

**Irish Medtech**  
Association  
**SKILLNET**

Irish Medtech Skillnet

# Training Programmes

QUALITY - TECHNICAL - MANAGEMENT & BUSINESS



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.

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# Introduction

## Foreword Pauline O'Flanagan



**Skillnets actively supports and works with businesses in Ireland to address their current and future skills needs. Skillnets was established in 1999 and is funded from the National Training Fund (NTF) through the Department of Education and Skills (DES). The Irish Medtech Skillnet, established in 2008 provides training to Medical Technologies and Engineering sector.**

On behalf of our Steering Committee I am pleased to present our training. Programmes have been designed to reflect the training needs of the industry. The network provides opportunities to develop and deliver both new and existing training programmes. Apart from delivering QQI level 5 training in Continuous Improvement (Lean/6 Sigma) for operators – the network goes a great deal further – with programmes in quality, technical, research and development, as well as highly strategic sectoral programmes developed for middle and senior management and includes accredited programmes level 5 to level 9 recognised on the National Framework of Qualifications.

In 2015, the Irish Medtech Skillnet developed the first Masters in Medical Technology Regulatory Affairs to up skill RA professionals ahead of the new EU Medical Device Regulatory Framework. In 2016, the skills need was further addressed with the development of a Fundamentals in Regulatory Affairs, Level 8 programme to meet the growing requirements of Irish companies in filling regulatory assurance roles. The network also provides some opportunities to assist with company specific training events. Since 2011, the Irish Medtech Skillnet has run programmes for the unemployed to keep the unemployed workers close to the labour market. The Biopharma Conversion Programme converted 90% to employment in 2015 and the reduction in cost to the state in terms of social welfare payments was approximately €15,000 per month. Building on this success in 2016, we worked in conjunction with the Department of Social Protection, IDA Ireland and Skillnets Ltd to deliver a Level 6 Process Technician programme to convert skilled unemployed to the medtech sector.

If you are not already involved I would encourage you to sign up to-day and:

- Avail of at least 25% funding towards your training

- Access novel training methods for operators at QQI 5 that will minimise impact on your operations
- Access online E learning for Continuous Improvement and Core Skills modules
- Develop best practice training models through a network of experts
- Access high quality low cost training providers through the network
- Avail of co-ordinated training via a dedicated network manager and administrator
- Access training programmes for graduates or job seekers

Companies interested in participating in the network are asked to complete the membership form indicating the size of their company and their proposed financial contribution towards the project. Note that the contribution is from €250 to €500 and is based on company size.

For further information, contact [Michelle.Reinecke-Quain@ibec.ie](mailto:Michelle.Reinecke-Quain@ibec.ie) or visit our website at [www.irishmedtechskillnet.ie](http://www.irishmedtechskillnet.ie)

*Pauline O'Flanagan*

**Pauline O'Flanagan**  
Irish Medtech Skillnet Manager,



**Michelle Reinecke-Quain**  
Network Executive



**Jennifer McCormack**  
Network Executive

**Total expenditure (2008-2015) €4.2m**

### Funding contribution

**40%**  
member companies

**60%**  
state funding

### Targets achieved

**6,000**  
trainees

**30,000**  
training days



# Introduction

## A message from Irish Medtech Skillnet Contracting Organisation Sinead Keogh



**The Irish Medtech Association, the sector within Ibec that represents the Medical Devices and Diagnostics industries in Ireland is delighted to present an overview of Irish Medtech Skillnet training programmes and Irish Medtech Skillnet sponsored programmes.**

As the contracting organisation for the Irish Medtech Skillnet, I wish to pay tribute to the tremendous work done by the Irish Medtech Skillnet Steering Committee under the leadership of Pauline O'Flanagan the Irish Medtech Skillnet network manager and outgoing Chairman Pat O'Neill, Zenith Adhesive Components throughout the year in steering the course and taking professional development within the sector and Irish Medtech Association Statement of Strategy 2016-2020 to the next level. I would also like to welcome incoming Chair Emma Kilgallon, West Pharma and wish her every success in the role.

The availability of key skills and provision of industry-specific, high-quality, cost-effective training has been identified as a key driver. Since 2008, the Irish Medtech Skillnet has been extremely successful in developing niche bespoke programmes in direct response to industry needs. The programmes presented here will support the preservation and growth of jobs, as well as the enhancement of new skills to create new jobs. I would like to thank Irish Medtech Association's working groups for their commitment, foresight and energy in supporting the development of key programmes that will deliver current and future skills needs for the sector.

Ireland is now recognised as a leading emerging global hub for medical technologies. The sector employs over 29,000 people in Ireland which represents 6% of Europe's medtech workforce.

Ireland is one of the largest exporters of medical products in Europe with annual exports of €12.6bn and companies here directly export to over 100 countries worldwide. 18 of the world's top 25 medical technology companies have a base in Ireland and 50% of the 400 medtech companies based here are indigenous. Four decades of developing appropriate policies and competing for international investment have resulted in many of the world's top medical devices and diagnostic companies locating themselves in Ireland, in addition to the growth of a thriving indigenous base.

The sector is evolving at an incredible pace - the global medtech market size is predicted to grow 4.4% over 2011-2018 to reach a value of €325bn by 2018, creating new opportunities and challenges. Ireland's sustained and continued success on the international stage will be underpinned by the availability of key skillsets. We would also like to acknowledge and thank Skillnet Ltd. for their continued commitment and their role in delivering and supporting the future success of the sector here.

To each of our member organisations, I encourage you to ensure that you are getting the most out of what is on offer through the Irish Medtech Skillnet.

**Sinead Keogh**  
Irish Medtech Association Director



**Dr Áine Fox**  
Senior Executive



**Adrienne McDonnell**  
Senior Executive

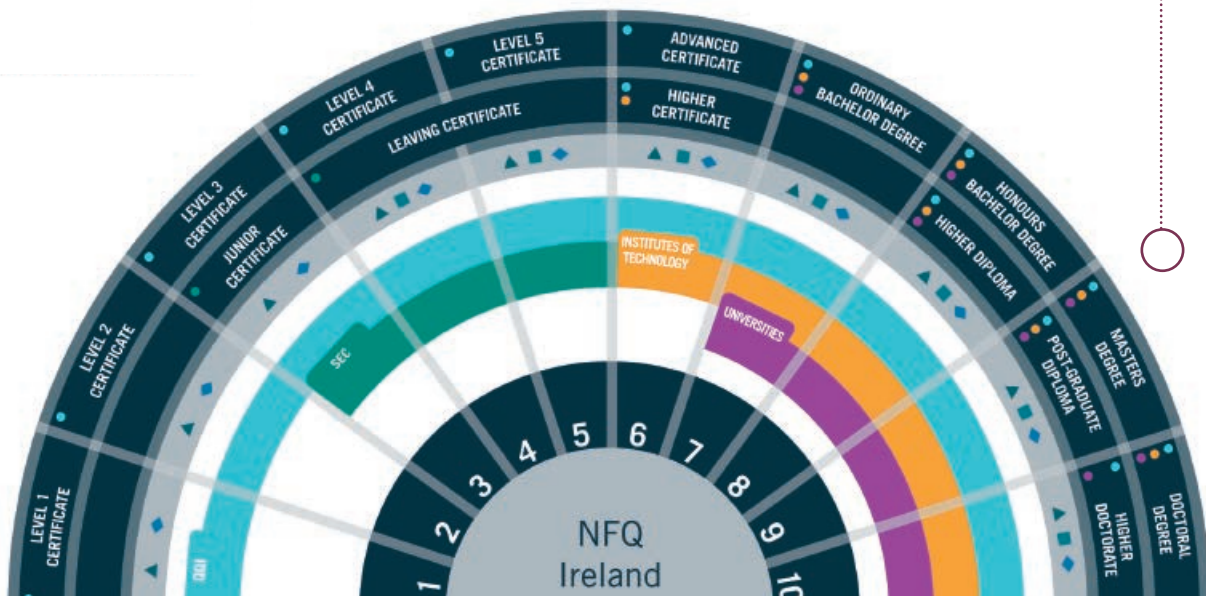


**Ciara Finley**  
Executive

## Awards in the NQF Framework


The NQF, through its ten levels, provides a means of comparing and contrasting national and international education and training qualifications. It helps learners to plan their education and training and employers to identify the qualifications they require.

