



(Policy & Procedure for Validation of all Programmes at Level 6-10 NFQ,)

NEW TAUGHT PROGRAMME EVALUATION PANEL REPORT

MINOR AND SPECIAL PURPOSE AWARDS

1. GENERAL INFORMATION

1.1	Provider:	Institute of Technology Carlow
1.2	Provider Locations:	On Institute of Technology Carlow approved sites as per differential validations if necessary.
1.3	Date of Visit:	7 th May 2020 Virtual Panel 14 th May 2020

1.4	Overview:	<p>The pharmaceutical industry is heavily regulated and trainee operatives are required to have a minimum competency level before being considered for the role on a full-time/part time basis. Designed specifically to address a growing need in the biopharmaceutical industry, this Certificate in Biopharmaceutical Operations aims to provide a scientific understanding to operatives currently working in the biopharmaceutical industry. The certificate is being developed with MSD Carlow but can also be offered to other biopharmaceutical companies.</p> <p>Carlow is the first plant from MSD that is a stand-alone human vaccine facility. It is a state-of-the-art, 200,000 sq. ft biologics operations plant in which €220 million has been invested. At this facility, formulation and filling of vaccines and biologic products occurs for use by people right across the world. Blockbuster products include Gardasil 9 and Keytruda, which are used in the prevention of HPV and in the treatment of cancer patients. MSD Ireland currently employs approximately 1800 people across its sites in Ireland, which encompasses manufacturing, R&D, commercial and marketing facilities in addition to global support services.</p> <p>An expansion project is currently under way at MSD Carlow with the addition of two new production lines at its Vaccine Biologics Sterile Facility. By 2024, this will increase the overall workforce by up to 500 employees, 200 of whom will be directly involved in the manufacturing process. MSD Carlow want to attract the best employees to suit their business, however more importantly want to develop their employees within the company to build a culture of commitment and a strong knowledge based team. At MSD Carlow the aim with every new employee is to set them up for success through our onboarding process and individual training plans.</p>
-----	------------------	--

1.5 Proposed Programmes:

1.5.1

Type of Award	Level	Proposed Programme Title Evaluated	Total Credits
Special Purpose	6	Certificate in Biopharmaceutical Operations	10
Number of Annual Intakes:		Multiple intakes subject to demand. (5 intakes per year planned)	
Duration:		The programme includes industry based induction training for a biopharmaceutical operator and a 5 day academic based work programme.	
Target Learner Groups:		Operatives employed by any Biopharmaceutical industry or those seeking to enter/re-enter the industry	
Enrolment Date:		September 2020	
Expected Number of Learners per Intake:		18 per intake	
Approved Countries for Provision:		Ireland	

1.6 Evaluation Panel Membership:

Name	Role	Affiliation
Dr Karen Hennessy	Chairperson	Head of Wexford Campus, Institute of Technology Carlow
Dr Yvonne Kavanagh	Secretary	Assistant Registrar, Institute of Technology Carlow
Dr Orla Sherlock	Academic Expert	Lecturer in the Applied Science Department, Dundalk Institute of Technology
Mr Conor O'Rourke	Industry Expert	Validation Manager, Digital & Engineering, Sanofi, Waterford

1.7 Attendance by Institute of Technology Staff:

Name	Role
Dr Frances Hardiman	Head of Engineering Faculty, Institute of Technology Carlow.
Dr Paula Rankin	Head of Department, Science & Health.
Ms Anne Meaney	Extended Campus Coordinator
Mr Brendan Abbey	Operations Coach, MSD Ireland
Ms Aine Stapleton	Operations Specialist, MSD Ireland
Dr Carloalberto Petti	Academic Specialist, Lecturer in Bioscience
Dr Guiomar Garcia Cabellos	Senior Technical Officer in Science and Health Department.

