



**Trinity College Dublin**

Coláiste na Tríonóide, Baile Átha Cliath

The University of Dublin

# Master of Science in Regulatory Affairs for Medical Devices

Course Duration: 2 years part-time

Closing Date Details: [www.tcd.ie/courses/postgraduate/az](http://www.tcd.ie/courses/postgraduate/az)

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Next Intake: September 2023

[www.tcd.ie/medicine/mdra](http://www.tcd.ie/medicine/mdra)



## Planning a career in MedTech?

This course is offered to graduates looking to develop a career in a MedTech organisation, who would like to learn about the regulation of medical devices in Europe, and who may have an interest in becoming a person responsible for regulatory compliance.

This new Masters in Science to be delivered on a part-time basis over 2 years has been designed to provide flexibility for students, who may already be working, to manage the challenge of balancing work, study and family responsibilities.

Developed by regulatory specialists, in collaboration with leading clinical, academic and industry experts, the programme will be delivered by professionals who contributed to the negotiations and implementation of the Medical Device Regulation (MDR) in Europe, in addition to experts who apply the MDR in practice on a daily basis.

This course will teach students about regulatory rules and principles, in addition to explaining the context in which these rules were developed, and the way in which they have been implemented in Europe.

Ireland is a global leader in medical device development, manufacturing and export, with the highest *per capita* employment in the MedTech sector in the European Union. Medical devices are a vital, and increasingly important component of modern and integrated healthcare.

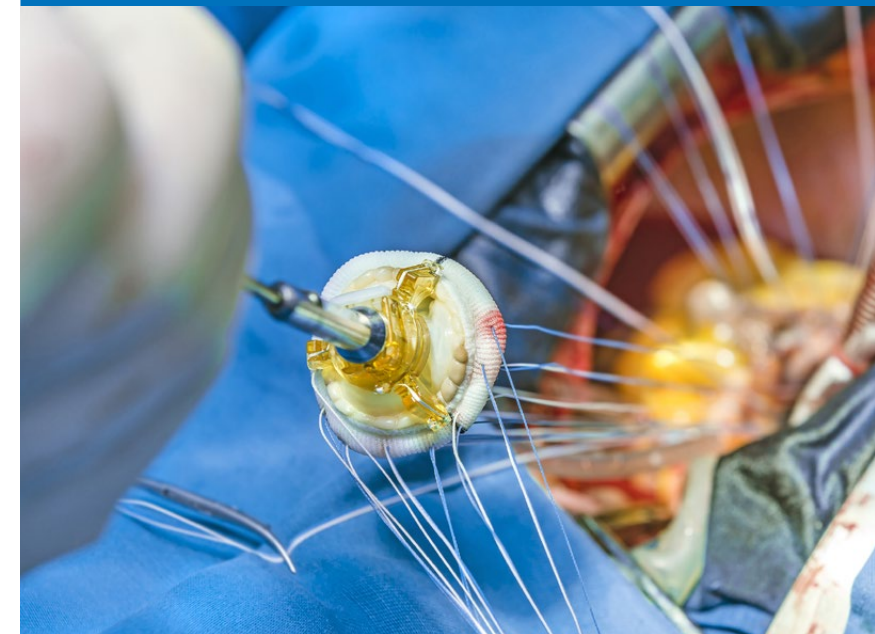
In recent years, the medical device regulation in Europe has undergone a fundamental redesign and this is leading to changes in market dynamics and the nature of the medical device ecosystem. Understanding these rules, and their application is of increasing relevance to ensuring that MedTech organisations meet their strategic goals and will be a key advantage in career development in the sector.



## Admission Requirements

Applicants are expected to have an Honours Bachelor degree ideally 2.1 or above in one of the following disciplines: pharmacy, medicine, allied health professions, biomedical engineering, biology, law. Other disciplines may also be considered as suitable on a case-by-case basis, and an interview may be offered to assess suitability.

Applicants will ideally have some experience in MedTech development, manufacturing or regulation, however applicants with other relevant experience are welcome to apply.





## The Course

The course is a part-time taught program, run over 2 years for a total of 12 modules, with a dissertation to be completed by August of year 2. 5 modules are delivered online. Each in-person module typically has 3 days face-to-face teaching which consists of a combination of formal teaching sessions, workshops, and interactive/practical sessions.

Pre-module reading lists and self-directed learning material are provided and form part of the module teaching. In addition, all registered students have access to Trinity’s web-based virtual learning environment facility. Students are expected to interact with other class members and the course coordinators via the e-learning platform.

Throughout the year participants are required to attend, either in person or virtually, a number of module tutorials, workshops, regulatory lectures, networking events and examinations. These have been designed to facilitate students who are working in addition to undertaking the course.

Each module contains several sessions. Tutorials accompany a majority of the online or in-person lectures. Details regarding the schedule for tutorials will be released at the beginning of each module and an indicative timetable is included in the student handbook.

## Course Content and Structure (Modules)

To achieve the MSc, students must complete a dissertation, in addition to completing taught modules, totalling 90 ECTS. The distribution of credits is 45 ECTS of taught modules in year 1 and 45 ECTS in year 2, including 30 ECTS of research dissertation.

These modules include:

<b>M1</b>	Introduction to device regulation, regulatory roles and responsibilities
<b>M2</b>	Person responsible for regulatory compliance
<b>M3</b>	Regulation of Digital Health Technology
<b>M4</b>	Clinical Investigations
<b>M5</b>	Clinical evaluation, post-market assessment
<b>M6</b>	Biocompatibility and medical devices
<b>M7</b>	Risk management and medical devices
<b>M8</b>	Quality management and conformity assessment pathways
<b>M9</b>	Qualification, classification, borderline products and device traceability
<b>M10</b>	Preparing a clinical development plan for a novel active implanted medical device
<b>M11</b>	Regulatory policy
<b>M12</b>	Research project and dissertation



## Application Procedure

Application for this course should be made online through the Graduate Studies website: [www.tcd.ie/courses/postgraduate/how-to-apply](http://www.tcd.ie/courses/postgraduate/how-to-apply)

Should you have any queries or difficulties, please call or e-mail the office and we will do our best to resolve any issues (contact details below).

The link to the School of Medicine is located at the bottom of the 'Health Sciences' section - click on this for the list of postgraduate courses in the School.

**Note:** For this course, company or personal references may replace the requirement for academic references. Applicants should therefore inform their referee that a general reference is required, including the suitability of the applicant for the course. This may be done on the academic reference form which is automatically e-mailed to nominated referees or referees may prefer to write a letter of reference and upload it instead.

## Fees

Part time M.Sc

EU: €6,130

Non EU: €12,867

## Contact details

Further information may be obtained by contacting Assoc. Prof. Tom Melvin, [MELVINTO@tcd.ie](mailto:MELVINTO@tcd.ie)

[www.tcd.ie/medicine/mdra](http://www.tcd.ie/medicine/mdra)

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