WE PROVIDE PROGRAMMES AT  
AT LEVELS 5, 6, 8, AND 9



- Quality and Qualifications Ireland (QQI) makes awards in further and higher education and training
- SEC - State Examinations Commission (Department of Education & Science)
- Institutes of Technology
- Universities





**We must embrace the skills revolution, adopting strategies to ensure continuous upskilling and development of Ireland's workforce so that they have the skills needed today for the medtech businesses of tomorrow.**

(Irish Medtech Association Statement of Strategy 2016-2020)



# Quality/Regulatory

Exceeding expectations and  
raising the standards

## Quality/Regulatory

### Lead Auditor Training ISO 13485 IRCA Certified

#### Objectives

During the 5 days participants will acquire knowledge and skills in auditing. However, auditing like any other acquired skill requires practice. The best place to practice and extend your experience is during actual audits.

#### Content Includes

By the end of the course participants will be able to:

- Describe the purpose of a quality management system and explain the 8 principles of quality management
- Explain the purpose, content and interrelationship of ISO 9000, ISO13485, ISO 9004 and ISO 19011
- Interpret requirements of ISO 13485 in the context of an audit
- Manage an audit programme
- Understand the different types of audits.
- Describe the roles and responsibilities of auditors and lead auditors
- Plan and conduct an audit in accordance with ISO 19011, demonstrating ability to:
  - a) Plan and prepare effectively
  - b) Gather objective evidence, through effective interviewing, observation, sampling and note taking
  - c) Analyse and interpret information in order to determine conformance with requirements
- Report the audit, including writing valid, factual and value-adding non-conformity reports
- Undertake audit follow-up activities, including evaluating the effectiveness of corrective action
- Professionally liaise with external auditors
- During the 5 days participants will acquire knowledge and skills in auditing

#### Who Should Attend

Personnel involved in internal auditing, developing and implementing QMS, quality department staff and also those who wish to become practising auditors.

#### Qualification

ISO13485 IRCA certification

#### Training Days

5 days

#### Training Location

Available nationally based on demand

#### Course Cost

Irish Medtech Skillnet Member €680





# Quality/Regulatory

## Internal Auditor Training ISO13485 IRCA Certified

### Objectives

During the two days participants will acquire knowledge and skills in internal auditing. However, auditing like any other acquired skill requires practice. The best place to practice and extend your experience is during actual audits.

### Content Includes

By the end of the course participants will be able to:

- Describe the purpose of a quality management system and explain the 8 principles of quality management
- Explain the purpose, content and interrelationship of ISO 9000, ISO 13485, ISO 9004 and ISO 19011
- Understand the key requirements of ISO 9001
- Interpret requirements of ISO 9001 in the context of an audit
- Understand the different types of audits
- Describe the roles and responsibilities of auditors and lead auditors
- Plan and conduct an audit in accordance with ISO 19011, demonstrating ability to:
  - a) Plan and prepare effectively
  - b) Gather objective evidence, through effective interviewing, observation, sampling and note taking
  - c) Analyse and interpret information in order to determine conformance with requirements

- Report the audit, including writing valid, factual and value-adding nonconformity reports
- Undertake audit follow-up activities, including evaluating the effectiveness of corrective action
- Professionally liaise with external auditors

### Who Should Attend

Personnel involved in internal auditing, developing and implementing QMS, quality department staff and also those who wish to become practising internal auditors.

### Qualification

ISO13485 IRCA certification

### Training Days

2 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €280



**Course very effective as was teaching method used, would recommend.**

**NORMA CONWAY**

Training Coordinator,  
BD Medical Dublin



# Quality/Regulatory

## Design of Experiments

### Objectives

Using advanced analytical tools based on mathematical techniques, this programme will enable trainees to gain a deep understanding of their processes efficiently using a minimum numbers of experimental runs. Modern DOE tools will be presented.

### Content Includes:

On successful completion of this training course, delegates should be able to:

- Plan designed experiments to include appropriate factors and responses
- Analyse factor effects and interaction effects using Minitab computer software
- Interpret the outcome of designed experiments so as to choose factor settings for optimum process performance
- Demonstrate knowledge of the statistics underlying the design of experiments
- Select sampling sizes for inspection using the international sampling plans, such as ANSI/ASQZ1.4, ISO 2859, or BS 6001

### Who Should Attend

Product design and process design engineers  
R&D Engineers and Scientists, QC and QA Personnel

### Training Days

3 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €3,675  
per course or  
€450  
per person

## Statistics with Minitab

### Objectives

Much time and effort is devoted to the collection of data in industry. It is not possible to get most value from this data without using the statistics. There are several brands of reasonably priced computer statistical software packages available to assist in the application of statistics, and most people with a reasonable background in maths (example, pass leaving certificate level) can be readily trained to use this software so as to utilise data for continual process improvement, and better decision making.

### Content Includes:

On completing this course the participant will:

- Understand basic statistical principles
- Know how to analyse the variation that arises in manufacturing processes and business
- Understand the concepts of hypothesis testing and how statistics is used in data-based decision making
- Understand how to establish confidence for the results of data analysis
- Know how to obtain sample sizes for hypothesis testing
- Know how to use Minitab software for statistical analysis
- Have completed Sections VI A, B, C, D, E of the ASQ Certified Quality Engineer curriculum

### Who Should Attend

Engineers, technicians, laboratory, R&D, and scientific staff. All personnel involved in quality control. All personnel who have a role in analysing and understanding manufacturing and business data. Inspection staff.

### Training Days

3 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €450



**Excellent course, one of the best presented courses I have attended. All engineers/ individuals involved in technical roles within manufacturing should attend.**

**SHANE CANNY**

Validation Engineer,  
Stryker Cork



# Quality/Regulatory

## Quality Risk Management and ISO 14971

### Objectives

This ISO 14971:2012 (Risk Assessment to Medical Device) training course is designed to provide attendees with an understanding of the impact that ISO 14971 has on the decision making process at medical device manufacturing firms.

### Content Includes

- State the differences between the various revisions of ISO 14971 and the implications that these have for the manufacture of medical devices
- Interpret the regulations pertaining to Risk Management and ISO 14971 in particular
- Identify and quantify risks associated with medical devices
- Decide on the acceptability of those risks
- Re-evaluate risks following corrective action
- Apply various risk assessment techniques such as FMECA, Fault Tree Analysis and HAZOP

### Who Should Attend

R&D Managers and Engineers, Engineering / Technical / Production personnel, Quality Auditors

### Training Days

1 day

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €1,300 per course or €200 per person

## Process Validation

### Objectives

This is a foundation course in process validation for medical technology industry.

