# VALIDATION REPORT

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| 1. | Title of Programme(s): (incl. Award Type and Specify Embedded Exit Awards) | Higher Diploma in Science in Medical Technology Regulatory Affairs |
| 2. | NFQ Level(s)/ No. ECTS: | 8<br>60 ECTS |
| 3. | Duration: | 1 year Full-time |
| 4. | ISCED Code: | 0914 |
| 5. | School / Centre: | School of Science |
| 6. | Department: | Biopharmaceutical and Medical Science |
| 7. | Type of Review: | External Panel |
| 8. | Date of Review: | 11th November 2020 |
| 9. | Delivery Mode: | Blended |
| 10. | Panel Members: | Dr Andrew Power, Registrar, IADT (Chair)<br>Prof Brendan Duffy, CREST Gateway Manager, TU Dublin<br>Prof Joe Eustace, Director of HRB Clinical Research, UCC<br>Ms Dympna Power, Medica Device Auditor with TUV SUD<br>Ms Carmel Brennan, Assistant Registrar (Quality), (Secretary) |
| 11. | Proposing Staff: | Dr Eugene McCarthy, Head of Department of Biopharmaceutical and Medical Science, GMIT<br>Dr Ian O'Connor, HCI Manager, GMIT<br>Ms Carmel McGrath, Alphamed & Irish Medtech Association<br>Ms Ann O'Connell, Head of Funded projects for Medtech & Engineering<br>Ms Shane Beirne, Irish Medtech Association & Polymer Technology Ireland Project Executive<br>Mr John Martyn, Managing Director at Atlas Quality Consultants<br>Ms Esther Keating, Director of Regulatory Affairs at Medtronic Vascular<br>Mark Mullaney, Director, Regulatory Affairs, Europe, Merit Medical<br>Richard Tully, Director, Compliant Medical Device Ltd<br>Trish Breen, Medtech & Polymer Apprenticeships Manager, IMA<br>Ms Olivia Odhiambo, Regulatory Affairs Manager EMEA at Nanosonics Ltd |
| 12. | Programme Rationale: | This conversion programme will focus on regulatory affairs principles and practices providing students with the skills required to work within the medical technology sector. The programme is aimed at graduates who have a NFQ level 8 award and are aiming to build on their technical skills in the regulatory profession. GMIT have collaborated with industry experts and the Irish Medtech Association to develop this programme which will equip graduates with a firm grounding in regulatory affairs practices and skills to ensure next generation medical technologies are compliant with relevant regulations. |

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| | | The programme will be delivered by the Irish MedTech Association and quality assured under GMIT policies and procedures. A memorandum of agreement is in place to govern these arrangements and protect the learner and the standard of the programme.<br><br>Learners will cover key areas such as the new European medical device regulation and current global legislation. Other key areas covered include quality management systems, design and clinical studies along with post market responsibilities. This programme has the support of a large number of indigenous and multinational-based medical technology companies and will be delivered through a flexible blended approach.<br><br>The Western Region has a globally recognized cluster of life science multinationals and indigenous companies. Given that 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 the changing profile of skills needs, the demand for this proposed programme is evident based on focused exploration of the sector's current and future needs.<br><br>The Irish Medtech Association commissioned a national Medtech Skills Report to 2020 published in April 2017. Senior business leaders were asked to identify the number of employees required to meet their current skills demand as well as the forecasted number of employees required by speciality up to 2020. It was estimated that 4,000 jobs would be added, with 36% increase in the engineering function and 17% in the quality and regulatory function.<br><br>The National Skills Bulletin 2019 stated "we are not producing enough graduate technicians, engineers to take up roles in quality assurance and regulatory affairs". With over 96% of science and engineering workers in fulltime employment, the critical skills occupations listing as of Jan 2020. Employment growth is above average, and employers are frequently citing that these roles are difficult to fill due to limited training opportunities. |
| 13. | Potential Demand for Entry: | 30 student per intake. This is feasible given the cluster of MedTech companies in the west, the shortage of qualified staff and the availability of HCI funding. |
| 14. | Stakeholder Engagement: | The Irish MedTech Association crafted a survey to help understand the impact of MDR/IVDR on the Medtech Businesses at national level. Industry highlighted 3 of its top concerns as a) notified body capacity, b) uncertainty regarding regulatory requirement interpretation & the need for clear regulatory guidance and c) competition of resources/ availability (and/or lack) of expert Regulatory Affairs (RA) professionals. The Irish Medtech Quality and Regulatory Steering group in collaboration with the Industry Programme Manager and Course Director designed & developed the learning outcomes for this programme to assist in supporting the concerns identified in b & c above. |