1.8 Agenda

Time	Details
10 am	Set-up of Teams and Private Meeting of Panel Members
10.20 am	Meeting with Programme Development Team
11.30 am	Private meeting of Panel Members and prepare outline of decisions
11.45 am	Provisional Feedback to the Programme Development Team
12 noon	Conclusion

2. EVALUATION AGAINST THE VALIDATION CRITERIA

Examination of the Programmes:

Examining Criteria	Yes/ No	Panel Comment	*Panel Condition(s)	**Panel Recommendation(s)	Faculty Response
2.1 Are the proposed programmes aligned to the criteria set out in the <i>Core Policies and Criteria for the Validation by QQI of Programmes of Education and Training 2016</i> (including sub criteria set out in the QQI template for <i>Independent Evaluation Report on an Application for Validation of a Programme of Education and Training</i>)?	Yes	The Panel commend the Programme Team on the comprehensive and clear documentation. The Panel wish to commend the Programme Team on being proactive in addressing this specific industry need. The Panel agreed that the proposed programmes are in-line with the <i>Core Policies and Criteria for the Validation by QQI of Programmes of Education and Training 2016</i> (including sub criteria set out in the QQI template for <i>Independent Evaluation Report on an Application for Validation of a Programme of Education and Training</i>)			Noted
2.2 Are the proposed programmes in line with the Institute's <i>Policy and Procedures for the Design, Development, Validation and Withdrawal of all Programmes at Award Levels 6-10 in the NFQ</i> ?	Yes	The Panel agreed that the proposed programmes are in-line with <i>Institute of Technology Carlow's Policy and Procedures for the Design, Development, Validation and Withdrawal of all Programmes at Award Levels 6-10 in the NFQ</i> .			Noted
2.3 Are the proposed programmes in line with the requirements of the <i>Qualifications and Quality Assurance (Education and Training) Act 2012</i> ?		The Panel is satisfied that the programmes meet the requirements of the <i>Qualifications and Quality</i>			Noted

		<i>Assurance (Education and Training) Act 2012.</i>			
2.4 Do these programmes fit within the Institute's <i>Strategic Plan</i> ?	Yes	The Panel recognise the positive impact that the collaboration between Institute of Technology Carlow and MSD will have on the community. The Panel is satisfied that these programmes are consistent and align, in particular, with Priority 1 and 3 of <i>Institute of Technology Carlow Strategic Plan 2019-2023</i> .			Noted
2.5 Has the programme team provided evidence to demonstrate interaction with relevant prospective employers in the development of these programmes?	Yes	This programme has been developed in consultation with MSD who would be an employer of these graduates.			Noted
2.6 Has the programme team provided evidence to demonstrate demand from prospective learners to study on these programmes?	Yes	It is envisaged that MSD will require upskilling of existing employees / training of new employees, totalling 200 employees that may require this certification by 2024, ensuring demand for the course. Other employees working in or returning to the pharmaceutical workforce may also benefit from this programme.			Noted: This programme will be offered to other pharmaceutical companies.
2.7 Is the programme(s) concept, implementation strategy well informed and soundly based – considering social, cultural, educational, professional and employment objectives?	Yes	The integration of work based training with the proposed academic based programme of work, provides the learner with opportunities for development socially and culturally, as well as providing academic and			Noted

		employment advancement opportunities.			
2.8 Are the proposed programme titles fit for purpose? Do they reflect the intended programme learning outcomes and award level?	Yes	The Panel agree that all programme titles are fit for purpose, reflect the intended learning outcomes and award level.			Noted
2.9 Do the programmes meet the requirements set out in the relevant <i>QQI Awards Standards</i> ?	Yes	The Panel agree that the programmes meet the requirements set out in the relevant <i>QQI Award Standards</i> .			Noted
2.10 Are programme objectives and outcomes clear, transparent and appropriate with the awards being sought and detailed in the submission document?	Yes	The Panel agree that the proposed programme objectives, programme learning outcomes and module objectives and module learning outcomes are clear, transparent and appropriate with the awards being sought and detailed in the submission documentation. Biopharmaceutical operatives will be equipped with the knowledge of "WHY" tasks in this industry are regulated, controlled and monitored.			Noted
2.11 Are the rationale and requirements for the programmes, including the graduate attributes associated with the programmes, clear, transparent and appropriate and detailed in the submission document?	Yes	The Panel agree that the rationale and requirements for the programmes, including the graduate attributes associated with the programmes are clear, transparent and appropriate and detailed in the submission documentation			Noted
2.12 Are the access, transfer and progression arrangements clear, transparent and appropriate? Are	Yes	The Panel note that the access, transfer and progression arrangements are transparent and appropriate and are detailed in the		The Panel recommend that the documentation clarify that prospective	Section 3.13 has been amended to clarify the entry criteria for