### Content Includes

- Understand the context of Process Validation within the Quality Management System
- Be familiar with the definitions and terminology of validation
- Know about the lifecycle of validation.
- Appreciate the quality regulations pertaining to the Medical Device industry
- Be familiar with the documents containing quality regulations
- Consider what happens if validation goes wrong
- Appreciate their own role in the product they validate, make or support
- Understand the role of process control in maintaining a validated state
- Consider the difference between validation and verification
- Appreciate the documents and records required to support process validation.
- Understand basic concepts of supporting regulations such as Part 11 compliance

### Who Should Attend

Personnel who require an introduction to process validation

### Training Days

1 day

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €150



**Course was very good and well presented and kept my interest all the way through.**

**FINBARR SMITH**

Validation Engineer,  
ProTek Medical Sligo.



# Quality/Regulatory

## Biological Evaluation of Medical Devices, including Chemical Characterization

### Objectives

This course provides an overview of the biological evaluation of medical devices following the guidance contained within the ISO 10993 series and deliver the following learner outcomes:

### Content Includes

- Introduction to biological evaluation concepts
- Understanding and knowing the device as first crucial step to approach biological evaluation
- Chemical characterization of the materials: what does it mean in practice
- Extractable/Leachable studies as a perfect way to characterize many medical devices
- Toxicological assessment (ISO 10993-17) application in order to evaluate obtained data from chemical characterization
- Bridge approach and change management optimization thanks to chemical characterization
- Biocompatibility tests overview
- Biocompatibility testing acceptance by international authority: accreditation requirements and philosophical differences

### Who Should Attend

Medical Technology Professionals

### Training Days

2 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €390

## Quality and Good Manufacturing Practice

QQI 5 Minor Award 5N1959

### Objectives

This programme aims to provide the Life Sciences Sector with a course in quality and good manufacturing practice, which will be available to employees and potential entrants to the sector. It will provide the opportunity to equip trainees with the knowledge, skill and competence to perform a range of manufacturing tasks in compliance with quality standards and good manufacturing practice.

### Content Includes:

- Explore the related regulatory framework as it applies to the life sciences manufacturing sector
- Gain knowledge of the key elements of quality management systems and good manufacturing practice and related documentation
- Distinguish between conforming and non-conforming products and practices
- Acquire skills necessary to implement good manufacturing practice in line with appropriate procedure and regulation
- Develop the academic and vocational language, literacy and/or numeracy skills related to quality and current good manufacturing practice

### Who Should Attend

Personnel working in the Life Sciences Sector

### Qualification

QQI 5 Minor Award 5N1959

### Training Days

2 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €2,970 per course.



A very interactive course that encouraged a fresh look at GMP.

DEIRDRE O'BRIEN  
Merck Millipore



# Quality/Regulatory

## Behaviour Based Quality

### Objectives

Developed specifically to promote accountability, ownership and responsibility for achieving desired quality and performance in the Life Sciences Sector.

Behaviour-based quality is a proven methodology that utilises behavioural psychology processes and techniques to promote accountability, ownership and responsibility for achieving desired quality and performance. This course equips frontline employees and supervisors/team leads/managers with the necessary knowledge and skills to lead and manage quality and performance, using a 6 step behaviour-based quality process, problem solving, communication tools and techniques.

### Content Includes:

- Understand what is Behaviour Based Quality (BBQ)
- Understand the importance and benefits in getting the workforce to buy in to behavioural based quality
- Understand the 6-step behaviour based process
- Improve analysis of behavioural issues
- Maximise people's sense of accountability, ownership and responsibility of behavioural policies
- Understand leadership behaviours
- Communicate quality and performance issues more effectively
- Know how and when to use high impact awareness-raising techniques with a behavioural theme
- Know how to sustain BBQ into a Life Sciences existing Quality Management System

### Who Should Attend

Front line employees, supervisors, managers, team leads working in the Life Sciences Sector

### Training Days

3 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €2,900  
per course

## Cleanroom Operations

QQI Minor Award 5N1921

### Objectives

This programme aims to provide the Life Sciences sector with a course in cleanroom operations, which will be available to employees and potential entrants to the sector. The course will provide the opportunity to equip trainees with the knowledge, skill and competencies to perform a range of tasks in compliance with cleanroom best practice, within the sector.

### Content Includes:

- Define key microbiology terms related to cleanrooms operations in life sciences manufacturing
- Understand the basics of micro-organism growth promotion and control, including the role of heating, ventilation, air conditioning and area classification
- Understand the purpose of viable and non-viable particulate monitoring
- Acquire the skills necessary to perform a range of tasks in compliance with procedure, guidelines, legislation, contamination control and quality assurance
- Develop the academic and vocational language, literacy and/or numeracy skills

### Who Should Attend

Personnel working in the Life Sciences Sector

### Qualification

QQI Minor Award 5N1921

### Training Days

2 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €2,970  
per course



## Quality/Regulatory

### Preparing a Site for a Regulatory Audit

#### Objectives

To give personnel working in a regulatory environment an appreciation of their role in a regulatory audit.

#### Content Includes

By the end of the workshop attendees will:

- Understand the context of the pending regulatory audit
- Appreciate the audit process and their role in the audit
- Remind themselves of the importance of day to day GMPs and working to SOPs
- Consider the consequences of successful / unsuccessful audit outcomes
- Learn about audit behaviour
- Get a chance to practice / role play audit situations that may arise

#### Who Should Attend

All personnel who require an introduction / refresher to regulatory audits

#### Training Days

½ day

#### Training Location

Available nationally based on demand

#### Course Cost

Irish Medtech Skillnet Member €75

### Preparing Subject Matter Experts for a Regulatory Audit

#### Objectives

To prepare subject matter experts for a regulatory audit

#### Content Includes

By the end of the workshop attendees will:

- Understand the context of the pending regulatory audit
- Appreciate audit methods that may be used (focus on the FDA's Quality System Inspection Technique)
- Consider current hot topics / 483'S / Warning Letters etc
- Consider how to explain an overview of their process clearly
- Practice being interviewed on a part of their process
- Receive feedback on their performance, focusing on their audit behaviour

#### Who Should Attend

Process owners, subject matter experts and supervisors who may be audited directly.

#### Training Days

½ day

#### Training Location

Available nationally based on demand

#### Course Cost

Irish Medtech Skillnet Member €75





# Quality/Regulatory

## Foundation Course in ISO 13485:2016

### Objectives

To understand the Medical Devices Quality Management System ISO 13485:2016.

### Content Includes:

- Provide an insight to the use of ISO13485 as the basis for a Quality Management system implemented by medical device manufacturers
- Review the requirements of ISO13485 and make comparisons to ISO9001:2015
- Give participants an understanding of ISO13485 and its alignment to FDA's Quality System Regulation
- Assist participants in the relationship between ISO13485 and ISO14971- Application of risk management to medical devices
- Identify what ISO13485 requires and also what is not required within the standard
- Clarify process management in the context of the requirements of ISO13485
- Give basic audit techniques in meeting the ISO13485 requirements

### Who Should Attend

Personnel working in the Medical Technology Industry

### Training Days

1 day

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €150

## Quality Systems Regulations (QSR's) and Good Manufacturing Practice (GMP) Objectives

### Objectives

To give personnel working in a regulatory environment an appreciation of the quality system regulations and current good manufacturing practice.

