

Irish Medtech
Association
SKILLNET

Fundamentals in Regulatory Affairs for Medical Technologies

Developed
by Industry
for Industry

NFQ Level 8
(approval pending)



The Irish Medtech Skillnet is funded by member companies and the Training Networks Programme, an initiative of Skillnets funded from the National Training Fund through the Department of Education and Skills.

Fundamentals in Regulatory Affairs for Medical Technologies

About the course

The Irish Medtech Skillnet and contracting organisation, the Irish Medtech Association, the Ibec group that represents the Medical Technology sector and Reidh Consulting group in collaboration with University of Limerick are delighted to present the new Fundamentals in Regulatory Affairs programme for the Medical Technology sector.

This programme has been designed to meet the growing requirements of Irish companies in filling regulatory assurance roles. The impetus for the development of this specialist programme emerged from industry needs and the content has been developed in conjunction with a taskforce comprised of regulatory experts from Irish Medtech Association's Regulatory and Quality Working Group. In particular, this industry led programme will assist companies as they prepare for the new EU regulatory framework and offer unique flexibility to companies to adapt rapidly to changing regulatory workloads ahead of the entry into force of the new EU Medical Device and IVD Medical Device Regulations. The course will enable personnel in the medical technology industry to understand all current device and diagnostic regulations and to develop the skills necessary to address and prepare for the ever-changing global environment of regulatory affairs. Upon successful completion of the programme, participants receive an award at NFQ Level 8.

About Irish Medtech Skillnet

Working in partnership with Skillnets Ltd and our contracting organisation, the Irish Medtech Association (Ibec sector), the Irish Medtech Skillnet has over the past number of years grown substantially in direct response to the training needs of Industry. Total expenditure (2008 - 2015) is over €4.2 million with 40% contribution from member companies and the remaining 60% funded by the State. Targets of over 6,000 trainees and 30,000 training days have been achieved.



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About Irish Medtech Association

The Irish Medtech Association is a business sector within Ibec that represents the Medical Technology sector and is a proactive membership organisation with over 180 members located throughout Ireland. It works directly with government and policy makers nationally and internationally, to shape business conditions and drive economic growth. Led by a board of 18 industry leaders, and facilitated by a dedicated professional executive staff, our working groups, forums and task forces are the primary enablers of Irish Medtech Association's strategy.



Irish Medtech
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Ibec

Programme description

The regulatory affairs professional is critical to making safe and effective medical products available to patients worldwide. These professionals ensure compliance to international medical device regulations for safety and efficacy. Regulatory Affairs is one of the most in-demand professions in the medical device industry.

The aim of the course is to introduce participants to the Fundamentals of Regulatory Affairs, providing them with basic knowledge of the regulations as they apply to the medical technology industry. This course will cover international regulatory requirements with emphasis on the US, European Union, Japan, Australia, Canada and other global territories with market implications. Regulatory requirements for each system will be presented including classification, marketing submissions and post-approval requirements. Developing regulatory strategies for global market introduction and organising for the challenges of global regulation will be considered.

The course content will address the following themes:

1. What regulatory and certification bodies look for from Regulatory Affairs function in an organisation.
2. Similarities and differences between EU, US and Global regulatory market requirements, with special attention to the recently published MDR and IVDR texts.
3. Risk and Risk management and corresponding links to Post Market Surveillance for Regulatory Affairs.
4. Quality Management Systems and where regulations align for the Business and Regulatory function.
5. Clinical Studies and the Design Process including the various interfaces with Regulatory Affairs.
6. Significance of product labelling, associated promotional material and device changes and the watch-outs for Regulatory Affairs.

Duration: 12 days

Delivery schedule

Day 1	Introduction to Regulatory Affairs
Day 2	Quality Management Systems
Day 3	EU Regulatory Affairs
Day 4	Clinical Studies
Day 5	US Regulatory Affairs
Day 6	Product Design and Risk Management
Day 7	Global Regulatory Affairs
Day 8	Product Labelling
Day 9	Regulatory Reporting and Post Market Surveillance
Day 10	Strategic Approach to Regulatory Affairs
Day 11	Device Changes Post Approval
Day 12	Case Study Presentation

Costs

€2,250

Irish Medtech
Skillnet Members

€3,000

Non-Members

Who should attend?