they detailed in the submission document?		submission document. The Panel have recommendations to ensure clarity.		<p>learners need to be in employment/ have RPL, to gain access to this programme.</p> <p>The Panel recommend that the documentation clearly states the progression opportunities that are available to the graduates.</p>	<p>applicants in accordance with the recommendation.</p> <p>Progression opportunities have been identified and specific programmes of studies that learners may apply for are included.</p>
2.13 Are the criteria and procedures for recognition of prior learning (RPL) clear, transparent and appropriate in the submission document?	Yes	The Panel note that the criteria and procedures for recognition of prior learning (RPL) are transparent and appropriate in the submission document. The Panel have recommendations regarding the clarity of the RPL in the documentation.		The Panel recommend that the RPL requirements in relation to the work based experience requirements are clearly articulated in the documentation.	<p>The document articulates the requirements in terms of work based learning and tasks for the portfolio (Appendix 1).</p> <p>Details of the actual RPL portfolio will be fleshed out for applicants, who will be advised on the completion of the portfolio by the RPL coordinator</p>

2.14 Is the curriculum content outlined in the submission document structured and fit for purpose?	Yes	The Panel note that the curriculum content outlined in the submission document is structured and fit for purpose.		<p>The Panel recommend that the Learning Outcomes are reviewed to ensure that they are specific, measurable and achievable in respect to this programme.</p> <p>The Panel recommend that it is clearly articulated in the documentation that material will be provided via Blackboard to scaffold independent learning, in addition to the contact hours.</p>	<p>The Learning Outcomes have been reviewed and updated as a result of the panel feedback and the documents and module descriptor now reflect this.</p> <p>The document has been updated with details of resources that will be available on Blackboard to support the learner in their independent learning</p>
2.15 Where it exists, are the practice placement / work based elements clear, transparent and appropriate for both the learner and the employer? Are they outlined in the submission document?	Yes	The Panel note that work based elements of this programme are compulsory and an essential component of the programme. They are clear, transparent and appropriate for both the learner and the employer			Noted
2.16 Are the assessment strategies robust, reliable and valid and are they clearly documented in the submission?	Yes	The Panel note that the assessment strategies are robust, reliable, valid and programme specific. The Panel have recommendations to ensure that they are documented in the submission.		<p>The Panel make the following recommendations to ensure clarity for the learner:</p> <ol style="list-style-type: none"> 1. Clearly articulate the timeframe for submission of the Portfolio. 	<ol style="list-style-type: none"> 1. Timelines will be outlined to the learner at induction and in the WBL template 2. Weighting of assessments has

				<p>2. Reconsider the assessment weighting with regard to the Learning Portfolio.</p> <p>3. Include a sample rubric for the assessment of the components.</p> <p>4. Remove the 100% attendance requirement if not required or clearly articulate the remedial options available to the learner.</p>	<p>been amended to reflect the input into the WBLP (now 40%)</p> <p>3. A marking rubric will be available in the learners induction pack.</p> <p>4. The requirement for 100% attendance has been removed</p>
2.17 Are the teaching and learning strategies sound and programme specific?	Yes	The Panel agree that the teaching and learning strategies are sound and programme specific.		The Panel recommend that the documentation clearly articulates the Teaching and Learning strategies and how they are incorporated into the programme at each stage.	The document Teaching & Learning strategy has been updated for the programme.
2.18 Are all ethical perspectives covered within all programme syllabi and is it clearly evidenced in the submission document?	Yes	The Panel are satisfied that all ethical perspectives are covered within all programme syllabi and are clearly evidenced in the submission document.			Noted
2.19 Is the teacher-learner dialogue process clear, transparent and appropriate in the submission document to ensure that learners will	Yes	The Panel are satisfied that the teacher-learner dialogue process is clear, transparent and appropriate in the submission document to ensure			Noted

be well informed, guided and cared for?		that learners will be well informed, guided and cared for.			
2.20 Where relevant, are special arrangements for joint/collaborative provision articulated in the submission document?	Yes	The Panel note that these programmes are delivered as part of the MOU with MSD.			Noted
2.21 Has the management of the programme being clearly detailed in the submission document to ensure it will be well managed and resourced and that any joint/collaborative provision has been taken into account?	Yes	The Panel are satisfied that the management of the programme is clearly detailed in the submission document to ensure it will be well managed and resourced and that the joint/collaborative provision has been taken into account.			Noted

Note:

* **Conditions:** The evaluation panel require that the Programme Development Team should take note of conditions and that a satisfactory response to address those conditions shall be received before the validation is considered by Academic Council of the Institute of Technology Carlow.