### Content Includes

By the end of the workshop attendees will:

- Appreciate the quality regulations pertaining to the Medical Device industry
- Understand the context of these regulations within the Quality Management System
- Appreciate how regulations translate into day to day Good Manufacturing Practices and SOPs
- Be familiar with the Quality System Regulations (FDA's cfr 820)
- Understand their own role and responsibility in applying the above regulations to their job function
- Understand the role of the quality auditor.
- Consider what happens if personnel do not comply with regulations from product and regulatory perspectives
- Appreciate the importance of records and documentation necessary to support a Quality System

### Who Should Attend

Personnel who require an introduction to Quality System Regulations in the medical technologies industry

### Training Days

1 day

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €150



## Root Cause Analysis

### How to use in investigations

#### Objectives

Inadequate CAPA resolution remains one of the leading findings in FDA audit. Identifying the root cause of issues for corrective and preventive actions and complaints can be challenging, but a number of tools can help. A further challenge can be recognizing where and when to use a particular tool, such that the investigation progresses in a timely manner. This course is designed as an overview of the various Root Cause Analysis tools available and, with examples evaluate when each one could and should be used.

#### Content Includes

- The requirements of CAPA
- Problem Solving Approaches – DMAIC, 5 P's 8D's, PCDA
- Analysing Data Sources – incl. SPC, Pareto Analysis
- The initial recording of the investigation, including a look at Cognitive Dissonance and Hindsight Bias
- Defining the Problem – incl IS/IS NOT
- Practical Application of Root Cause Analysis Tools, including:
  - Brainstorming
  - 5 Whys
  - Ishgawa (Fishbone) Root Cause Analysis
  - Fault Tree Analysis
  - Cause & Effect Analysis
  - Failure Mode Effects Analysis

- HAZOP
- Process Mapping
- Barrier analysis
- Force Field Analysis
- Contradiction Matrix
- Pitfalls in RCA and how to avoid them
- Identifying appropriate Corrective & Preventative Actions
- Measuring Effectivity
- Dealing with Repeat Issues
- Preventing Human Error
- Presenting CAPA's at audit

#### Who Should Attend

This course is designed for quality engineers or anyone with a role in investigating or documenting failure investigations in the medical device, industry.

#### Training Days

1 day

#### Training Location

Available nationally based on demand

#### Course Cost

Irish Medtech Skillnet Member €1,125  
per course



**Tools used for CAPA investigations were very well presented, and very interesting overall.**

**BRIAN GARVEY**  
Cook Medical



# Quality/Regulatory

## Technical Report Writing

### Objectives

Having trouble writing technical memos, reports or documents? Attending this comprehensive training course will help you get your message across clearly and save you time. Our structured, practical programme will help you to identify the key message you need to deliver in your written document and to deliver it clearly and concisely in a way that will ensure it is understood.

### Content Includes:

- Get the report right first time
- Analyse the Audience
- Analyse and Interpret Data
- Use Graphics Effectively
- Structure the Report
- Achieve Clarity
- Write a Concise Summary

### Who Should Attend

Engineers, Managers, Scientists and other Technical Personnel involved in disciplines such as Quality, Engineering, Regulatory Affairs, Technical Services and Research and Development

### Training Days

1 day

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €1,388  
per course

## Fundamentals in Medical Technology Regulatory Affairs

(Approval Pending)

### Objectives

A new medical device regulatory framework for the EU has been agreed and will enter into force during 2017. Irish Medtech Skillnet has identified a need for a Level 8 Special Purpose Award to convert/upskill employed life sciences personnel to work in specialist roles in the medical technology regulatory affairs function. In particular, this short condensed industry led programme will offer unique flexibility to companies to adapt rapidly to changing regulatory workloads as remediation activity ahead of the new medical device and IVD Regulations increases.

### Content Includes:

- Introduction to EU, US and Global medical device regulation
- Design control/risk
- Labelling/IFU
- Vigilance/Medical Device Reporting/post market surveillance
- Clinical Studies
- Regulatory Affairs strategy
- Quality Systems for Regulated Industries

### Who Should Attend

Level 7 or higher qualified or persons with over 2 years experience in the regulated life sciences sector

### Qualification

Level 8 Special Purpose Award (approval pending)

### Training Days

12 days over 1 semester

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €2,250





# Quality/Regulatory

## Masters in Medical Technology Regulatory Affairs

NFQ Level 9

### Objectives

The course will enable Regulatory Affairs 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 MSc award at NFQ Level 9.

### Content Includes

#### YEAR 1 SEMESTER 1

- EU Medical Technology Regulatory Affairs - Introduction
- US Medical Technology Regulatory Affairs - Introduction
- Technical Report Writing

#### YEAR 1 SEMESTER 2

- Global Medical Technology Regulatory Affairs - Introduction
- Clinical Evaluation
- Quality Management System

#### YEAR 2 SEMESTER 1

- EU Medical Technology Regulatory Affairs - Advanced
- US Medical Technology Regulatory Affairs - Advanced
- Risk Management, Labelling & Promotion

#### YEAR 2 SEMESTER 2

- Global Medical Technology Regulatory Affairs - Advanced
- Design Assurance, Sterilisation and Biocompatibility
- Post Market Surveillance

### Who Should Attend

Open to students who have obtained a Level 8 primary degree in a science/engineering subject related to the life sciences. Previous or current experience in regulatory affairs (minimum 2 years) may be taken into account in assessing entry qualifications for candidates with relevant Level 7 qualification with appropriate experience.

### Qualification

NFQ Level 9 – 90 credits

### Training Days

Blended learning over 2 years incl. dissertation

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €8,100 per person



The 'blended learning format' and the professionalism demonstrated by both IT Sligo and NUI staff makes the pursuit of the required knowledge both beneficial and enjoyable

**BRIAN O'CONNELL**  
Training and Quality  
Manager, Filtertek



# Quality/Regulatory

## Medical Software Quality Assurance

Level 8 15 Credits NQF award and ISTQB qualification.

### Objectives

Developed specifically to enable computer, science, engineer, technician graduates or equivalent with software background to convert to the Medical Technology Sector.

### Content Includes:

MODULE ONE: Foundations of Software Testing

MODULE TWO: Software Quality Assurance Standards (Medical Devices)

2-3 days per week for 8 weeks

On successful completion of this module, students will be able to:

- 1) Explain the key terminology in medical software testing and inspection
- 2) Understand Medical Software Quality principals, methods and tools
- 3) Understand the difference between Medical Device Software and Generic software
- 4) Recognise the effects of regulations on the Quality Assurance process
- 5) Be knowledgeable on how testing is implemented in the Medical Device industry
- 6) Create documentation in line with a Quality Management System
- 7) Verify that user manuals are regulatory and standards compliant
- 8) Participate in localisation teams
- 9) Review design documentation
- 10) Acknowledge the professional and ethical responsibility of medical software practitioners to produce safe and reliable software

### Who Should Attend

3rd level qualification (certificate, diploma, degree) in Software Engineering or related discipline desired. Experience in software Quality Assurance activities, such as software testing, would be essential if no suitable third level qualification. Applicants may be required to undertake an interview and satisfy the course admission team that they have the ability to complete and benefit from this course.

### Qualification

Level 8 15 Credits NQF award and ISTQB qualification

### Training Days

17 days training

### Training Location

University of Limerick

### Course Cost

Irish Medtech Skillnet Member	€2,300
	per person
	based on 15 people

“

**I would definitely recommend this course for anyone with a software background who wishes to move into the Medical Devices Industry or for people who are already in the industry but wish to move into the Software QA field.**

**The training is excellently structured and presented in a highly professional manner!”**

**MIKE DELANEY**

– Co Limerick, 2015 graduate



## Quality/Regulatory

### Quality and Regulatory Forum for Medical Technologies

#### Objectives

Irish Medtech Association's Quality & Regulatory Forums are held twice yearly and represent important face to face networking events for QA/RA specialists in the medtech sector in Ireland. Forum agendas are developed based upon Irish Medtech Association member feedback and in conjunction with the Chair and the Vice-chair of the Forum and members of Irish Medtech Association's Regulatory Steering Committee. In 2014 and 2015, a major theme of forum meetings was the Revision of the Medical Devices Directives. Forum meetings provided Irish Medtech Association members with updates on the status of the regulations, the legislative process and major milestones as well as updates on important shorter term measures including notified body oversight and unannounced audits. Forum participants are presented with a unique opportunity to benchmark on wide ranging topical quality and regulatory issues and assess impact to business of same.

