

VALIDATION REPORT

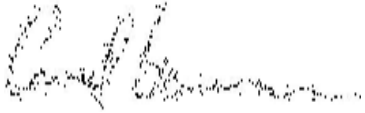
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| 1. | Title of Programme(s): (incl. Award Type and Specify Embedded Exit Awards) | MSc in Biopharmaceutical Manufacturing Certificate in Biopharmaceutical Science The Certificate will also act as exit awards for the Master's programme. |
| 2. | NFQ Level(s)/ No. ECTS: | 9 MSc: 90 ECTS Certificate: 35 ECTS |
| 3. | Duration: | MSc: 1.5 years Certificate: 1 year |
| 4. | ISCED Code: | 0510 |
| 5. | School / Centre: | School of Science and Computing |
| 6. | Department: | Department of Biopharmaceutical and Medical Science |
| 7. | Type of Review: | New Programme |
| 8. | Date of Review: | 16 th June 2021 |
| 9. | Delivery Mode: | Full-time, Blended |
| 10. | Panel Members: | <ul style="list-style-type: none"> • Dr. Derek O Byrne, Vice President for Academic Affairs and Registrar, Waterford Institute of Technology (Chair) • Professor Tewfik Soulimane, Head of School of Natural Sciences/Head of Department of Chemical Sciences, University of Limerick • Dr Damien Brady, Lecturer in Microbiology, IT Carlow • Dr Gregory Williams, Senior Research Scientist, AMRI Global • Ms Carmel Brennan, Head of Academic Quality GMIT (Secretary) |
| 11. | Proposing Staff: | <ul style="list-style-type: none"> • Dr Des Foley • Dr Eugene McCarthy • Dr Mary McMahan • Dr Karen Finn • Dr Olga Lyashevskaya • Ms Rita Woodings • Dr Trish O'Connell |

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| | | <ul style="list-style-type: none"> • Dr Teresa Hanley • Dr Orla Slattery |
| 12. | <p>Programme Rationale:</p> | <p>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.</p> <p>The Master’s degree aims to address the unique challenges posed by the manufacturing of Biologics by the provision of skills pertinent to the biopharmaceutical sector through delivery of a suite of modules, namely: Advanced Biopharmaceutical Science, Bioprocessing Technology, Immunology, Immunotherapeutics and Vaccine Technology, Biopharmaceutical Facilities, Machine Learning & Vision and Research project.</p> <p>Moreover, the Biopharma industry is highly regulated with stringent clean and safe operational requirements and stringent quality compliance and regulatory demands. To address this, students will be trained in Validation of Biopharmaceuticals; Six Sigma Management; Analysis and Design of Experiments and Quality Management Systems and Regulatory Affairs.</p> <p>Global and domestic drivers of growth are impacting on Biopharma skills demand. These include the challenge of achieving innovation and operational excellence, maintaining global standards of product and process compliance, and delivering on the specific skills required for both Pharma and Biologics manufacturing</p> <p>The proposed programme will also allow for continued reform and innovation in higher education provision. The Department of Biopharmaceutical and Medical Science has a proven track record in blending traditional learning with online resources. In this course, the blended approach will facilitate increased access to third level education for lifelong learners. This will ensure that the course, through digitalisation and harnessing innovative technologies addresses the needs of learners seeking opportunities for upskilling and reskilling through lifelong learning.</p> |

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| 13. | Proposed Student Intake Number: | 16-20 |
| 14. | Stakeholder Engagement: | Demand for this proposed programme was initially identified through the development of our Human Capital Initiative funded Postgraduate Diploma in Advanced Biopharmaceutical Science industry consultation. An extensive consultation with industry stakeholders (Skillnets, IDA, National Biopharmaceutical skills working group and industry partners) committed to developing disruptive life science technologies. The consultation process was facilitated through a detailed questionnaire and one-to-one consultations. |
| 15. | Graduate Demand: | <p>The Masters in Biopharmaceutical Science and Technology will equip graduates with a strong fundamental knowledge in high tech biopharmaceutical science. Graduates are expected to fill roles in:</p> <ul style="list-style-type: none"> - Biotechnical production specialists - Process Sciences Associates - Process engineer - Cell Line Engineers - Cell Biology & Bioanalytical Analysts - Data Science & Analytics Engineers - Technical Operations Specialist - Technical Services Specialist - Validation Specialist - Manufacturing Support Specialist - Operations Lead/Manager - QA Specialist/Manager <p>Industry stakeholders have also indicated the proposed MSc would qualify people for leadership roles in R&D. Indeed, significant efforts are being made in Ireland to develop therapeutics to eradicate Covid-19, with the emergence of new vaccines in the format of RNA based vaccines and the development of Immunotherapeutics for the treatment of the symptoms of COVID 19. These new developments have brought the biopharmaceutical sector to the forefront of this activity and has highlighted its importance globally. Highly skilled graduates will be required to drive efforts of the sector to develop novel therapeutics to eliminate or dampen the impact of the virus.</p> |
| 16. | Entry Requirements, Access, Transfer & Progression: | Candidates must hold a H2.2 Bachelor degree at level 8 in a cognate science discipline such as biochemistry, microbiology, biology, chemistry, biomedical science/engineering or equivalent. |