Entry requirement will be minimum Level 7 with two years' experience working in a regulated environment in the life sciences sector.

Prior experiential learning will be assessed using guidelines recommended by the Academic Council of University of Limerick.

Accreditation

The course will be accredited by University of Limerick, to **Level 8 with 9 ECTS credits** (approval pending)

Note: Approximately 90 – 100 hours are required outside course work.

Delivery

The programme will give all participants very clear and unambiguous information on current regulations. The tutor will be a Subject Matter Expert (SME) in the area and will be knowledgeable on current regulatory expectations and application. Guest speakers at the cutting edge of current industry regulatory affairs will present during the programme. Each tutor will not only be technically competent but will also transfer knowledge in an interactive and stimulating manner. It is planned that each course day will be a combination of lectures, syndicate sessions and case studies with accelerated learning also built into the course.

Assessment grading system

Assessment of students will be based on continuous assessment with assignments throughout the course. The submission of a final dissertation based on the new Medical Device and IVD Medical Device Regulations at the end of the course is a key deliverable. Each participant must have full attendance and pass the set criteria established for this case study to be successful on this course.

Additional lecturing and workshop contributions, as required, will be provided along with use of Moodle software system to manage assignments and participant deliverables.

Programme enquiries

This programme can be booked online at www.irishmedtechskillnet.ie

Contact: Michelle Reinecke-Quain,
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Course plan

Module 01

Introduction to Regulatory Affairs

- Introduction to Regulatory Affairs
- Regulatory Body overview
- Role of RA Professional
- Regulatory Responsibilities
- Pre-Approval, Maintenance and Post Approval
- Legal Basis for Regulation
- Group Case Study Overview

Learning objectives

The student will be generally knowledgeable and know how to access general information on the following:

- A framework for the stages of medical technology innovation and development.
- The roles and responsibilities of key agencies affecting policy development including Food and Drug Administration, Notified Bodies and Competent Authorities.
- A framework for classifying the types of policies that affect medical technology innovation.
- The history of selected public policies affecting medical technology development.
- The role of regulatory affairs and the expectations of regulatory professionals in the medical device Industry.

Module 02

Quality Systems for Regulated Industries

- Product Lifecycle
- FDA – QSR Part 820
- MDR/ IVDR – Changes
- ISO 13485: 2016
- Regulatory Inspections & Internal Audits
- Case Study Review & Presentation Skills

Learning objectives

The student will become generally knowledgeable and know how to access general information about the following:

- The history and importance of quality systems in the medical technology industry.
- Understand how to interpret and implement applicable quality requirements for QSRs, ISO 13485, and related quality standards/ guidance documents.
- Process for regulatory agency inspections and internal quality system auditing including the QSIT approach.
- The role of quality systems throughout the medical device life cycle from design through market release to market phase out.
- The roles and responsibilities of a Quality organisation and staffing for implementation and compliance with quality requirements.

Course plan continued

Module 03

EU Regulatory Affairs

- **Current Regulatory Framework**
- **Medical Device Directives**
- **CE Marking**
- **Product Classification & Certification {Class I, IIa, IIb & Class III}**
- **Design Dossier versus Technical File**
- **Essential Requirements & Conformity Assessment**
- **Guidance Documents & Standards**

Learning objectives

The student will become generally knowledgeable and know how to access general information on the following:

- The history of medical device regulation in Europe and the current Medical Device Directive (MDD, AIMD, IVDD).
- The CE Marking requirements and conformity assessment routes.
- Technical documentation required for CE Marking dependent on classification.
- Classification of medical devices per the requirements of the Directives.
- The use of MEDDEV guidance, harmonized standards and other regulatory documents in compliance processes.
- An overview of the new Medical Device Regulation.
- The concepts associated with the new IVD Regulation.

