## **VALIDATION REPORT**



1.	Title of Programme(s):	MSc in International Medical Technologies, Innovation and	
	(incl. Award Type	Development	
	and Specify		
	Embedded Exit		
2.	NFQ Level(s)/	9	
	No. ECTS:	90 ECTS	
3.	Duration:	1.5 years	
4.	ISCED Code:	0914	
5.	School / Centre:	School of Science and Computing	
6.	Department:	Department of Sport, Exercise & Nutrition Science	
7.	Type of Review:	New Programme	
8.	Date of Review:	8 <sup>th</sup> June 2021	
9.	Delivery Mode:	Blended	
10.	Panel Members:	Mr David Denieffe, Registrar and Vice-President, Academic Affairs at IT Carlow, (Chair)	
		Prof Brendan Duffy, CREST Gateway Manager, TU Dublin	
		Prof Christof Karmonik, Associate Research Professor of	
		Member & Director, MRI Core, Research Institute	
		Houston Methodist	
		Ms Marie McCarthy, Senior Director of Product Innovation,	
		Ms Carmel Brennan, Head of Academic Quality GMIT	
		(Secretary)	
11.	Proposing Staff:	Dr Des Foley	
		INF Eugene McCarthy Ms Carmel McGrath	
		Dr Sharon White	
		Dr Patrick Delassus	
		Ms Olivia Odhiambo	

12.	Programme	Medical Technology is characterised by a constant flow of
	Rationale:	innovations, which are the result of a high level of research
		and development within the industry, and of close
		cooperation with users. Medical technology products
		typically have a lifecycle of only 18-24 months before an
		improved product becomes available. In 2019, nearly 14,000
		patent applications were filed with the European Patent
		Office (EPO) (Patent Index 2019) reflecting the high level of
		innovation activity in the sector. The European medical
		technology industry is made up of 32,000+ companies, with
		95% classified as small to medium-sized enterprises,
		employing directly more than 730,000 people (MedTech
		Europe, National Associations survey 2019). The European
		medical technology market was estimated at roughly €120
		billion in 2018 and the Research Priority Steering Group
		report issued by Government in 2018 highlighted medical
		technologies as a key priority area that offers the greatest
		potential for economic return to the state. Ireland is one of
		the top five emerging global hubs for medical technologies in
		the world, contributing to over €12 billion in exports annually.
		Ireland has the highest number of medical technology
		employees per capita is Europe with over 450 companies
		operating in this sector nationally employing directly 40,000+
		people in 2019 (MedTech Europe, National Associations
		Survey).
		And Task slusters within Firm of CNUT's main semans
		Columnia vibrant economic mode un of a bland of modical
		Galway's vibrant ecosystem is made up of a blend of medical
		technology start-ups, multinationals, research centres and
		Calway medical technologies' accustom is the high level of
		Galway medical technologies ecosystem is the high level of
		companies (academia and the innevation partnerships
		between enterprice and academic research control funded
		through state agoncies such as Enterprise Ireland and SEL The
		ModToch innovation cycle is primarily led by MNCs or start
		uns identifying an unmet clinical need or market ennerturity
		Concepts which are sufficiently inneyetive and differentiated
		progress to the development phase. However, a significant
		risk to advancing technologies in the development phase is
		the availability of relevant talent and the changing profile of
		chills poods
		The MSc in International Medical Technologies Innovation
		and Development aims to develop the necessary skills
		required to strategically support the innovation and

		development of medical technologies from prototype to pre- clinical phase. Learners will not alone develop critical research skills but will also understand regulatory requirements for each international market for the approval of new medical technologies. Learners will cover advanced pre-clinical evaluation and assessment methods and appreciate their alignment to the business strategy and plans for the marketing of next generation medical technologies. The CEO Masterclass module will enhance learners' knowledge of intellectual property, commercialisation strategies; research and development funding landscape; reimbursement models and expertise from industry leaders or key opinion leaders on bringing technologies to market.
13.	Potential Demand for Entry:	It is expected that the profile of the learners enrolled onto the programme will have a relevant level 8 qualification in a health-related science, technology or engineering discipline, preferably with some research and development experience. It is anticipated that the primary target market will focus on employees of medical technology companies, who wish to up-skill or move into a research and development role. The MedTech sector was reported to employ over 40,000 people across 450+ companies (Medtech Europe). From the proposal team's market analysis approximately 150, primarily start-up and MNC, of these companies have some form of research and development division. Companies operating in this space have expressed an ambition to increase the level of research and innovation and have identified the lack of skills within the company to scale their activity. Based on this information, it is anticipated that the programme will attract between 16-20 learners each year, primarily from the local region.
14.	Stakeholder Engagement:	Demand for this proposed programme was initially identified through the Enterprise Ireland funded Medical & Engineering Technology (MET) Gateway. GMIT's MET Technology Gateway was established in 2016 to deliver innovative solutions to companies operating in the Life Sciences sector. Since 2016, MET has secured €10.6M in funding and delivered 165+ projects for companies developing medical technologies in Ireland. In addition to its national portfolio, MET also works with companies based in the US, Europe, China and India. Key to achieving these targets is the business development team, which includes 3 business development technologists who continually engage with the sector and MET's industry steering committee who oversee its strategic direction.