Typically, industry specialists from across Irish Medtech Association member companies and invited expert national and European speakers (including Notified Bodies/ Competent Authorities etc.) guide Forum participants through a dynamic series of presentations and discussions on diverse topics including post-market surveillance & risk management, CAPA, continuous improvement in quality assurance and audit trends among many others depending on member feedback and requests. Round table breakout sessions are also typically held to facilitate informal interaction between Forum participants, on the day.

#### Who Should Attend

Senior Quality Engineers, Quality Managers, Regulatory Affairs Managers

#### Training Days

1 day

#### Training Location

To be advised

#### Course Cost

Irish Medtech Skillnet Member €75 per person



# Quality/Regulatory

## Global Access Medtech QA/RA Conference

**Irish Medtech Skillnet sponsored event**

### Objectives

Irish Medtech Association's biennial QA/RA Conference (the "Global Access" conference series) plays a critical part in the development and formulation of the future strategy of Ireland's medtech industry. This important forum enables stakeholders from across the US, EU and global locations to discuss and better understand global regulatory developments. The conference has gained an exceptional reputation as one of the best across the EU.



The conference, usually attended by almost 200 national and international leaders in quality and regulatory, typically hosts a large number of key international speakers, including senior representatives from; the European Commission, US Food and Drug Administration (FDA), Eucomed, EDMA, the HPRA, corporate QA/RA Directors and VPs. Past conferences have covered recent developments, trends and case studies related to quality regulations worldwide including perspectives from across Europe, USA, India, China, Russia and the Middle East.

### Who Should Attend

Quality Engineers, Snr Quality Engineers, Quality Managers, Regulatory Affairs and Managers

### Training Days

1.5 days

### Training Location

Galway

### Course Cost

Irish Medtech Association Member    €550  
(ex VAT)





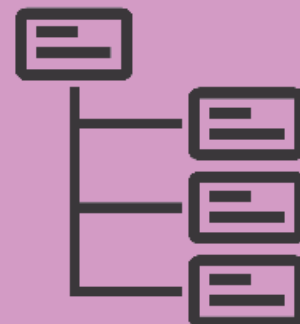
**MAIN:**  
Quality and regulatory Forum,  
Radisson Blu Limerick 18-05-2016

**BELOW LEFT:**  
Launch of the Design for Medical  
Technologies programme,  
University of Limerick 11-02-2015

**BELOW RIGHT:**  
Launching of the MÓR™ Benchmark  
Model Standard at the Irish Medtech  
Association's Manufacturing Conference,  
29-04-2015







# Technical

Innovating today to deliver the healthcare solutions of tomorrow.

On completing the *"Design Innovation for the Cardiovascular Sector"* programme, 95% of the participants state that their overall knowledge, skill and attitude has significantly increased arising from participation in the course.

## Technical

### Design Innovation for the Cardiovascular Sector

#### Objectives

This seminar is developed to enhance understanding of cardiovascular anatomy, physiology and pathophysiology for engineers and researchers working in the medical device sector.

#### Content Includes

The course will go through the basic fundamentals of cardiovascular medicine required for medical device innovation. The focus of the course will be to increase understanding of the cardiovascular system with special focus on emerging medical devices for this area. This is a very practical course with real life every day examples of medical devices in use for cardiovascular diseases.

During the course a session is dedicated to a live transmission from the department of cardiology on a complex percutaneous coronary intervention (PCI). The attendees will also be able to perform a PCI on a simulator as part of the training in the course. The programme was designed in conjunction with National University Hospital Galway and the Irish Medtech Association's R&D Working Group.

“

Perfectly pitched, with excellent balance of theory and practical. Expert's knowledge and presentation skill made this the best course, I have attended. Well done to all concerned.

**TOM O'DONNELL**

Vice President Research & Development,  
New technologies,  
Europe, Merit Medical  
Galway



#### Who Should Attend

Design Engineers and other Medical Technology Professionals

#### Training Days

3 days

#### Training Location

Croí House, Galway

#### Course Cost

Irish Medtech Skillnet Member €875

# Technical

## Design Engineering for Medical Technologies (QQI Level 9 36 ects)

### Objectives

The structure and content of this course will be predominantly motivated by the current observations and challenges encountered by Product Development Managers in building a design engineering team in the medtech sector in Ireland. As such it will be industry led with support from the academic sector and influenced by best in class practices internationally. It will be delivered by seasoned practitioners in the Design Engineering Space.

This course seeks to introduce the “grammar and punctuation” of the design engineering process in translating innovation into a Commercially viable & robust design that delivers against expectations of all stakeholders from upstream marketing to advanced manufacturing to payers, clinicians & patients. Design Engineering knowledge & experience which is relatively nascent in comparison with Ireland’s competitors in this area. This course will serve to help close that gap, to breed a new generation of design engineers in Ireland.

### Proposed learning outcomes to include / Methodologies and Tools:

- Design thinking
- Systematic innovation, brainstorming and creativity
- Interrogation of knowledge/functional/patent databases
- The expertise infrastructure currently available in Ireland, how to engage 3rd level institutes
- Concept Development/ Concept Selection
- The role of prototyping and Testing/ Test Engineering for the Design Engineer
- Human Factors Engineering
- DFMEA/ Design for Manufacture/ Design for Assembly
- Quality Function Deployment

Please note that this list is not exhaustive and is subject to change.

Course content being developed by a taskforce from Irish Medtech Association’s Innovation, Research, Development & Commercialisation Working Group.



### Who Should Attend

Design Engineer/ Manager

### Qualification

QQI Level 9 36 ects

### Training Days

15 days over 8 months

### Training Location

Limerick

### Course Cost

Irish Medtech Skillnet Member €3,750

# Technical

## Machine Upskilling

### Objectives

To design a programme and model to allow for the up-skilling of Machine Operatives in the Medical Technology Industry. Such a model will be modularised and allow for the opportunity for further educational progression

### Content Includes

- Basic Mechanics
- Pneumatics
- Electro-Technology
- Programmatic Logic Control (PLC)
- Injection Moulding
- Extrusion
- Hydraulics
- Vacuum Technology
- Industry Specific Modules

### Who Should Attend

Level 5 Operatives or equivalent who want to up skill to work as technicians

### Qualification

Level 6 on NFQ, or equivalent

### Training Days

To be advised

### Training Location

To be advised

### Course Cost

To be advised

## MÓR™ Benchmarking Model

### Objectives

The MÓR™ Benchmark Model is an Operational Excellence self-assessment tool, which provides a framework that you can take away instantly and use in your organisation. This pioneering industry-driven framework; aptly named MÓR™ (meaning 'great' in Irish), has been developed by the Irish Medtech Association Op Ex Taskforce to support companies drive Operational Excellence. To date almost 50 companies have completed training on the MÓR™ Benchmark Model, equating to 80+ individuals.

The model considers Best in Class lean approaches (for example Shingo, Toyota Production System, Koyibashia, Deming, Schonberger) that enhance companies who are beginning or who are further down the lean journey.

