VALIDATION REPORT

1.	Title of Programme(s): (incl. Award Type and Specify Embedded Exit Awards)	Certificate in Computerised Systems & Data Quality for MedTech Special Purpose Award
2.	NFQ Level(s)/ No. ECTS:	8 25 ECTS
3.	Duration:	1 Year
4.	ISCED Code:	0720
5.	School / Centre:	School of Science & Computing
6.	Department:	Department of Biopharmaceutical and Medical Science
7.	Type of Review:	New Programme
8.	Date of Review:	3rd December 2020
9.	Delivery Mode:	Blended
10.	Panel Members:	Prof Graham Heaslip (Chair) Dr Adrienne Fleming, TU Dublin Dr Liam Morris, Lecturer/Academic Council, GMIT Ms Jackie Byrne, Validation Services Director, CSS Compliant Systems Solution, Athlone Ms Carmel Brennan, Assistant Registrar (Quality) (Secretary)
11.	Proposing Staff:	Dr Eugene McCarthy Ms Rita Wooding Ms Catherine Kehoe Dr Ian O'Connor
12.	Programme Rationale:	According to the Irish Medtech Association, "the medical technology sector in Ireland is recognised as one of the five global emerging hubs. The sector employs over 40,000 people in Ireland and is the second largest employer of medtech professionals in Europe, per capita. Ireland is one of the largest exported of medical products in Europe with annual exports of €12.6 billion and companies here directly export to over 100 countries worldwide. As many as 9 of the world's top 10 medical technology companies have a base in Ireland and 60% of the 450 medtech companies based here are indigenous. Pressures on healthcare systems have resulted in a greater focus on enhanced efficacy of treatments and cost reduction. The proposed Special Purpose Certificate aims to address the skillset

		shortage specifically identified in this area through delivery of a suite of practical modules, namely: Software and Automated System validation, Data use and Integrity, Managing Validation projects and a unique module in Advancing Technologies. Moreover, the medical device industry is highly regulated with stringent requirements around the use of software and data. Hence each module will address the regulatory requirements and regulators perspective on each topic.
13.	Potential Demand for Entry:	25 students per intake
14.	Stakeholder Engagement:	The Special Purpose Award was developed in collaboration with industry to address the medical device sector's current and future needs. The modules for this programme were designed with industry input, tailoring the programme to identified companies' needs. Review of graduate employment statistics combined with employer feedback identified skills gaps that are addressed by this course. Following consultation with regional skills fora, an endorsement of the proposed course was obtained, outlining the need for the programme based on the research and consultation they had conducted.
15.	Graduate Demand:	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 the sector's current and future needs.
16.	Entry Requirements, Access, Transfer & Progression:	Minimum Entry Requirements A level 7 major award or equivalent in Engineering, Science or related discipline. Recognition of Prior Learning GMIT 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. Recognition of Prior Learning may be used to gain access to this programme in accordance with GMIT's Recognition of Prior Learning policy. Applicants for RPL will be provided with application guidance. English Language Requirements English Language Requirements will be as determined by GMIT and as published in the Access, Transfer and Progression code.
17.	Programme Structure:	The programme consists of a mixture of year-long and semester-long modules, with four modules in total.

18.	Learning, Teaching & Assessment Strategies:	Blended learning, Project-based learning (PBL), Team-Based Learning (TBL) and Self-Directed Learning (SDL) will be the approaches used in delivering this programme. Lecturer delivery will be enhanced through the use of industry guest speakers. This programme will be delivered using a blended approach using a variety of teaching strategies: • Lectures (live online and recorded): provided by academic staff and industry. • Individual exercises: in group - with tutoring online. • Collaborative workshops: Brainstorming for creation of system development outputs. • Seminars: sessions in which specific topics in advancing technology are discussed by industry experts. • Research based learning: learning through study of applicable regulations, guidance documents and investigation of industry
19.	Resource Implications:	This programme will be a self-funding programme. 7.5 hours weekly teaching hours will be required. In addition, there are costs involved in running practical laboratories and administration.
20.	Synergies with Existing Programmes:	None.
21.	Findings and Recommendations:	General: The panel approve the programme with the commendations (1) listed below and subject to the following condition(s) (4) and recommendation(s) (16): Commendations: 1. The development of a programme responsive to the latent needs of industry. Special conditions attaching to approval (if any): 1. Review all module learning outcomes to ensure that they are written appropriately for the level of the module using measurable active verbs. 2. Ensure all hours associated with modules are recorded as blended delivery so that the hours on the APS display correctly. 3. Expand on the teaching and learning strategy ensuring that it reflects the proposed pedagogies and the blended nature of the programme. 4. Review the title of the programme to ensure that it is appropriate given the content of the programme and the module titles. For example, quality does not appear in any module title, with validation appearing in two module titles.

			1. Provide further clarity on the research undertaken and the outcomes of same which informed the idea for and the structure, content and delivery of this programme.
			2. Clarify the scope of the programme to ensure that there is clarity for prospective students. Ensure that the document clearly articulates the nature of the student who would be targeted by the programme and describes the profile of graduates.
			3. The structure of the programme and its thematic areas should be clearly articulated in the documentation and linked to the needs of industry.
			4. Include reference to Recognition of Prior Learning and English Language requirements in the Access section of the document.
			5. Clarify how group projects will be managed and assessed.
			6. Consider ISPE student membership so they can be involved in a community of practice to support their learning in addition to gaining access to the baseline guides.
			7. Write module syllabi as topics rather than learning outcomes.
			8. Review the range of resources listed for each module to ensure that they are adequate to support learners in achieving the module learning outcomes.
			9. Ensure that prospective students are clear about the workload requirements if they choose to engage with the programme.
			10. Include an outline delivery schedule to ensure that there will be clarity for prospective students as to the programme requirements and nature of engagement on a weekly basis.
			11. Include the programme's strategy for the provision of feedback to students on assessment.
			12. Ensure that the AQA2 document is programme specific e.g. review the employability section to ensure that it is written specifically for this programme and remove reference to a capstone project.
			Modules:
			13. Software and Automated System Validation: Include preparation for audit scenarios. Reconsider the use of the term 'Foundation' in the assessment description. Record the failed element for the open book final exam. Clarify that part of the assessment involves a group project.
			14. Managing Validation Projects: Consider the use of a generic project management module or amend the module to be more specific to this discipline e.g. emphasise the identification of risk and management of risk throughout validation projects.
			15. Data Use and Integrity: Move the cybersecurity component from the Advancing Technology Module into this module. Be more specific about the nature of assignment. Record the failed element for the open book final exam.

		16. Advancing Technology: Amend the title of the module e.g. 'Emerging Trends in...'. The module should examine test support tools and the benefits of them. Given the module is designed around guest lecturers, clarify how this will be managed and assessed. Clarify the scaffolding of learning prior to each guest lecturer. Ensure that the duration of the module is stated consistently. Enhance the detail related to the assessment of this module and ensure that there is structure and support for learners undertaking this. Consider inclusion of a module learning outcome related to the critical analysis of the application of advanced technologies.	
22.	FAO: Academic Council:	Approved:	
		Approved subject to recommended changes:	X
		Not approved at this time:	
	Signed:		
		Chair	Secretary