		The need for this programme was initially scoped out by profiling the innovative projects undertaken with companies enhancing their technologies from prototype selection to pre- clinical evaluation. Further consultation was carried out with the industry steering group on the 21st of June 2019 and the profile of the data capture was refined to a list of proposed modules. An extensive consultation with industry partners (Start-ups to MNC's) committed to developing disruptive life science technologies that address unmet patient needs was carried out in Q1 of 2021. The consultation process was facilitated through a detailed questionnaire followed by one-to-one consultations. Each of the respondents highlighted the need for this programme emphasising its uniqueness to other offerings.
		Facilitated through the Galway chamber, consultation on the international needs for the programme were identified through the China-Ireland Health Technology Cooperation conference in 2019. Further consultation in collaboration with GMIT iHubs and Innocare (China based) in 2020 (Q3), on the skills' requirement of the Medical Technology sector further cemented the international needs for such a programme.
15.	Graduate Demand:	<ul> <li>The proposed MSc in International Medical Technologies, Innovation and Development will equip graduates with necessary skills to ensure that future needs of the Medical Technologies sector in the West are met to further enhance the region's continued reputation as a recognised Life Sciences cluster, a strategic objective of the West Regional Enterprise Plan to 2020. Data collated from the questionnaire and consultation expect graduates to fill roles in the following areas: <ul> <li>R&amp;D Scientist/Engineer</li> <li>Quality/Regulatory</li> <li>Design Assurance</li> <li>Manufacturing Scientist/Engineer</li> <li>Process Development Scientist/Engineer Core Technology Operations Representative</li> </ul> </li> </ul>
16.	Entry Requirements, Access, Transfer & Progression:	A H2.2 Bachelor's degree at level 8 in any cognate discipline or equivalent in science, technology or engineering, is the minimum entry requirement for this programme.

		English Language Requirements will be as determined by	
		GMIT and as published in the Access Transfer and	
		Progression code	
		Progression code.	
		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. 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	The proposed programme is multidisciplinary by nature and	
	Structure:	will cover a range of subjects to facilitate the convergence in	
		medical technologies. Module content will contain emerging	
		be based on expert advice of the proposal team and best	
		industry practice to satisfy the regulatory bodies for various	
		target markets.	
		The structure of the programme reflects the success of the Medical & Engineering Technologies Gateway in delivering innovative solutions to industry and the working relationship across 3 schools in GMIT i.e. School of Business, School of Engineering and School of Science and Computing.	
		The programme consists of a number of 5 and 10 ECTS taught	
		modules delivered over the first two semesters and a	
		substantial research project delivered over semester 2 and 3.	
18.	Learning, Teaching &	A variety of teaching modalities will be used including:	
	Assessment	- Blended learning: Lectures (live online and recorded):	
	Strategies:	provided by academic & research staff, industry.	
		- 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.	
		<ul> <li>Practical exercises: sessions in laboratory facilities in which students get hands on practical training</li> </ul>	
		which students get hands-on practical training.	
		or passively involved in a research activity	
		- Work-based learning: the research project will be	
		conducted in a company or within an applied research	
		centre. Practical elements embedded in the Pre-	
		clinical Evaluation and Assessment module will also	
		contribute to work-based learning.	

		<ul> <li>Peer review learning will be used to developed skills associated with critical enquiry, reflection, organisation and collaboration. Peer review strategies will be used at research project group meetings, preclinical and evaluations practical and clinical engagement activities and through the networking and workshop activities scheduled for the CEO Masterclass module.</li> <li>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, oral presentations, statistical analysis and a literature review.</li> </ul>
19.	Resource	A full-time member of staff is required to supplement existing
		technical and administrative hours are also proposed to support this programme.
		This programme will be delivered on a self-financing basis.
20.	Synergies with Existing Programmes:	There is limited overlap with approved postgraduate programmes.
21.	Findings and	General:
	Recommendations:	Commendations:
		The panel commended the proposers on the development of a programme in this discipline area that is meeting a clearly identified need.
		The programme is well structured and presented, and the proposers are complimented on the work they have put into progressing the proposal and their positive engagement with the validation panel.
		The programme was approved subject to the following condition(s) (0) and recommendation(s) (7).
		Special conditions attaching to approval (if any):
		None.

		Recommendations of the panel in relation to award sought:		
		1. Ensure that there are appropriate arrangements in place		
		to ensure confidentiality by and between students in		
		relation to IP issues.		
		2. Explicitly include patient requirements, the patient voice,		
		patient mapping and the patient journey within the		
		enhanced through the involvement of a national and		
		IPPOSI in the CEO masterclass sessions.		
		3. Consider including an opportunity for physician		
		interaction during the programme.		
		<ol> <li>Clarify the arrangements that will be put in place to ensure that students undertaking project work in MET</li> </ol>		
		can be accommodated appropriately. This should		
		include the use of equipment and storage of materials.		
		Modules:		
		5. DESI09009 Medical Technologies: Include smart devices		
		(predictive and diagnostic) and SaMD within this module.		
		6. STAT09011 Design and Analy	STAT09011 Design and Analysis of Experiments: Evaluate	
		on a regular basis the most a	on a regular basis the most appropriate tools to use in	
		this module.	this module.	
		7. DESI09010 Design Control an	DESI09010 Design Control and Risk Management: Clarify	
			expectations of minutes and simes in respect of risk.	
22.	FAO: Academic	Approved:		
	Council:	Approved subject to	Х	
		recommended changes:		
		Not approved at this time:		
	Signed:		$\rho \rho$	
		Margaryhieric	Carmel Denn	
		$ \cup$	l l	
		Chair	Secretary	