Module 04

Clinical Studies

- **Clinical Evidence**
- **Clinical Investigations**
- **Good Clinical Practice (GCP) & ISO 14155**
- **Global Process & Design Paradigms**
- **Clinical & Regulatory Partnership**
- **Clinical Evaluation Reports (CER)**
- **Role of Competent Authorities, FDA, Ethics Committees & Investigational Review Bodies**

Learning objectives

The student will become generally knowledgeable and know how to access detailed general information on the following:

- General ethical philosophies and their application to ethical issues involving medical devices.
- Industry and company Codes of Conduct and FDA regulations and guidance documents relevant to the analysis of ethical issues with medical devices.
- Process to analyse the factors affecting decisions and responses to ethical issues affecting patients, physicians and regulators.
- Application of ethical principles in case studies.
- Regulations associated with the clinical evaluation of unapproved medical devices in the US and Europe including Clinical Investigation process, IDE etc.
- The content, approval process and post-approval requirements for Clinical Investigations.
- Clinical paradigms commonly used to determine the safety and effectiveness of medical devices.
- Defining clinical objectives and statistical considerations associated with clinical trial design.
- Methods for the analysis of clinical data and the formats and content of clinical evaluation reports and publications.

Module 05

US Regulatory Affairs

- **FDA Case Law/Statute**
- **Product classification**
- **PMA**
- **510(k)**
- **De Novo**
- **Path to Market**
- **Intro to the FDA Investigator**
- **Class assignment**

Learning objectives

The student will become generally knowledgeable and know how to access general information on the following:

- The history of the 510(k)/PMA regulation and current FDA interpretation of requirements.
- Traditional 510(k) submission structure and requirement and the similarities and differences to other types of 510(k) submissions (including De Novo designation).
- When changes to marketed devices require a new 510(k)/PMA.
- Understanding “Substantial Equivalence” and the basis for market clearance.
- Understanding and use of FDA guidance and consensus standards.
- Regulatory strategy and planning for submissions.
- Best practices in the preparation, review and clearance of PMAs/510(k)s.

Module 06

Product Design and Risk Management

- **Design Control Process Stages**
- **Customer Expectations**
- **User Interface**
- **Design Testing Methods**
- **Design Approval – RA Release control**
- **Advances in Risk Management and Application**
- **FDA Guidance documents & ‘Blue Guide’ on the implementation of EU product rules 2016**

Learning objectives

The student will become generally knowledgeable and know how to access general information on the following:

- Understanding the Design control process through documentation of objective evidence established throughout the product development process to prove the device is safe and effective.
- Demonstrate they have basic knowledge and understanding of the content and application of ISO 14971:2012 Medical devices - application of risk management to medical devices and risk management planning and the key components of a risk management file.
- Implement a risk management plan including risk analysis, risk evaluation, implementation of appropriate risk controls and conduct a risk/benefit analysis.
- Formulate judgements from a regulatory standpoint in each step of the risk management process and demonstrate basic ability to interact effectively with regulatory agents.

Course plan continued

Module 07

Global Regulatory Affairs

- Canada
- Australia
- Japan
- Emerging Markets including Eastern Europe
- Other Territories
- Global Regulatory Expertise
- IMDRF/Medical Device Single Audit Programme

Learning objectives

The student will become generally knowledgeable and know how to access general information on the following:

- Medical Device systems and regulatory bodies in the applicable markets.
- Regulatory systems and regulatory agencies in the applicable countries.
- Global medical device classification, pre-and post-market regulations applicable to each class of medical device in the key geographies.
- Regulatory submission/application processes for medical devices in the applicable markets including the global submission format, STED.
- Medical device registration and licensing requirements in the applicable markets.
- Principles and challenges of supporting international regulatory systems with the political, ethnic and economic differences in the applicable markets. Tools and approaches to communicate pre- and post-market regulatory issues to senior management in order to assure compliance.