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| 15. | Graduate Demand: | The proposed Higher Diploma in Science in Medical Technology Regulatory Affairs will future proof graduates with industry relevant skills for emerging technologies. The competition for regulatory affairs professionals has been extremely high for the past number of years and as the Irish Medtech Association survey outlined this is expected to continue long into the future.<br><br>The National Skills Bulletin 2019 identified a skills shortage for scientists in high Tech Manufacturing in quality control and process. The proposed Higher Diploma in Science in Medical Technology Regulatory Affairs will equip graduates with a strong technical and legislative knowledge in regulatory affairs through the provision of modules in European, U.S and Global regulations. In tandem, graduates will receive rigorous training in, Clinical Studies, Quality Management Systems, Design incorporating Risk Management along with the critically important Post Market Patient Safety Monitoring and relevant Regulatory Frameworks. Moreover, the course ensures that future needs of the life science sector in the West are met to ensure the region's continued reputation as a recognised Life Sciences cluster, a strategic objective of the West Regional Enterprise Plan to 2020. |
| 16. | Entry Requirements, Access, Transfer & Progression: | The minimum entry requirement is a level 8 Bachelor degree or equivalent.<br>English language requirements are according to GMIT's policy.<br>Recognition of Prior Learning can be used for entry in accordance with GMIT's RPL policy. |
| 17. | Programme Structure: | The programme is semesterised and consists of a mix of 5 and 10 ECTS modules. |
| 18. | Learning, Teaching & Assessment Strategies: | Student-centred teaching strategies will maximize problem-based learning focussed on authentic real-world scenarios relevant to the discipline. Active learning approaches (rese) will ensure that learning through doing dominates the programme rather than passive learning achieved by traditional lecturing approaches. A variety of teaching modalities that fit to the content of the course will be used: 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. Intensive group activities: for example in class debates and role play. Research based learning: learning from being actively or passively involved in a research activity.<br><br>A wide variety of assessment strategies employed will ensure that students with a wide range of learning styles will be facilitated. Assessment methods will include: continuous assessments, written technical reports/assignments based on work carried out during critical analysis, online quiz and oral presentations. 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. |

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| 19. | Resource Implications: | No additional resources are required to deliver this programme at this time. The programme is HCI funded. | |
| 20. | Synergies with Existing Programmes: | None | |
| 21. | Findings and Recommendations: | General: | |
| | | The panel approve the programmes with the commendations (3) listed below and subject to the following condition(s) (0) and recommendation(s) (2): | |
| | | Commendations: | |
| | | 1. The team were congratulated for the timely development of the programme through a successful collaboration between GMIT and IMDA.<br>2. The programme documentation presented was clear and of a high standard.<br>3. The programme responds to a market need and the team were commended for the currency of the programme content. | |
| | | Special conditions attaching to approval (if any): | |
| | | None | |
| | | Recommendations of the panel in relation to award sought: | |
| | | 1. Consider providing students with the option of undertaking a certified course in Good Clinical Practice in Medical Devices as part of the programme given that they will have covered the material required.<br>2. Ensure that the 'Fundamentals in Regulatory Affairs – Introduction' module includes an introduction to medical devices, including the range of devices by class, in recognition of the diverse backgrounds of students. | |
| 22. | FAO: Academic Council: | Approved: | |
| | | Approved subject to recommended changes: | X |
| | | Not approved at this time: | |
| | Signed: |  |  |
| | | Chair | Secretary |