GMIT
INSTITIÚID TEICNEOLAÍOCHTA NA GAILLIMHE-MAIGH EO
GALWAY-MAYO INSTITUTE OF TECHNOLOGY

School of
Science
and Computing

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Computerised Systems and Data Quality for MedTech

There is a shortage of skilled professionals in the area of computerised system, software and automated system validation in the Medtech manufacturing sector.

This course will provide you with the knowledge and practical skills required to add value in an ever-evolving medical device manufacturing environment. This course is also of special interest to those wanting to convert from electronics / pure software disciplines / roles into Medtech sector.

Course Title	Credits	NFQ Level	Campus	Duration
Certificate in Science in Computerised Systems and Data Quality for MedTech	25	8	Galway	1 Year

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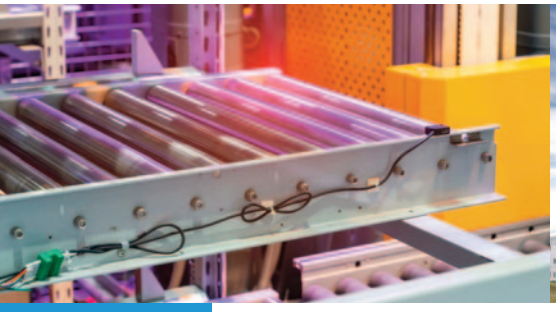

Why Study Computerised Systems and Data Quality for Medtech?

All aspects of medical device manufacturing and quality management are becoming more and more dependent on data, software and automation, which are present everywhere in today's manufacturing environment. From increasingly sophisticated process-control equipment, to automated business process flows in ERP (Enterprise Resource Planning) systems, and the management of a myriad of data, from process data and analytical test outputs to quality trend analysis and other management data. Validation of software and automated systems; and meaningful use and care of data are areas very much in need of increased knowledge and experience in the medical device manufacturing area. The aim of this programme is to meet this current and growing industry need, locally, nationally and internationally.

What to expect

The course will be fully online in 2021, with fully online lectures, tutorials and workshops. Future iterations will be delivered in a blended format to include monthly Saturday workshops on campus.

Course Content:

The course comprises four modules:

SEMESTER 1	SEMESTER 2
Software and Automated System Validation (10 credits)	
Data Use and Integrity (5 credits)	Managing Validation Projects (5 Credit)
Emerging Medtech Software Trends (5 credits)	

Lecturers from industry working directly in the area of validation and specialist guest lecturers with direct working knowledge of advancing technologies will contribute to the teaching on the course.

Entry Requirements – A Level 7 major award in any Science or Engineering discipline. Candidates with experience in the area will be considered for entry using RPL (Recognition of Prior Learning).

How to Apply – This course has been approved in 2020/21 for Springboard funding. Unemployed applicants may be eligible for free fees. Employed applicants are liable for a 10% fee contribution of €250. Applications should be submitted through www.springboardcourses.ie

Industry Endorsements

"We expect this course will provide industry with a pool of people who have a mind-set that enables them to add value quickly in this subject area. This will ease the recruitment and induction training burden for industry".

Declan Slemon,
Director Business Programmes, Aerogen.

"I have worked both in the USA and Ireland and am connected with regulatory bodies both in Europe and the USA. I am a hiring manager for Boston Scientific and always find it difficult to source qualified individuals who understand software quality and can apply the regulations to computer system validation".

Damien McPhillips,
Director of Quality with responsibility for Global Software & Digital Health, Boston Scientific

"There is certainly a shortage of experienced validation professionals, specifically relating to software and software validation. I envisage that demand increasing with time, as manufacturing environments become more highly automated, so it is good news that GMIT are directly focussing courses in this space.

Martin Rooney
Automation Manager, Creganna

"Given the shortage of skilled professionals in the areas of software development and the associated testing and validation of these systems, coupled with the growing demand for these skills across all sectors, it is vital that the engineers of tomorrow come to the market with a good understanding of these processes and how they can be applied across the many applicable sectors".

Declan Hennessey
COO with Secto

I want to know more. Who can I talk to?

Rita Woodings lectures on this course.
She will be happy to help you.
E rita.woodings@gmit.ie
Or find out more at **www.gmit.ie**

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