MMI Clinical & Translational Research Scholars Programme
Online/Blended Learning Graduate Education Module Descriptor

Programme Title	**MMI Clinical & Translational Research Scholars Programme**
Module Title	**Regulation of Medicines and Medical Devices**
Module Code	MMICTRSP-010
Module Coordinators	Dr Mary Teeling (TCD), Dr Mary-Jo MacAvin (TCD)
Contributors	Irish Medicines Board
Credits (ECTS)	2.5
Module Places	
Module Dependencies	None
Indicative Module Description	This module provides comprehensive information on the role of regulation on the authorisation of medicines and medical devices from a global perspective. It details the current national and international regulatory requirements for medicines, including medical devices. The aim of the module is to enable the student gain competence in the handling of all regulatory lifecycle issues of a medicine both prior to and during the authorisation process in the various jurisdictions. **Syllabus** Background to general principles of medicines regulation at a global level: differences & similarities between the major regions (EU, US, Japan, ROW). **Current EU Regulatory requirements for drug development:** EU Directives vs. Regulations; regulation of novel vs. established active ingredients; clinical trial legislation; Centralised vs. Decentralised applications; procedures for approval, rejection, appeal; special therapeutic groups: orphan drugs, paediatrics, advanced therapies, generics, biosimilars; Prescription-Only & Over-The-Counter medicines; provisions for & use of unlicensed medicines; role of the European Medicines Agency (EMA) & National Agencies; impact on the activities of the pharmaceutical Industry. **Regulatory management systems in US, Japan, ROW & local special requirements:** Current non-EU regulatory requirements for drug development; differences & similarities with EU regulatory system; regulation of novel vs. established active ingredients; clinical trials legislation **Medical device regulations in the EU & non-EU:** EU Directives and Regulations CE marking Conformity assessment and notified bodies

	Clinical data Classification of medical devices Post market surveillance IVD medical devices New regulatory proposals		
Indicative Learning Outcomes	**On successful completion of this module students should be able to:** • Describe the background to the development of medicines regulation at a global level and discuss the similarities and differences between the current regulatory systems in the major regions (EU, US, Japan, ROW). • Critically review and evaluate the similarities and differences in legislation relating to drug development in the different regions and explain the impact on the various stakeholders, including regulators, pharmaceutical companies, healthcare professionals and patients. • Explain the background to the development of the International Conference on Harmonisation (ICH) and evaluate its role and main activities, including the Common Technical Document (CTD). • Explain the principles and practical application of the Medical Devices regulations in the EU and other major regions.		
Learning Activities	Interactive online learning.	Hours 10	Total 50
	Tutorial workshop	Hours 2	
	Autonomous student learning and assignments.	Hours 20	
	Further Reading	Hours 18	
Assessment Strategies	Online MCQ. Short questions.		
Delivery & Schedule	The module employs a combination of e-learning using materials delivered via Blackboard and a face-to-face workshop with discussion of specific case studies.		