufacturing	Stage 5	Semester 9	Mandatory	2	0	5	50	0	50
BIO09012	FACILITY DESIGN AND OPERATION	Stage 5	Semester 9	Mandatory	2	0	5	60	0	40
REGU09022	Regulation, Risk and Compliance	Stage 5	Semester 9	Mandatory	2	0	5	40	0	60
BIO09093	Introduction to BioIndustry 4.0	Stage 5	Semester 9	Mandatory	2	0	5	50	0	50
VALD09006	Commissioning, Qualification & Validation	Stage 5	Semester 10	Mandatory	2	0	10	30	40	30
BIO09006	SCALE-UP AND TECHNOLOGY TRANSFER	Stage 5	Semester 10	Mandatory	2	0	5	60	0	40
BIO09095	Bio-Industry 4.0 Theory and Practice	Stage 5	Semester 10	Mandatory	4	0	10	50	0	50
SCI09010	Work Practice and Placement	Stage 5	Year Long	Mandatory	0	0.6	10	30	0	70
SCI09011	Job Readiness	Stage 5	Semester 9	Mandatory	0	0.5	5	100	0	0

SG_SCQVC_M09 **Master of Science in Commissioning, Qualification and Validation CQV for Biologics Manufacturing**

Module Code	Module Title	Stage	Semester	M/E	PT Hours	OL Hours	Credits	CA %	PRAC %	PROJ %
VALD09007	Biologics Manufacturing	Stage 5	Semester 9	Mandatory	2	0	5	50	0	50
BIO09012	FACILITY DESIGN AND OPERATION	Stage 5	Semester 9	Mandatory	2	0	5	60	0	40
REGU09022	Regulation, Risk and Compliance	Stage 5	Semester 9	Elective	2	0	5	40	0	60
VALD09006	Commissioning, Qualification & Validation	Stage 5	Semester 10	Mandatory	2	0	10	30	40	30
BIO09006	SCALE-UP AND TECHNOLOGY TRANSFER	Stage 5	Semester 10	Mandatory	2	0	5	60	0	40
BIO09051	Research Methods Biopharma	Stage 5	Semester 9	Elective	2	0	5	100	0	0
BIO09075	BioProcesssing Thesis	Stage 6	Year Long	Mandatory	0	40	60	30	0	70

SG_SBIOI_M09 **Master of Science in BioIndustry 4.0**

Module Code	Module Title	Stage	Semester	M/E	PT Hours	OL Hours	Credits	CA %	PRAC %	PROJ %
BIO09093	Introduction to BioIndustry 4.0	Stage 5	Semester 9	Mandatory	2	0	5	50	0	50
BIO09094	Biologics Manufacturing: Current and Future	Stage 5	Semester 9	Mandatory	2	0	5	50	0	50
REGU09022	Regulation, Risk and Compliance	Stage 5	Semester 9	Elective	2	0	5	40	0	60
BIO09095	Bio-Industry 4.0 Theory and Practice	Stage 5	Semester 10	Mandatory	4	0	10	50	0	50
BIO09096	Bio-Industry Data & Digital Technologies	Stage 5	Semester 10	Mandatory	2	0	5	50	0	50
BIO09051	Research Methods Biopharma	Stage 5	Semester 9	Elective	2	0	5	100	0	0
BIO09075	BioProcesssing Thesis	Stage 6	Year Long	Mandatory	0	40	60	30	0	70