



The **Medical Technology Leadership Programme** (incorporating Connected Health) has been developed by Irish Medtech Association members to enhance the capabilities of the sector's current and future leaders and to provide the industry in Ireland with value for money training at the highest level of quality.

The Future Leaders programme, now in its fifteenth year, is specifically aimed at middle to senior management in the medical technology industry and is fully accredited by ILM, a City & Guilds business.

About the programme

Many in or aspiring to leadership positions will often specialise in a specific function or area within their company. This programme has been developed to provide participants with a fundamental knowledge of all aspects of the medtech business required for strategic leadership, from finance to strategy, clinical investigations to employment law. The programme is delivered through a series of interactive full day workshops and practical demonstrations, facilitated by industry experts.

Accreditation

The programme is fully endorsed by ILM, a City & Guilds business.

Who should attend

Aimed at middle to senior management from all functions (scientists, quality & regulatory affairs, engineering, product and product development, business development, marketing, investment and acquisition, HR etc).

Delivery

Interactive, module-based workshops delivered virtually over 10 online sessions as outlined below.

*Candidates will be required to participate in all modules. (Please note, places cannot be offered on missed modules during future programmes)

Member Price: €1,400

October 2021 | Virtual Classroom

Monday 18 October Personal Development Strategy

Wednesday 20 October Regulatory Affairs

November 2021 | Virtual Classroom

Monday 22 November Innovation

Tuesday 23 November Clinical anatomy, Applied Physiology and Cardiology Wednesday 24 November Diagnostics and Clinical Trials

January 2022 | Virtual Classroom

Monday 10 January Sales and Marketing Tuesday 11 January Employment Law Wednesday 12 January Finance

Programme enquiries:

Book your place online: www.connectedhealthskillnet.ie or contact: jennifer.mccormack@ibec.ie / 01 605 1537



October 2021

Venue: Virtual Classroom



Personal Development

9:30 - 16.30

Personality profiling / coaching

Pre-course assessment with feedback given on the first day. There is also an option of one to one call with the course tutor to discuss results.

- Understanding yourself and others
- What are your strengths?
- Identify your management profile
- Who are those you relate best to and why?
- Identifying the challenges in your role

Profiling in Practice

- What are your personal values?
- Identifying the important things in your life
- Thinking about how you live your life now

Leadership & Self Awareness

- Styles of leaders
- Your style
- Situational leadership
- Leadership in your organisation
- Best practice in leading organisations

The role of power and influence in being a leader:

- Types of power
- Making decisions with confidence
- Developing leadership strategies that work
- Drawing up a vision for your area
- Understanding the role of teams when leading others

20th Regulatory Affairs

9:30 - 13.00

The Session will be delivered via a live half-day virtual workshop on 20th October, plus, a 2 x 1-hour pre-recorded lectures that should be viewed in advance of the live workshop.

Introduction to Regulatory Affairs

- Overview of key players in the International regulatory world
- Overview of New EU Regulations (MDR and IVDR), Former Directives (AIMD, MDD) and current IVD Directive and key
- Update on the UK including Brexit and the UKCA
- Introduction to EU Regulatory Affairs
- Overview of New EU Regulations (MDR and IVDR), Current Directives (AIMD, MDD, IVDD) and key changes
- **EU Classification**
- CE Mark
- Conformity Assessment (ERs and GSPRs)
- Technical Documentation
- Standards and Harmonisation
- EU Commission Guidance
- US FDA regulations and standards
- **US Classification**
- Overview of Submission types
- Quality Management systems standard: ISO 13485 and QSRs
- MDSAP
- Overview of regulatory system for other key markets: Canada, Australia and Japan
- Product Lifecycle and Regulatory Affairs
- Risk management and 14971
- Cybersecurity
- Design Cycle
- Planning for Future Regulatory Changes
- Recap & Quiz



Strategy

9:30 - 16.30

Introduction to Strategy

- Perspectives on strategy and what they mean today
- What kind of strategy do you have for your team?
- Putting Strategy into action
- Understanding what strategy is
- What does it mean for my team and me?
- Steps involved in drawing up a strategic plan for my area.

Profiling in Practice

- Best practice examples of innovative strategies
- What is my style and approach and how does this affect my people?