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| | | <p>In accordance with GMIT policy, recognition of prior learning can be used to gain access to or exemption from this programme.</p> <p>English Language Requirements will be as determined by GMIT and as published in the Access, Transfer and Progression code.</p> |
| 17. | Programme Structure: | The programme consists of 30 ECTS mandatory module and in addition the student may chose from a range of 5 ECTS electives subject to demand. Students also undertake a 55 ECTS research project. |
| 18. | Learning, Teaching & Assessment Strategies: | <p>Students will be supported in their learning in a collaborative learning environment. The programme team plan to integrate the use of circle style peer support meetings and group projects into module delivery in addition to Student-centred teaching strategies will maximise problem-based learning focussed on real-world scenarios relevant to the discipline. A variety of teaching modalities fit to the content of a course will be used:</p> <ul style="list-style-type: none"> - Lectures (live online and recorded): provided by academic & research staff. - Seminars/workshops/networking events: a session in which a specific topic fitting the scope of the course is discussed by an expert in the field. - Research based learning: learning from being both actively and passively involved in a research activity. <p>On site face-to face delivery is minimal and is restricted to one module which runs as a practical workshop at the end one semester.</p> <p>Assessment methods will include continuous assessments, written technical reports/assignments, oral presentations, MCQs, statistical analysis and a literature review.</p> |
| 19. | Resource Implications: | <p>Up to 18 additional teaching hours per week are required to deliver this programme in addition to a small number of technician and administrative hours.</p> <p>This programme will be delivered on a self-financing basis.</p> |
| 20. | Synergies with Existing Programmes: | Approximately half of the modules are offered as part of the Postgraduate Diploma in Biopharmaceutical Science. |

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| 21. | Findings and Recommendations: | <p>Commendations (if any):</p> <p>The panel commended the proposers on:</p> <ol style="list-style-type: none"> 1. The extensive work done in developing the programme and preparing comprehensive documentation explaining the rationale and proposed delivery and management of the programme. <p>The programme was approved subject to the following condition(s) (0) and recommendation(s) ().</p> <p>Special conditions attaching to approval (if any):</p> <p>None.</p> <p>Recommendations of the panel in relation to award sought:</p> <ol style="list-style-type: none"> 1. Further clarify the intended target group(s) for the programme and ensure that each aspect of the programme, and in particular the project module, is designed and delivered with the needs of that target group in mind. 2. Should applicants who are not in relevant employment be admitted to the programme ensure that the manufacturing process focus is maintained for those students who undertake their projects in GMIT. 3. Map the progression pathway for students on the Postgraduate Diploma to the Masters. 4. Review the Programme Assessment Strategy considering whether students are being over assessed and take remedial action as required. The assessment strategy, both the nature and volume of assessments should be appropriate for the targeted cohort. 5. Consider involving guest lecturers from industry as part of the teaching and learning strategy. Students will benefit from industry perspectives and gain insights into future trends. 6. Consider whether the 'Research Project' should be retitled to reflect the fact that it takes place in industry. 7. Standardise the layout of modules to ensure a consistent appearance. 8. Consider adding an elective module on health and safety in the future. 9. Consider and review the modules in light of the discussions at the panel session and the general recommendations. |
| 22. | | Approved: |

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| | FAO: Academic Council: | Approved subject to recommended changes: | X |
| | Signed: | Not approved at this time: |  |
| | | Chair | Secretary |