### Content Includes

- Introduction to lean concepts and principles
- How to start a strategy of lean in your organisation
- Provides a lean framework tool that you can download and use to manage and assess your ongoing lean improvement activity

### Who Should Attend

Senior Managers responsible for Lean and Productivity Improvement in your organisation: CEO, COO, Production Manager; Quality Manager; Operational Excellence Manager; Operations Director, Continuous Improvement Manager etc.

### Training Days

½ day

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €150

“

**Excellent training course**

**GER TARPEY**

Production Manager,  
Accellent Galway

## Technical

### Mobile Computer Training

#### Objectives

Capable of converting any training room in to an IT training facility and deliver over 50 computer training programmes nationally at location of choice e.g. Office computer Skills, DTP and Graphic Design, Internet and Web design, PC Support and Maintenance at beginners, intermediate and advance levels.

#### Who Should Attend

Not sector/education specific: as appropriate to each programme level

#### Training Days

1 day

#### Training Location

Available nationally based on demand

#### Course Cost

Irish Medtech Skillnet Member €670 per course

### Total Knee Replacement Surgery

#### Objectives

The orthopaedics programme provides an insight in to total knee replacement surgeries. The procedures are demonstrated from theatre with a Live Video Link from the surgery suite, built exclusively for training and viewing of surgeries from the Lecture Room

#### Content Includes

- Anatomy & Physiology of the Knee
- Disorders of the knee
- Demonstration of two total knee replacement surgeries from theatre explained by a professional as it progresses
- Medical devices in use and recommended improvements.

The programme also provides an opportunity to talk to surgeons and operating room staff. The programme was designed by the IMDA in conjunction with leading Clinicians at Cappagh Orthopaedic Hospital and Irish Medtech Association's R&D Working Group.

#### Who Should Attend

Design Engineers, Technicians, Operators

#### Training Days

1 day

#### Training Location

Cappagh National Orthopaedic Hospital, Dublin

#### Course Cost

Irish Medtech Skillnet Member €150



**Well presented and great interaction with surgeons**

**TRIONA KENNEDY**  
Snr Project Manager &  
Business Process Dev,  
R&D – Stryker Cork





## Technical

### Executive Lean Awareness Training

#### Objectives

Highlight the culture required for an effective and sustainable lean initiative. Outline Irish Medtech Skillnet Lean programme and share experiences of how successful sites implement Lean.

#### Content Includes

- 1-hour preparatory teleconference to evaluate current Lean implementation
- Build observations into 3-hour feedback and awareness training to be delivered to the site Leadership team on site

#### Who Should Attend

Site leadership team

#### Training Days

3 hours

#### Training Location

Available nationally based on demand

#### Course Cost

Irish Medtech Skillnet Member €750

### Lean Intensive Foundation Training

#### Objectives

Generate an understanding of the key elements of Lean and 6 Sigma.

#### Content Includes

- Overview of VSM
- 5S Workplace Organisation
- Flow Process
- Problem solving Techniques
- DMAIC Process
- Equipment Effectiveness and OEE
- Changeover SMED
- Metrics

#### Who Should Attend

Lean leaders and front line associates

#### Training Days

1 day

#### Training Location

Available nationally based on demand

#### Course Cost

Irish Medtech Skillnet Member €920

“

Provides a great foundation to increase awareness and understanding of lean and 6 sigma methodologies and their application to process improvement.

ORLA KEADY-GIBLIN

Snr HR Officer - Projects  
Hollister ULC,  
Co. Mayo





**MAIN:**  
Launch of Medtech & Engineering  
EHS/OHS forum, Thermo King,  
Galway 25-08-2015

**BELOW LEFT:**  
Driving Operational Excellence  
through Lean Leadership (NFQ 9)  
Allergan Pharmaceuticals 11-11-2015

**BELOW RIGHT:**  
Launch of Medtech & Engineering  
EHS/OHS forum, Thermo King, Galway  
25-05-2015



## Technical

### Applied Continuous Improvement

#### Objectives

Developed specifically to promote the application of Continuous Improvement programmes and to accelerate lean initiatives in the Life Sciences Sector

Applied Continuous Improvement focuses on the practical application of CI throughout a facility. It teaches participants techniques to successfully gather, assess and implement lean improvements and demonstrates a step by step path through the process. It promotes accountability, ownership and responsibility for achieving desired performance improvements. This course equips leaders and project team participants with the necessary knowledge and skills on Project Management, Flow, Problem Solving and Managing CI and uses company specific examples and opportunities in an applied learning environment.

#### Content Includes

- Understand what is Continuous Improvement (CI)
- Enable and support the site CI initiative through facilitated and applied learning
- Use DMAIC in Project Management
- Managing Transformation
- Understand the Theory of Constraints
- Understand ways to identify and prioritise CI projects
- Use 5 methods of data gathering/interrogation
- Know how to implement proactive error proofing
- Practice methodologies to maximise project team effectiveness
- Maximise people's sense of accountability, ownership and responsibility for CI
- Know how to sustain CI in a Life Sciences environment

#### Who Should Attend

Frontline employees, Project team participants, Project Managers, Team Leads/ Supervisors, Managers

#### Training Days

4 days

#### Training Location

Available nationally based on demand

#### Course Cost

Irish Medtech Skillnet Member €3,900 per course

“

**My expectations were fully met. Really well designed.**

**AGNIESZKA PIASKOWSKA**  
Quality Engineer -  
Accellent Galway



## Technical

### Continuous Improvement in Manufacturing

QQI 5 Minor Award 5N1915

#### Objectives

The primary objective of this CI blended learning programme is to train and certify employees within the Life Sciences sector in CI methodologies and tools (Lean & Six Sigma). It is expected that participants will gain a thorough understanding of Lean Principles and be able to implement 'lean' improvements in their areas of responsibility, thereby assisting in the transformation of their organisation into a leaner and more competitive enterprise leading to added value to products and services.

#### Content Includes

- Introduction to Continuous Improvement
- Value Stream
- 5S and the Visual Factory
- Problem Solving / Mistake Proofing
- Control of Variances
- Equipment Effectiveness & Performance (TPM, OEE, SMED)
- 7 Sustaining Progress

“

This course brings the perfect balance between training & application of continuous improvement principles. The training is excellently structured and presented in a highly professional manner”



**PETER KEATING**

OpEx Program Lead,  
Abbott Diabetes Care,  
Donegal

#### Who Should Attend

Personnel working in the Life Sciences Sector

#### Qualification

QQI Level 5 minor award on NFQ

#### Training Days

7 x 2 hour modules

#### Training Location

Delivered nationally by blended learning or direct training

#### Course Cost

Irish Medtech Skillnet Member €3,360 per course (based on 12 people). For blended learning costs contact Irish Medtech Skillnet



# Technical

## Product Development Best Practice Assessment Model

Identify Invent Implement Integrate

### Objectives

The process of bringing new products and services from initial concept to commercialisation is hugely complex and it is Irish Medtech Association's vision that Ireland will be a world leading centre for medical technology product development. Irish Medtech Association's Product Development Best Practice Assessment model enables companies to assess their current R&D practices against leading edge Design Thinking and integrated Knowledge-Based approach.

The industry developed model highlights the standards required at each step along the iterative journey from early stage observation of problems through to final stage prototyping and product selection. It specifically covers Technology Readiness Levels 2 to 6 and succinctly demonstrates what needs to be done and how best practice companies integrate these activities. In an easy to use format, it allows companies of all sizes and at all stages of Innovation engagement to compare their current practice with the key attributes of leading-edge principles.