** **Recommendations:** Recommendations are suggestions made by the Programme Evaluation Panel in the spirit of improving the proposed programme. While these are not binding, the reasons for not incorporating a recommendation have to be clearly stated by the Programme Development Team in its response to the Evaluation Report.

3. DECISIONS *(For the attention of Institute of Technology Carlow Academic Council)*

3.1 Determination

Having considered the documentation presented, and based on discussions with the Programme Development Team, the New Programme Evaluation Panel recommend the validation of the following programmes for a period of the next five academic years or until the next programmatic review, whichever occurs sooner:

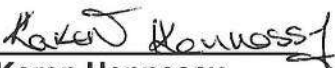
Type of Award	Level	Proposed Programme Title Evaluated	Total Credits
Special Purpose	6	Certificate in Biopharmaceutical Operations	10

3.2 Approval

This approval is conditional and is based on receipt of the following (all of which must take into account the conditions and recommendations outlined in Section 2 of this report):

1. Completed Faculty Response, Section 2 of this Report
2. Revised programme documents for each of the awards being sought
3. Revised programme schedules for each of the awards being sought
4. Programme abstract for each of the awards being sought
5. Prospectus extract for each of the awards being sought.

Programme Evaluation Report and Faculty Response Approved by:


Dr Karen Hennessey
Chairperson to Panel
(Head of Faculty of Business
Institute of Technology Carlow)


Dr Yvonne Kavanagh
Secretary to Panel
(Assistant Registrar,
Institute of Technology Carlow)

Date: 15/6/2020

Date: 15/6/2020

The Institute of Technology Carlow is committed to protecting the rights and privacy of individuals with respect to the processing of their personal data. A copy of the Institute's Privacy notice is available on the Institute's website (<https://www.itcarlow.ie/resources/data-protection.htm>). This website also contains further information relating to your rights regarding subject access requests, records retention and data protection in general. Any further queries in relation to the GDPR can be addressed to the Institute's Data Protection Oversight Group (e-mail: gdpr@itcarlow.ie)

Certificate in Biopharmaceutical Operations

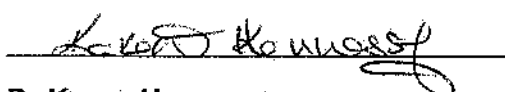
10 Credit Special Purpose Award – NFQ Level 6

Programme Abstract

This is an employee based programme that will provide learners with fundamental knowledge and skills to support their role as an operator in the biopharmaceutical industry. A combination of work based learning and a short academic programme of work, this programme will ensure that operatives are proficient in the principles of microbiology, asepsis, will understand the differences between biologics and chemically synthesised drug products and have a basic scientific knowledge of the fundamentals of sterilisation relevant to their role in the biopharmaceutical sector.

The programme will include practical laboratory sessions to provide learners with the hands-on application of theoretical concepts and the development of a work based learning portfolio.

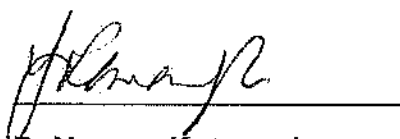
Programme Abstract Approved by:



Dr Karen Hennessy

Chairperson to Panel

*(Head of Faculty of Business
Institute of Technology Carlow)*



Dr Yvonne Kavanagh

Secretary to Panel

*(Assistant Registrar,
Institute of Technology Carlow)*

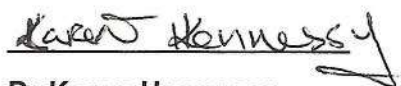
Date: 15/6/2020

Date: 15/6/2020

Programme Schedule

Module Title	Level	Credits	Class Contact Hours	Work Based Learning	Independent Learning	Continuous Assessment	Practical
Certificate in Biopharmaceutical Operations	6	10	36.25 Hours (5 days)	110 Hours (3 weeks)	100 Hours (3 weeks)	70%	30%

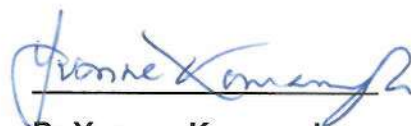
Programme Schedule Approved by:



Dr Karen Hennessy

Chairperson to Panel

*(Head of Wexford Campus
Institute of Technology Carlow)*



Dr Yvonne Kavanagh

Secretary to Panel

*(Assistant Registrar,
Institute of Technology Carlow)*

Date: 29/6/2020

Date: 29/6/2020