- Bringing my team along
- What impacts on the way a team 'lives' the strategy we put together?
- Keeping motivation levels high throughout the process
- Practical tips in making the strategic plan work, delivering real results
- How to set strategy internally and its importance to you and your department
- 'How to live it' impact on the individual
- How to influence strategy development at senior Level



November 2021

Venue: Virual Classroom



Innovation

9:30 - 16.30

This interactive virtual session will explain the innovation process from ideation to commercialisation using real world examples and case studies to accelerate learning.

Content includes:

- The Innovation Process:
 - Introduction to Innovation
 - Overview & Value of Innovation
 - Innovation Makeover for Medtech
 - · Innovation Process Flow & Output
 - New Services & Business models for Medtech growth

Approaches to innovation in multinationals

• Innovation culture in a regulated environment

The Patent Process:

Patent Overview - Europe and US

· Connected Health

Idea to Commercialisation: Output & Action

- Ideas to Commercialisation Output Actions
- Lab Notebooks
- CTM & Assignment
- · Bond with Clinicians; Start-up Vs Multinational
- Innovation output Summary
- Recap and quiz



Clinical Anatomy, Physiology & Cardiology

9:30 - 16.30

This virtual session is facilitated by the Royal College of Surgeons in Ireland (RCSI) and will include:

- Cardiovascular System
- Applied Physiology and Cardiology
- Mechanisms of Disease and Applied Pathology
- Bone, Cartilage and Orthopaedic Applications



Diagnostics & Clinical Trials

9:30 - 16.30

This virtual session is facilitated by the Royal College of Surgeons in Ireland (RCSI) and will include:

- Applications of diagnostic equipment and test in pathology
- Clinical evaluation
- · Clinical trials management



Programme

January 2022



Sales & Marketing

9:30 - 13.00

This virtual workshop will explain the importance of and key considerations for Medical Device sales and marketing strategies. Content will include:

- Medical device marketing
- Sales and marketing cross-functional interface
- R&D, RA, Manufacturing
- Marketing's role in product development
- Health economics and reimbursement Creating value
- Customer needs identification
- Case study Medical Device Sales Strategies
- Shifting environment of medical device sales
- Selling into hospitals decision makers
- Selling channels
- Key Account Management
- Selling challenges and prioritization
- Recap and quiz

To accelerate learning, pre-reading taking approximately 30 minutes is required in advance of the session.





Employment Law

9:30 - 13.00

This half-day virtual session will cover fundamental aspects of Employment Law including:

- Contracts of Employment
- Maximum working time, breaks, and rest requirements and right to disconnect
- Employment Equality
- Discipline and Dismissals
- New developments in the legislation
- Recap and quiz



Finance

9:30 - 13.00

Confused by the language of finance? – many people are, yet as managers we need to understand the impact we and others have on our business and the levers to pull to improve performance. This interactive virtual workshop will build your confidence and understanding of the essential principles of finance, including:

- The key financial statements what they tell us and what they don't
- How to interpret the statements, key performance indicators and the right questions to ask
- How to approach forecasting and budgeting
- How to evaluate a project's financial viability
- Recap and quiz

To accelerate learning, pre-work taking approximately 30 minutes is required in advance of the session.



Programme Team



Deirdre BarrowSENIOR REGULATORY AFFAIRS CONSULTANT, INDEPENDENT RA

Deirdre Barrow - Deirdre is the founder of Independent RA which provides remote regulatory services to medical device companies. Deirdre has 20+ years extensive industrial experience primarily focused in the RA field. Her experience to date has ranged across the full set of Medical Device classification levels in all the major international markets. She has worked with many industry leaders and innovators, including Abbott Vascular, Medtronic and Biomedical Research and has extensive experience working in the United States including four years as a RA specialist with a CRO exclusively retained by the Division of AIDs (a sister body of the FDA). Deirdre holds a Masters Degree in Medical Technology Regulatory Affairs from Cranfield University and has qualified for both US and EU RAPS Certification.



Laura Caden 1360 MEDICAL

Laura works as Development and Operations manager for i360medical, a healthcare Solutions and Medical Device Innovation Company that provides its innovation to commercialisation programs to Global Hospital Systems, the medical device industry and clinical communities. Laura has worked across all sectors of the medical device industry, inclusive of start-ups, multinationals and corporations looking to diversify their business portfolios into medical device design and manufacture. Her role in i360medical involves overseeing the design and development of novel applications, from concept prototyping through to commercialisation readiness. With a background in Biomedical Engineering from NUI Galway and a Master's of Science in Mobile Application Design, Laura is deeply involved in the detail of the projects, and aims to drive innovation using insight to user/clinical needs and design inputs.



