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

School of
Science
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THE TIMES
THE SUNDAY TIMES
GOOD UNIVERSITY GUIDE 2022
INSTITUTE OF TECHNOLOGY OF THE YEAR

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	Fee
Certificate in Science in Computerised Systems and Data Quality for MedTech	25	8	Galway	1 Year	€1250

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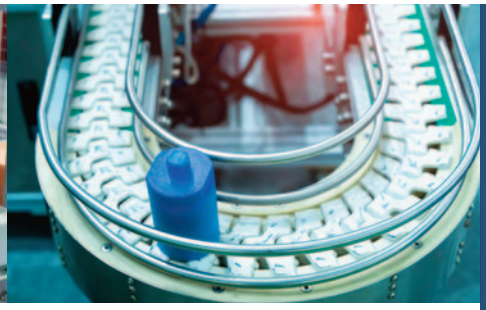

Why Study Computerised Systems and Data Quality for Medtech?

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

This is a blended course, with fully online lectures and tutorials and occasional on-campus seminars and workshops.

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 credits)
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 – If you are interested in applying for this course please contact **learn@gmit.ie**

Student Testimonials

"This programme has provided an understanding of system validation in the regulated medical device setting. As a result, our business has moved to another level as we customise data systems for industry. I recommend this practical course for anyone in industry involved in gathering data or with computerised systems approval."

Tony Hegarty, Student / MD Ordu Ltd

"The material in this course is well-structured, and presented in an interactive way, which allows everyone to get involved. The feedback and support of the learning team is amazing, and they are always there to answer questions. I would highly recommend this program for someone wishing to get involved in MedTech industry or someone who wishes to upskill and put their current knowledge into context."

Olga Sazenova, Student

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. As a hiring manager for Boston Scientific, I 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

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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