### Learning Objectives

- Succinct presentation of best practice thinking that allows companies to readily assess their relative position versus optimal Product Development
- Highlight opportunities for improvement and help prioritise next actions on the Journey to Excellence

(Note: In the next phase of development of this model, it is intended to set up a community of users who will share best practice tactical tools and techniques used to deliver the iNNOVATE4 best practice recommendations).

### Who Should Use the Tool?

- Start Ups to MNC's engaged in Product Development
- CEO's together with their Leadership Team when developing strategy or seeking Product Development process improvements
- R&D Manager to trigger a regular (annual) review of system performance
- Extended Product Development team members as a learning tool on Best Practice

### Training Days

1 full day consultant led facilitated sessions

### Training Location

In company

### Course Cost

Irish Medtech Skillnet Member €1,500



**Irish Medtech Association's Product Development Assessment Tool represents best international practice in product and process design, and provides a framework for Irish Medtech companies to prepare a roadmap to product development excellence.**

**DECLAN SLEMON**

Director Homecare Programmes, Aerogen Ltd





## Technical

### Behaviour Based Safety Programme for the medical technology and engineering sectors.

(To be developed)

#### Rationale

As the medical technology and engineering sectors are becoming more advanced with increased automation, a strong safety culture is critical to maintaining a high safety record. How often have we experienced situations in which an employee's competence in a work process is assessed at the point that they leave the training room with the assumption that, once learned, the process will be applied correctly and safely? This fails to take account of the many factors that influence and reinforce learning and behaviours. Behaviour Based Safety (BBS) addresses these factors. The Irish Medtech Association's Occupational Health and Safety & Environment Health and Safety (OHS/EHS) group proposed the development and/ modification of their existing Behaviour Based Safety programme and tailor it to industry's needs.

#### Who Should Attend

All personnel working in the medical technology and engineering sectors.

#### Qualification

None

#### Training Days

In development

#### Training Location

Available nationally based on demand

#### Course Cost

To be advised

### Engineering Process Technician Programme

#### Objectives

The Medical Technology and engineering sector have requirements for skilled workers in engineering process technicians' roles. This programme was designed to meet the educational and vocational needs of the unemployed to support their progression to fill these roles in the medical technology and engineering sector in Ireland.

#### Content includes

GMP & Quality Assurance, Electromechanical Technology, Hydraulics & Pneumatics, Basic metrology, Reading Drawings, Injection Moulding 1

#### Who Should Attend

Ideally level 6 education or equivalent experience in engineering, mechanical, medical technology or life science environment

#### Qualification

Special Purpose Award Level 6 30 ects on NFQ

#### Training Days

2 days per week/ 15 weeks

#### Training Location

Available nationally based on demand

#### Course Cost

Irish Medtech Skillnet Member	€2,850 per person based on 16 participants
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**MAIN:**  
Engineering Process Control  
Technician Conversion Programme,  
IT Sligo 07-09-2015

**BELOW LEFT:**  
Quality and Regulatory Forum, Clayton  
Hotel Galway 18-11-2015

**BELOW RIGHT:**  
Midlands Industrial Expo Mullingar  
18-06-2015





# Management & Business

Developing industry leaders  
of tomorrow

100% of senior professionals from 14 Medical technology companies across Ireland stated that they could apply the learning to the job after completing a practical value stream mapping exercise in Beaumont Hospital as part of the *"Driving Operational Excellence through Lean Leadership"* programme.



# Management & Business

## Medical Devices and Diagnostic Leadership Programme

Programme run by the Irish Medtech Association



### Objectives

There are currently over 400+ medical technology companies in Ireland, exporting €12.6bn worth of product annually and employing 29,000 people –the highest number of people working in the industry in any country in Europe, per head of population. This 8 day programme was developed by industry leaders for the industry leaders of tomorrow to enhance the capabilities of the sector's current and future leaders.

The Programme, now in its tenth year, is specifically aimed at middle to senior management. The Programme has been reviewed every year and is fully accredited by the Institute of Leadership and Management (ILM).

### Contents Includes:

- Personal Development
- Strategy
- Finance
- Quality and Regulatory Affairs
- Clinical Anatomy, Physiology and Cardiology
- Diagnostics and Clinical Trials
- Innovation
- Marketing and Sales
- Employment Law



### Who Should Attend

The Programme is specifically aimed at middle to senior management

### Qualification

Institute of Leadership and Management (ILM) certification

### Training Days

8 days

### Training Location

To be advised

### Course Cost

Irish Medtech Association Member €1,950



**A great learning opportunity for those committed to leadership and advancement within the medtech sector**

**PATRICK REDMOND**  
Managing Director,  
Siemens Healthcare  
Diagnostics

# Management & Business

## Driving Operational Excellence through Lean Leadership

QQI Level 9 Award

### Objectives

The aim of the programme is to introduce delegates to the importance of Lean Leadership and Lean operational transformation skills. This programme has been uniquely developed by the Irish Medtech Association Operational Excellence Taskforce, and will incorporate a 3 day immersed practical hands-on approach to learning.

### Content Includes:

- The evolution of Lean Thinking and Understanding Demand and Planning for Change
- The Key concepts of Lean Thinking and the points of view of several key writers
- The development of the concept of the “Lean Enterprise” and its philosophy and principles and applying that knowledge to different environments
- Evaluating existing levels of competence in relation to Lean to promote self-directed future learning and identify the most appropriate strategy
- Identifying the potential benefits and challenges of Lean
- Describing how other improvement approaches link or integrate to Lean (specifically Six Sigma, BPR, TQM, and the Theory of Constraints)
- Discussion on the integration of the MÓR™ Benchmark Model with Lean Thinking and Practice

A practical value stream mapping exercise, enabling delegates to understand how to best analyse and improve their system performance:

- How to use mapping tools to make interventions at a “systems” level in an organisation and why this is an important precursor to other mapping methodologies
- Construction of a current state and the design of the ideal and future state maps

- How to derive a development plan from the mapping process in line with the strategic plan
- How to monitor the achievement of plans
- How the company describes productivity and what it does with this information

Case study materials will provide examples of the complete process.

The role of the Lean leader in “Providing Direction” and “Developing People”.

- An introduction to the strategic, operational and people aspects of lean thinking, as well as the concept of sustaining changes
- Understanding the role of lean management and leadership and the importance of being able to join up the dots – redesign without creating islands of excellence
- The role of the leader in the development of people both directly and systematically

### Who Should Attend

The course is relevant to senior management/ executive level personnel within Medical Device industry across a broad range of disciplines: Operations, Supply chain, Finance & Quality.

### Qualification

Level 8 on NFQ 6 ECTS

### Training Days

8 days

### Training Location

To be advised

### Course Cost

Irish Medtech Skillnet Member €1,750



**Exceeded expectations in content, delivery, academic references and facilitating student cross feedback. The professionalism of lecturers was exceptional.**

**PADHRAIC MCGINN**  
Plant Manager, Nypro





# Management & Business

## Managing People Skills

### Objectives

This programme is designed to assist managers to build on the skills introduced in our Managing People Programme. Participants will gain a greater understanding of their communication style and its impact on those they manage.

### Content Includes:

- The self-aware leader
- Personality profiling
- Managing your own performance
- Planning cascade: strategy to action
- Managing difficult people
- Getting your point across
- Effective teambuilding
- Managing meetings
- Presentation skills
- Understanding other's behaviour

### Who Should Attend

Front-line managers who wish to make a more effective contribution to the organisation.