Module 08


Product Labelling

- Legal Implications
- IFU'S
- Labelling
- Advertising
- Promotional Material
- Risk/Benefits
- Class Assignment (quiz)

Learning objectives

The student will become generally knowledgeable and know how to access general information on the following:

- Communicate a basic knowledge and understanding of the EU/ US/ Global legislation and regulations associated with medical device labelling and global perspectives on UDI, harmonised symbols, structure of IFU, intended use, contraindications, label/IFU review best practice, e-labelling.
- Demonstrate they have a basic knowledge and understanding of the legislation and regulations associated with medical device advertising and promotion from EU/US and Global perspective and also country specific requirements.
- Communicate a basic knowledge of context of off label use/on label use and particular requirements for website content.
- Understand the relevance of social media, twitter, blogs and future directions for advertising and promotion.
- Evaluate the impact of physician/customer contact and provide direction in relation to consumer advertising in promotion strategy.



Module 09

Regulatory Reporting and Post Market Surveillance

- **Authorised Representative**
- **Medical Device Reporting (MDR)**
- **Medical Device Vigilance (MDV)**
- **Complaint management overview**
- **Competent Authorities – EEA**
- **Other market reports**
- **Post Market Surveillance**
- **Annual/Interim/Special reports**
- **Remedial Action/Recalls/FSN's**
- **Regulatory Inspection watch-outs**
- **Case Study progress**

Learning objectives

The student will become generally knowledgeable and know how to access general information on the following:

- Post-marketing requirements in the applicable international markets.
- Business and ethical considerations for product performance issues and recalls.
- Interaction with independent Medical and Clinical expertise to support business decisions.
- Reporting to Government bodies, associated time lines, general expectations and audit/inspection impact.
- Similarities and differences between Vigilance, MDR's FSN (Field Safety Notice), voluntary and enforced recalls.
- Concepts and applications of corrective and preventive actions and root cause analysis in monitoring field performance.

Module 10

Strategic Approach to Regulatory Affairs

- **Regulatory Strategy**
- **Business Link**
- **Integrated Team & Ethical influence**
- **Parallel Methodology**
- **Regulatory Body – Partnership Approach**
- **Business culture – foster open consultation approach with RA professionals**

Learning objectives

The student will become generally knowledgeable and know how to access general information on the following:

- Business and legal responsibilities associated with facility registration, device classification and listing, pre-market submissions quality systems, post-marketing compliance activities.
- Strategies for minimising liability.
- Business and ethical considerations for product performance issues.
- Strategies for effective communication of negative information to multiple audiences.
- Understanding organisational structure for medical device design and manufacturing and applicable company policies and procedures.
- Researching and identifying regulatory requirements applicable to the project and developing a project plan.
- Communicating regulatory requirements to applicable project team members.
- Taking a leadership role in design and validation of the project including the regulatory submission or other project deliverable.
- Sustaining a long-term interest in current and evolving regulations and regulatory policies affecting the medical device industry.

Course plan continued

Module 11

Device Changes Post Approval and Re-Certification

- **Change Control**
- **Change Assessment**
- **RA Determinations**
- **Regulatory body notifications**
- **Technical File updates**
- **Re-certification & changing environment**
- **Annual/Supplementary reports**
- **Presentation Skills for Final Exam**

Learning objectives

The student will become generally knowledgeable and know how to access general information on the following:

- Basic requirements associated with device changes to a marketed device.
- The underlying principles to establish a clear and consistent approach to decision making associated with changes.
- Understanding the type of regulatory submission applicable to different changes and corresponding time frames.
- The business links involved and relevance of clear instructions and procedures to manage global markets.
- Templates developed by industry experts to ensure consistency in application and decision making will be explored.

Module 12

Final Case Study Presentation and Assessment

Participants having been grouped in teams at the beginning of the programme will prepare a synopsis of the relevant sections of the MDR/IVDR assigned to them for analysis. All students will present and facilitate a Q&A session with class, tutors, examiners and invited Industry guests. The content and clarity of the assignment along with the presentation will equate to 50% of each participants assessment. It is envisaged that all assignments will be collated in a standard format and be presented to the Irish Medtech Association for issuance to Industry members as a useful reference document.

