**VALIDATION REPORT**

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| 1. | Title of Programme(s):(incl. Award Type and Specify Embedded Exit Awards) | Postgraduate Diploma in Science in Advanced Biopharmaceutical Science |
| 2. | NFQ Level(s)/No. ECTS: | 960 ECTS |
| 3.  | Duration: | 1 Year |
| 4. | ISCED Code: | 0914 |
| 5. | School / Centre: | School of Science and Computing |
| 6. | Department: | Department of Medical and Biopharmaceutical Science |
| 7. | Type of Review: | New Programme  |
| 8. | Date of Review: | 19th October 2020 |
| 9. | Delivery Mode: | Full-time, Blended |
| 10. | Panel Members: | Dr Joe McGarry, Educational ConsultantDr Edel Healy, Head of School of Health Science, Dundalk Institute of TechnologyDr Joanne Gallagher, Head of Department of Science, Letterkenny Institute of TechnologyDr Gregory Williams, Senior Research Scientist at Albany Molecular Research Inc (AMRI), New York StateMs Carmel Brennan, Assistant Registrar (Quality) (Secretary) |
| 11. | Proposing Staff: | Dr Des FoleyDr Eugene McCarthyDr Mary McMahonDr Karen FinnDr Olga LyashevskaDr Orla SlatteryMs Rita WoodingsDr Teresa HanleyDr Teresa KenironsDr Trish O’ConnellDr Ian O’Connor |
| 12. | Programme Rationale: | In Ireland, the Biopharma industry is of significant economic importance. The Biopharma industry has made a capital investment of approximately $10 billion in new facilities in Ireland, most of which has come in the last 10 years. This represents close to the biggest wave of investment in new BioTech facilities anywhere in the world. In 2015, the Biopharma industry exported products to the value of €30.2bn, €6bn in imports and contributed €1.7bn in payroll. Ten of the top ten global pharmaceutical companies are in located Ireland. The Biopharma industry is regionally based, with main operations located in the South-West, Dublin, Mid-East, and West regions. The Western Region has a globally recognized cluster of biopharma life science indigenous and multinational companies including Allergan, Regeneron and Abbvie. In the most recent Future Skills Needs of the Biopharma Industry in Ireland report, an estimated 28,200 people were engaged in the Biopharma industry in Ireland in 2015. The report projected that total anticipated employment in the Biopharma industry would reach 33,200 in 2020. In assessing future skills demand, this report anticipated that Biologics manufacturing employment would grow from 6,700 in 2015 to 11,700 by 2020, whilst Pharmaceutical and related services employment would remain stable at 21,500. The primary difference between Biologics drugs and Pharmaceuticals drugs is the method by which the drugs are produced. The former are manufactured in living organisms, whereas the latter are manufactured through a series of chemical synthetic steps. Compared to the manufacturing of Pharmaceutical drugs, Biologics drugs present a number of unique challenges: there are complex production processes involved; fragile product - most are administered by injection rather than via the oral route; high risk of product degradation; high process variability; process losses can be high- 30% and upwards; high risk of contamination; complex analytical techniques required. The proposed Postgraduate Diploma 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: Biopharmaceutical science; Biopharmaceutical manufacturing; Applied immunology, immunotherapeutics and vaccine technology; Research project’. 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 Quality Management Systems and Regulatory Affairs; Six Sigma Management; Method Validation for Biopharmaceuticals; and Design of Experiments. |
| 13. | Potential Demand for Entry: | 16 students per intake. |
| 14. | Stakeholder Engagement: | The modules for this programme have been designed with industry input, tailoring the programme to identified companies’ needs. Review of graduate employment statistics combined with employer feedback has identified skills gaps that are addressed by the course proposal. Module content will contain emerging technologies based on the technological advice of biopharma on best industry practice such as the burgeoning area of immuno-therapeutics, cell-based therapeutics, bio-similars and gene therapy. Following consultation with the regional skills fora, an endorsement of the proposed course was obtained which outlined the need for the programme based on the research and consultation they had conducted. |
| 15. | Graduate Demand: | The Western Region has a globally recognised cluster of life science multinationals and indigenous companies. Global and local challenges will impact on the life sciences sector in both the short term and long term, including the demand for skilled workers and changing profile of skills needs. The demand for the proposed programme is evident from the focused exploration the sector’s current and future needs. The proposed Postgraduate Diploma in Advanced Biopharmaceutical Science will future proof graduates with industry relevant skills for emerging technologies. |
