



Product Development, Validation & Regulation

Module content

The Product Development part of this module will introduce you to the principles of concept generation, testing, development and the Stage Gate process. The importance of incorporating customer requirements, Voice of the Customer, into new product concepts is discussed and you are introduced to a technique, Quality Function Deployment, for doing this. Several techniques for selecting and testing new product concepts and for generating a final specification, are also described. Design for Manufacture, product marketing and launch are presented in detail.

The second part of this module covers regulatory requirements that govern the development and marketing of drugs and medical devices for human use in Europe and the US. As well as allowing you to get a broad overview of the requirements, the course notes may also serve as a useful road map and starting reference point for addressing specific regulatory issues in your professional career.

Learning outcomes

On completion of this module you will be able to:

- Relate anatomy & physiology relative to medical device design & development
- Describe the relevant pathology and patho-physiology of cardiovascular disease or injury in the context of product development
- Summarise how safe and effective medical devices are designed and the ways in which their efficacy is assessed
- Give an appraisal of regulatory requirements and issues of importance to the FDA
- Explain the purpose of the regulations and the principles and strategies by which they are underpinned
- Describe the various regulatory steps required for the development and marketing of drugs and medical devices
- Determine an appropriate regulatory pathway to bring a product to market



Module facts

Course level: Level 9

Module credit: 5 ECTS. Gain transcript or use towards PG Cert/PG Dip/MSc qualification in Biomedical Science

Duration: Over one semester

Entry Requirements: Please refer to the application section of the programme brochure

Fees: €1,000

Applying: www.nuigalway.ie/apply

Closing date: 2 – 8 weeks prior to module start date.

Module topics

New Product Development

- Goals of the new product process
- Critical success factors
- Models of New Product Development
- The Stage-Gate Model

Concept Generation and Testing

- Identifying Customer Needs
- Concept Generation Process
- Concept Selection Process
- Concept Testing Process

Product Specification and Design for Manufacture

- Steps to Target Specification
- Steps to Final Specification
- Product Specification Challenges
- Design For Manufacture

The Product Launch

- Market Analysis
- Definition of Target Market
- Product Position, Pricing, Distribution

Product Testing and Validation

- Requirement and Purpose of Product Testing
- Testing Strategies
- Design of Experiment
- Purpose and Elements of Validation

Medical Product Regulation

- Goals and Principles Underpinning Regulation
- Types of Legal Instruments
- Legal Definitions of Drugs or Medical Devices
- Regulation Goal Achievement Strategy
- European and American Regulatory Bodies

Drug Development and Non-clinical Studies

- Strategies for Drug Discovery and Development
- Pre-clinical Evaluation of Drugs
- Types of Non-clinical Studies
- Good Laboratory Practice

Clinical Trials

- Objectives and Strategies at Different Trial Phases
- Good Clinical Practice
- How to set up a Clinical Trial
- How to Conduct a Clinical Trial

Marketing Authorisation

- Content of Marketing Authorisation Application Dossier
- Format of Common Technical Document
- European and US Application and Approval Process
- Conditions for Reduced Applications Dossiers

Classification, Development and Authorisation of Medical Devices

- Regulatory Strategies for Devices in the EU and US
- The Design Control Process
- Evaluation of Devices in the EU and US
- Conformity Assessment Procedures for Device Authorisation

Student testimonial

Roisin Lenehan

Current position:

Medical Scientist (Haematology).

Position held when completing Masters:

Senior Clinical Trial Associate.

"I found the Product Development, Validation and Regulation module particularly interesting and useful when I studied it. The lecturer was very informative about his own personal experience of the development and validation of new products in industry. This module was very useful to me as I worked in a Clinical Research company at the time where by clinical trial management is outsourced to them by drug companies who are testing new drugs. This allowed the drug companies to see if the drugs they are developing are safe and effective in humans. This module gave me a great insight into the process which the drug companies had to work through before presenting the drug for clinical trials and of course new product development, validation and regulation in general. I gained a much greater understanding of the whole process; from concept generation and design to the release of the new product on the market."



Module Director

Mr John Kilmartin

This module is delivered by Mr. John Kilmartin, a Senior Director of Regulatory Affairs in Medtronic (based in Galway). Medtronic is a multinational Medical Technology company, headquartered in Minneapolis with a facility of approx. 2000 people

based in Galway. John has worked in the medical technology industries for over 17 years with particular emphasis on US, European and emerging market regulatory frameworks. Prior to joining Medtronic, he worked in the areas of in-vitro diagnostics, biotechnology and other medical device products.

He has a particular interest in high risk Class III cardiovascular devices, catheter based technologies and combination products.

Having completed his undergraduate and post-graduate degrees at NUI Galway in Microbiology and Immunology respectively, John worked in research and development for a number of years. He worked in R&D with NUI Galway, Trinity Biotech and Alltech Biosciences, prior to transitioning

into the regulatory affairs arena. He has also completed a Masters in Industrial Pharmaceutical Sciences ('Qualified Person' qualification in EU for pharmaceuticals). In his current role as the Senior Director of Regulatory Affairs in Medtronic John leads a regulatory team involved in the development and implementation of regulatory strategies and global submissions for various medical devices and combination products. He interfaces with various global regulatory authorities including FDA, Notified Bodies, Competent Authorities etc. He also works closely with various academic institutions on the development of relevant courses on regulatory affairs/validation/design control. John has worked closely with the local (IMDA) and European (Eucomed) industry associations on various regulatory developments and participates in a various task force teams. He is a member of RAPS and the IMDA regulatory steering committee.

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