### Qualification

Level 6 on the National Framework of Qualifications (5 ECTS)

### Training Days

4 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €560  
per course

## Health, Safety and Environmental Awareness

QQI 5 Minor Award 5N1959

### Objectives

This programme aims to provide the Life Sciences sector with a course in health, safety and environmental awareness, which will be available to employees and potential entrants to the sector. The course provides the opportunity to equip trainees with the knowledge, skill and competencies to perform a range of manufacturing tasks in compliance with current health, safety and environmental regulations and controls.

### Content Includes:

- Understand the related regulatory framework and licencing procedures as they apply to the life sciences sector
- Gain knowledge of the key elements of health and safety and environmental and waste management systems, related documentation and record keeping
- Gain an awareness of the impact of work practices on the environment
- Acquire skills and competencies necessary to manage/respond appropriately to a range of environment threatening situations
- Develop the academic and vocational language, literacy and/or numeracy skills related to health, safety and environmental awareness



### Who Should Attend

Personnel working in the Life Sciences Sector

### Qualification

QQI Level 5 minor award on NFQ

### Training Days

2 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €2,970  
per course

# Management & Business

## Project Management Essentials

### Objectives

This course will provide the learner with an understanding of Project Management, and supply them with tools and techniques they can use to plan the scope and timeline required for their project.

This course is delivered by a Project Management Institute (PMI) Registered Education provider. The attendees can continue on after this course and prepare themselves for the internationally recognized PMP certification.

### Content Includes:

Upon completion of this course, the participant will:

- Be able to identify and define the key project phases and stakeholders
- Understand all phases of a project
- Master fundamental project management skills, concepts, tools and techniques
- Be capable of using the essential tools and techniques to plan a project
- Estimate project resources and schedules
- Be able to schedule project tasks and work packages effectively
- Be capable of producing and implementing a PM growth plan encouraging continuing further learning
- Appreciate what project management can do for the business

“

**I see an immediate positive shift in behaviour in people managers who have attended. I would recommend this course when developing people management skills because we got great results**

**BARRY DAVIS**

HR Learning & Development  
Creganna-Tactx Medical

### Who Should Attend

Personnel in project management roles

### Training Days

1 day

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €150



# Management & Business

## Project Management Professional

### Objectives

The Project Management Professional (PMP®) certification is the most widely recognised certification available to Project Managers worldwide. This course combining classroom training and a web-accessible PMP exam simulator is geared towards achieving PMP certification. This course is designed and delivered by a Project Management Institute (PMI) Registered Education provider.

### Content Includes:

Upon completion of this course; the participant will:

- Be prepared to sit the PMP® exam
- Apply approved Project Management principles to their work
- Apply PMI recognised project management tools, techniques and methods for during the 5 process groups of planning, execution and monitoring and controlling and closing
- Comprehend and appreciate PMI® methodologies and definitions
- Demonstrate project management skills at a professional level
- Appreciate and manage the Triple constraints of Time, Cost & Quality with respect to project performance

- Exhibit the essential skills necessary for project managers
- Evaluate the importance of effective management of the project life cycle
- Apply methods, tools and techniques for planning, monitoring and controlling projects and for managing risk
- Demonstrate the core project management competencies
- Be comfortable with the examination format and typical question styles

### Who Should Attend

Given that this is a highly-focused course aimed towards final exam preparation; participants must already have experience of managing projects and intend to sit the PMP or CAPM exam.

### Qualification

Preparation for PMP exam

### Training Days

4 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €720



**Excellent and intense 4 day course that educates and prepares you for the PMI certification like no other. The PM learning and thought process packed into the time frame is time well spent.**

**PADRAIC BRODERICK**  
University Program Manager  
Transitions, Galway



# Management & Business

## Communications

QQI 5 Minor Award 5N0690

### Objectives

This programme aims to provide the Life Sciences Sector with a course in communications skills development, which will be available to employees and potential entrants to the sector. It is expected that the programme will lead to more effective interpersonal and work related communications between individuals and teams.

### Content Includes:

- Acquire communications skills relevant to work related, personal and interpersonal development
- Explore the use of modern information and communications technology (ICT), in personal and work related lives
- Develop an awareness of the essential role played by communications and relevant legislation in human interaction
- Develop the academic and vocational language, literacy and/or numeracy skills related to communications

### Who Should Attend

Personnel working in the Life Sciences Sector

### Qualification

QQI Level 5 minor award on NFQ

### Training Days

2 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €2,970  
per course

## Train the Trainer

QQI Level 6 award 6N3326

### Objectives

This programme is aimed at new and experienced trainers and is designed to equip participants with the knowledge and skills necessary to design, assess and evaluate training programmes and embraces a range of highly participative learning methods and features.

### Content Includes:

- Understand the different learning styles
- Understand the functions and processes of learning and training
- Evaluate different approaches to training
- Appreciate the importance of training on an individual, social and economic level
- Work effectively with a range of learner groups
- Design, deliver and evaluate training programmes
- Develop and implement appropriate assessment methods

### Who Should Attend

Participants are required to have achieved leaving certificate or equivalent level of qualification.

### Qualification

QQI 6 on NFQ

### Training Days

4 days

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €3,375  
per course



# Management & Business

## Digital Marketing Strategies for Medical Technologies

This is a bespoke programme to assist Medical Technology companies to understand the possibilities of using Digital Marketing in the Medtech sector. The programme is aimed at leadership teams who have not yet embraced or harnessed the opportunities digital marketing within their organisations.

The programme will allow delegates gain an appreciation and the merits of using Digital Marketing, without getting into the tactics. There will be case studies from Medtech companies who have already been using digital for their business, such as analytics, big data, customer journeys, social media, apps, etc.

### Objectives

- **Digital Trends – Ireland & beyond**
  - Internet behavior, Ireland, & globally
  - Mobile trends
  - Business to Business becomes Person to Person
- **5 Big Themes**
  - Mobile
  - Content
  - Social Engagement
  - eCommerce
  - Big Data
- **Digital Marketing Strategy**
  - The Steps to creating a great digital marketing plan
  - Scenario for B2B
  - Scenario for B2C
  - Examples from MedTech & broader

- **Digital Marketing Channels Overview**
  - High Level Overview of value of & relevant usage of following channels:
  - Search Engine Marketing
  - Content Marketing
  - Email
  - Social
  - Mobile marketing (apps & more)
  - Examples where possible from MedTech, but will need to showcase meaningful examples from other sectors also.
- **Measurement**
  - Track what's happening
  - Understanding the results
- **Industry Case study**

### Who Should Attend

Leadership teams – CEO, COO, CMO's, CFOs, or employees assigned to implement a digital marketing strategy for their company

### Qualification

QQI 6 on NFQ

### Training Days

1 day

### Training Location

Available nationally based on demand

### Course Cost

Irish Medtech Skillnet Member €120



# Irish Medtech Skillnet Steering Group



## Chair

**Emma Kilgallon**  
West Pharma

## Steering Group Members

**Padraic Broderick**  
Transitions Optical Limited, Galway

**Annette Costello**  
Stryker, Limerick

**Louis Davis**  
Anecto Ltd, Galway

**Lisa Egan**  
Sanmina, Cork

**Miriam Garry**  
Stryker, Limerick

**Thomas Glynn**  
West Pharma, Dublin

**Karen Kelly**  
Beckman Coulter, Clare

**Lorraine Kirk**  
Bellurgan Precision Engineering Ltd,  
Louth

**Paula O'Brien**  
Genzyme Ireland, Waterford

**Mary O'Donovan**  
Boston Scientific Ltd, Cork

**Pat O'Neill**  
Zenith Adhesive Components, Athlone

**Claire Ryan O'Keefe**  
DePuy Ireland, Cork

**Tony Scanlon**  
Medtronic, Galway





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Irish Medtech Association is a business sector within Ibec