| 16. | Entry Requirements, Access, Transfer & Progression: | Minimum Entry RequirementsA H2.2 Bachelor degree at level 8 in any cognate discipline, such as biochemistry, biology, microbiology, biomedical, chemistry or equivalent, is the minimum entry requirement for this programme.English Language RequirementsEnglish Language Requirements will be as determined by GMIT and as published in the Access, Transfer and Progression code. Alternative Admission RoutesGMIT is committed to the principles of transparency, equity and fairness in recognition of prior learning (RPL) and to the principle of valuing all learning regardless of the mode or place of its acquisition. For applicants without this qualification, the RPL process of GMIT will be used to determine admission to the programme. Academic Code of Practice No. 6 outlines the policies and procedures for the Recognition of Prior Learning and guidance for applicants is provided on myexperience.ie  |
| 17. | Programme Structure: | The programme consists of a mixture of 5 and 10 ECTS modules delivered over two semesters. The capstone module is a 10 ECTS research project. |
| 18. | Learning, Teaching & Assessment Strategies: | 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: Lectures (live online and recorded): provided by academic, research and industry personnel. Exercises: in group - with tutoring online Seminars: a session in which a specific topic fitting the scope of the course is discussed by an expert in the field.Practical exercises: sessions in laboratory facilities in which students get hands-on practical training. Intensive group activities: for example in class debates, role play, journal clubs. Research based learning: learning from being actively or passively involved in a research activity.The wide variety of assessment strategies employed will ensure that students with a wide range of learning styles will be facilitated. Assessment methods will include: terminal examinations, continuous assessments, written technical reports/assignments based on work carried out in the lab, oral presentations, statistical analysis and a literature review. An assessment schedule will be drawn up by the programme board at the start of the semester to ensure a balanced workload for students over the entire semester. |
| 19. | Resource Implications: | This programme will be a self-funding programme. One additional assistant lecturer will be required in addition to costs associated with running practical laboratories and administration. |
| 20. | Synergies with Existing Programmes: | None. |
| 21. | Findings and Recommendations: | General: |
| The panel approve the programmes with the commendations listed below and subject to the following condition(s) and recommendation(s): |
| Commendations: |
| 1. The panel acknowledges the engagement, enthusiasm and knowledge of the proposing team and their positive interaction during the validation.
2. The programme is timely and is meeting a clear industry need and will be a valuable addition to the sector and the region.
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| Special conditions attaching to approval (if any): |
| 1. Review and consolidate the Programme Learning Outcomes, so that duplication is removed and the number of outcomes is appropriate for a one stage programme.
2. Revise the title of the Design of Experiments module to ensure that it reflects the module’s content.
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| Recommendations of the panel in relation to award sought: |
| 1. Specify how diverse class cohorts with differing academic and experiential backgrounds will be integrated with emphasis on how bridging will be provided, if required.
2. Define clearly plans for graduates of this programme to progress their studies i.e. describe the relationship between this programme and any proposed masters programme.
3. Outline how industry will be involved in delivery of the programme to enhance the applied nature of the programme and provide students with insights into various career options and industries.
4. Clearly articulate the contingency plans which will be put in place should onsite practicals not be feasible due to the current pandemic.
5. Review the wording of module learning outcomes to ensure that they reflect higher order learning outcomes such as synthesis and evaluation in all instances.

Individual Modules:1. Research Project: Enhance the clarity in the module descriptor around the output of the project, the thesis word count, the project process and potential for industry involvement. Consider the supports that may be required for students who are not working in a relevant industry to complete this module. Ensure that the supervision hours are in line with Institute norms and recorded in a way which is clear to the reader.
2. Biopharmaceutical Manufacturing: Ensure that the NIBIRT practical experience for this cohort of students is differentiated from that provided to the undergraduate students.
3. Quality Management Systems & Regulatory Affairs: Include the National Regulator, EDQM and pharmacovigilance in the syllabus.
4. Applied Immunology, Immunotherapeutics & Vaccine Technology: The panel considers the volume of content will be difficult to achieve. The content is significant given the module’s ECTS weighting and will be challenging for students to complete in the time available. Consider whether the content can be streamlined and/or whether additional contact hours may be warranted.
5. Validation for Biopharmaceuticals: Review the module assessment strategy with a view to ensuring that students are not being over assessed.
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| 22. | FAO: Academic Council: | Approved: |  |
| Approved subject to recommended changes: | X |
| Not approved at this time: |  |
|  | Signed: |  |  |
|  |  | Chair | Secretary |