



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

CORE-MD Webinar

A needs-based modular curriculum

10 July 2023

Tom Melvin

Associate Professor of Medical Device Regulatory Affairs

Director MSc Medical Device Regulatory Affairs

Agenda

Introduction to course

Introduction to modules

Perspective on course
development

Introduction to the course

The course

2 year part-time MSc

11 taught modules + Dissertation in year 2

Online format - sessions on Blackboard and tutorials held remotely – twice per week

School of Medicine, but close links with School of Engineering

The context



MedTech is an important strategic sector for Ireland

c. 40,000 employees

450 companies (50 'large' and 400 SME)

Introduction to the modules

Year 1

Semester 1

Introduction / roles and responsibilities*

Person responsible for regulatory compliance

Digital health technologies

Clinical investigation

Semester 2

Clinical evaluation*

Biocompatibility

Quality systems*

Clinical development plan for a novel active implanted device

Year 2

Semester 1

Risk management*

Qualification / classification / traceability of devices

Dissertation

Semester 2

Regulatory policy

Brief perspective on course development

Perspective on course and module development

#1 Understand the target student

#2 Prepare for multi-disciplinary students

#3 Acknowledge the highly complex and changing nature of medical device regulation

A photograph of a large, multi-story stone building at Trinity College Dublin. The building features a prominent green wall on the right side, which is a vertical garden. The sky is blue with some light clouds. The text 'Thank you' is overlaid in white, and the URL 'www.tcd.ie/medicine/mdra' is overlaid in blue with a blue underline.

Thank you
www.tcd.ie/medicine/mdra