Bríd DeeringHR COMPLIANCE TRAINER/CONSULTANT, PEOPLESKILLS LTD

Bríd is the founder of PeopleSkills Ltd, a HR Compliance training company. Before setting up PeopleSkills Ltd in 2006, Bríd worked as the HR Manager Ireland for Wyeth Pharmaceuticals and as an Industrial Relations Executive for Ibec. During her time with Ibec Bríd advised employers on all areas of HR, employment law and industrial relations and represented companies before the Labour Court and IR Institutions. Bríd holds a Masters in Occ. Psych. & HRM; a Post Graduate Diploma in Employment Law and Certificates in Training & Development, Stress Management, Mediation, Conflict Resolution and Nutrition. Brid is an MII Certified Mediator.



Emma Heuston
BBS, MCIM, DIRECTOR, GLOBAL STRATEGIC MARKETING, COOK MEDICAL

Emma is a 20-year B2B expert in market strategy, driving demand and building successful, profitable organisations. Her work in many industries, including 8 years in Medical devices; is focused on helping them understand how to optimise their strategy and align organisational goals to accelerate growth. As Director, Global Strategic Marketing within the MedSurg division of Cook Medical, the world's largest privately held medical device manufacturer, she leads the global marketing function for areas including division strategy, go-to market planning and market category creation.



Prof Clive Lee
PHD, MD, SCD (DUBL), FRCSI, FRCSED, FAS, CENG, FIEI, HRHA, HONFTCD,
PROFESSOR OF ANATOMY, RCSI

Clive Lee is the Professor of Anatomy in the RCSI and the Royal Hibernian Academy (RHA) and Visiting Professor of Biomechanics in Trinity College Dublin (TCD). After qualifying in medicine and Internship, he was a Demonstrator and Locum Lecturer in Anatomy in TCD, obtaining his MSc in anatomy. He joined the Dublin Surgical Training Scheme and became a Fellow of both the Dublin and Edinburgh Royal Colleges of Surgeons in 1989. In the same year, he was appointed Lecturer in Anatomy in RCSI. After obtaining his PhD in bone biomechanics, he was a Fulbright Scholar at Harvard Medical School and was awarded his MD in 1997. He was appointed Chairman of Department in 2000 and Professor of Anatomy in RCSI in 2002, and in the RHA in 2007. He is a Chartered Engineer, past President of the Section of Bioengineering of the Royal Academy of Medicine in Ireland and past President of the European Society for Engineering and Medicine. In 2003, he was awarded the Fullbright Medal and, in 2010, the Samuel Haughton Silver Medal and his ScD for published work. In December 2013, he was elected the 61st President of the Anatomical Society.



John Lynam MANAGING DIRECTOR, THOMAS INTERNATIONAL

John has been working as a Management Consultant/Trainer for the past 32 years for a range of companies in the public and private sector together with third level educational institutes. He is currently the Chairman of Thomas International Ireland which he acquired 22 years ago. This company runs a range of personality, aptitude and ability, emotional intelligence and job profiling tools again for a range of companies mainly in the corporate sector. They provide training in the administration, scoring and interpretation of the tools and work on a consultancy basis with certain clients.



Tony Shore
DIRECTOR, INVISIO

Tony has over 25 years' experience training finance for non-financial managers and supporting new and growing organisations develop their finance and business plans. He is a facilitator and mentor for the highly acclaimed Enterprise Ireland New Frontiers Programme and works with a diverse range of organisations across Ireland and Internationally. Tony's passion is unleashing the potential in teams in both new and existing businesses. Tony has an MBA from the internationally renowned Henley Business School.



Derek Young
CEO 1360 MEDICAL

Derek is Founder and CEO of i360medical, a Healthcare Solutions and Medical Device Innovation Company that provides its Innovation to commercialisation programs to Global Hospital Systems, the medical device industry and clinical communities. He is a named inventor of 30+ patents with commercial success globally. Derek successfully co-founded several medical device start-ups before spinning into the RCSI where he established a Healthcare Innovation Hub (HIH) to develop the ideas of other clinicians and inventors. i360medical, which is a direct spinout of the HIH, is tapping into the growing expertise in Ireland and internationally to help generate and commercialise new world-class healthcare technology solutions. With a background in Mechanical Engineering, Surgical Innovation and Business Development, Derek holds a number of board positions on medical device companies, medical research groups and Government Healthcare Think Tanks at both a national and international level.

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Irish Medtech Association is a business sector within Ibec