Guest and industry expert lectures

Best Practice Case Studies delivered by industry

Programme team

Carmel McGrath CEO, AlphaMed Consulting Ltd

Carmel McGrath is Director of AlphaMed Consulting Ltd. a regulatory affairs, quality and training consultant to the Medical Device Industry. With 25+ years experience in the Life Science Industry, Carmel has held varying senior roles, incl. Medtronic, Life Care Medical Devices, Covidien and currently supports Creganna Medical along with Advotek International Ltd. Carmel is experienced in dealing with Global Regulatory Authorities including FDA, Notified Bodies (i.e. BSI, NSAI & TUV) European Competent Authorities along with the Canadian authority and TGA Australia and has been at the cold face of many regulatory inspections. She has represented industry on the Post Market Surveillance task force with Eucomed in developing the initial Med Dev. Vigilance guidance document. Carmel has conducted extensive field training throughout Europe, U.S. & China with electronic post market feedback systems introduced.



Robin Stephens CEO & Principal Consultant for Psephos Biomedica

Robin Stephens is CEO & Principal Consultant for Psephos Biomedica, a clinical, regulatory, quality and operations consultancy in client-partnerships / management relationships with entrepreneurial corporations and venture-backed companies. Robin has nearly 30 years' experience in clinical research and regulatory affairs for medical devices worldwide, principally in Europe. He has held several C-level & Board of Director positions, including COO of LCMD and Director of QA/RA/CA for Apica Cardiovascular (acquired by Thoratec). Robin was the Director, International Clinical Research & Regulatory Affairs for Medtronic Vascular, the Managing Director of Global Regulatory Associates, and before that held several positions with CR Bard. He has been Scientific Advisor to a medical technology publishing house as well as an author on regulatory matters and editor of a series of books on biomaterials.



Deirdre Barrow Founder, Independent RA

Deirdre is the founder of Independent RA which provides remote regulatory services to medical device companies. She has over 15 years industrial experience primarily focused in the Regulatory Affairs field. This experience has ranged across the full set of Medical Device classification levels in all the major international markets. Deirdre has worked with a wide variety of industry leaders and innovators, including Abbott Vascular, Medtronic and Biomedical Research. She has extensive experience working in the United States including four years as a Regulatory Affairs specialist with a CRO exclusively retained by the Division of AIDs (a sister body of the FDA). She has qualified for both US and EU RAPS Certification. Deirdre helped design and develop the MSC (Medical Technology Regulatory Affairs) run out of NUIG and SIT and delivers a number of the MSC modules.



Rena Daly Design Quality Assurance Manager, Creganna Medical

Rena is Design Quality Assurance Manager with Creganna Medical and has 16+ years experience in the Medical Device industry. She has extensive knowledge in the Design Control requirements and the expectations of Regulators in proving the Safety and Efficacy of products. Along with her involvement in external agency inspections which include Notified Bodies such as NSAI, DEKRA and BSI, Rena also has exceptional understanding of the FDA requirements and dealing with Investigators during site audits. She is a major contributor in the compilation of responses for (510k) FDA, Korean, ANVISA and Notified Bodies for design projects and is very strategic in her approach ensuring the best outcome for Customers. Rena has been successfully involved in 50+ device submissions to Regulatory Agencies. She is a strong advocate for risk management and the application of same to post market experiences.



Martin Reddington Managing Director, Reidh Consulting

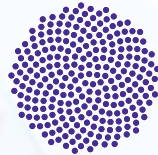
Martin Reddington, Managing Director of Reidh Consulting, is a highly experienced Business Management Consultant and Mentor. 28 years in global corporate leadership, both as an advisor and implementer. A focused, culturally aware expert, with the communication skills, drive, vision and problem solving ability to lead companies to enhanced competitiveness, customer retention and maximising profitability. Specialist in ISO9001, ISO13485 SIX SIGMA, LEAN, Excellence Through People, Quality Service System Standards, Root Cause Analysis & CAPA techniques.





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Irish Medtech Association is a
business sector within Ibec