



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

# VALIDATION PRINCIPLES AND PRACTICES FOR THE MEDTECH INDUSTRY



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.



# VALIDATION PRINCIPLES AND PRACTICES FOR THE MEDTECH INDUSTRY

## About the Course

The **Irish Medtech Association 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 Validation Principles and Practices programme for the medical technology sector.

This programme has been designed to meet the growing requirements of Irish companies in filling validation roles and is delivered through blended learning. 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 validation experts from the medical technology sector.

The course will enable personnel in the medical technology industry to understand all current device and diagnostic validation regulations and to develop the skills necessary to address and prepare for the scope of validation requirements in industry. Upon successful completion of the programme, participants receive 9 credits at NFQ Level 8.

## About Irish Medtech Skillnet

Working in partnership with Skillnets Ltd and our contracting organisation, the Irish Medtech (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 – 2016) is over €5.2 million with 40% contribution from member companies and the remaining 60% funded by the state. Targets of over 7,400 trainees and 39,000 training days have been achieved.

## 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 170 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 our strategy.

## Programme Description

The Validation professional is critical to making safe and effective medical products available to patients worldwide. These professionals ensure compliance to international medical device regulations for designing and manufacturing medical device products.

The aim of the course is to introduce participants to the fundamentals of Validation, providing them with a basic knowledge of the regulations, standards and the skills necessary for validation work in the medical technology sector. This course will cover international validation requirements pertaining to validation and all associated systems.

The course content will follow the following themes:

- Quality Management Systems and how validation aligns to the Quality Management Systems.
- Validation and regulatory bodies' requirements for Validation.
- Writing best practice protocols and documentation.
- Risk, risk management and compliance within Validation.
- The key elements of validation throughout the lifecycle of a medical device product.
- Support systems required to maintain a validated state.

Validation professionals are one of the most in-demand professions in the medical technology industry. This module allows for professionals in the medical device industry and those with an interest in validation to develop the fundamental skills to contribute as effective members of a validation team in the medical technology sector.



## Programme Schedule

### Programme Schedule

Duration: 12 weeks – 3 Classroom days, 9 weeks online

Online classes require 2 Hour lecture on line plus additional 5 hours (approximate) of research, reading and assignments. Tutor support will be available for online classes in the form of a tutorial (approx. 1 hour). Online material will be released in advance and students are expected to have completed the material for the tutorial.

Approximately 90 – 100 hours of study are required outside of the course work.

### Delivery Schedule over 12 weeks

|    |           |                         |   |
|----|-----------|-------------------------|---|
| 1  | Classroom | Galway Thurs Oct 19th   | Introduction to the Course and Introduction to Validation   |
| 2  | Online    | Tutorial Thurs Oct 26th | Validation Regulations & Introduction to Risk Management    |
| 3  | Online    | Tutorial Thurs Nov 2nd  | Quality Risk Management Practical & Design Validation       |
| 4  | Online    | Tutorial Thurs Nov 9th  | Documentation Practices & Sterilization                     |
| 5  | Online    | Tutorial Thurs Nov 16th | Generating and Executing Protocols                          |
| 6  | Online    | Tutorial Thurs Nov 23rd | Equipment Qualification (IQ, OQ, PQ)                        |
| 7  | Classroom | Galway Thurs Nov 30th   | Computer System Validation & Project Discussion             |
| 8  | Online    | Tutorial Thurs Dec 7th  | Test Method Validation & Sampling                           |
| 9  | Online    | Tutorial Thurs Dec 14th | Process Validation Statistics & Verification and Validation |
| 10 | Online    | Tutorial Thurs Jan 11th | Validation Lifecycle & Cleaning Validation                  |
| 11 | Online    | Tutorial Thurs Jan 18th | Supplier Qualification & Maintaining a Validated State      |
| 12 | Classroom | Galway Thurs Jan 25th   | Case Study Presentation                                     |

**Submission**      **Feb 8th 2018**      **4,000 word dissertation**

- Material for the tutorial will be released on Moodle the Friday before the tutorial, allowing 6 days to study the topic.
- Tutorial time will be 19.00 for 1 hour each week.

## Programme Schedule

### Delivery

The programme will give all participants very clear and unambiguous information on the validation expectations and industrial applications pertaining to Validation. The tutors will be Subject Matter Experts (SME) in the area and will be knowledgeable on current validation expectations and applications. Each tutor will not only be technically competent but will also be able to transfer knowledge in a competent manner. It is planned that each delivery will be a combination of lectures, assignments and case studies with accelerated learning built into the course.

Online lectures and workshops along with participant deliverables and assignments will be supported by the Moodle software system. University of Limerick will provide access and security information.

### Assessment Grading System

Students will be assessed at various stages throughout the 12 week course.

- There will be short tests and assignments throughout the programme, both online and in classroom.
- Students will present a validation case study at the end of the programme. A dissertation of approximately 4,000 words will be required to support the case study. Further details will be given to registered students.
- Marks will be awarded based on the case study (30%), dissertation (30%), online / classroom short tests (30%) and attendance / engagement (10%). Technical competence, presentation and research will all be taken into consideration.
- Full participation for classroom dates and online work is expected.

### Who Should Attend

Entry requirement will be minimum Level 7 with two years' experience working in a regulated environment. Prior experiential learning will be assessed using guidelines recommended by the Academic Council of University of Limerick.

### Accreditation

The course is accredited by University of Limerick, to Level 8 with 9 ECTS.

### Costs

Irish Medtech Skillnet Association Member €1,950/person.

Non Member €2,600/person.

## Course Plan

### WEEK 1

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#### INTRODUCTION TO VALIDATION

- Introduction to Validation and the Validation Lifecycle.
- Benefits of Validation.
- Current trends and Validation expectations.
- The role of the validation professional.

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#### LEARNING OBJECTIVES

- The scope of validation throughout the lifecycle of a medical device product.
- The scope of medicinal products (traditional medical devices and combination products).
- The terminology used for validation.
- Introduction to the various regulations, standards and guidance documents that support the full scope of validation. (ISO 13485, CFR 820, ISO 9001, GAMP 5, ISO 14971, ASTM E 250, EU GMP Regulatory Requirements Annex 15 Qualification and Validation, Annex 11 etc).
- The benefits of validation to all stakeholders.
- The evolution of validation and the current industry trends and validation expectations.
- The roles and responsibilities of the validation professional and the regulatory agencies.

### WEEK 2

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#### VALIDATION REGULATIONS & INTRODUCTION TO RISK MANAGEMENT REQUIREMENTS

- Regulatory Requirements for Validation
- Validation in the context of the Quality Management System (QMS).
- Understanding the ISO 13485:2016 and relevant U.S. requirements as per CFR part 820.
- Overview of Risk Management.

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#### LEARNING OBJECTIVES

- The ISO 13485:2016 and CFR part 820 Validation regulations pertaining to the various elements of Design and Manufacture of Medical Device Products.
- The pharmaceutical regulations and guidance pertaining to combination products. (including EU GMPs Annex 15 Qualification and Validation).
- The ISO 9001:2015 standard key validation requirements as required.
- The key concepts of the ASTM 2500 standard guide.
- The theory and practical application of ISO 14971 Quality Risk Management standard.



## Course Plan

### WEEK 3

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#### DESIGN VALIDATION

The basic principles and practices of Design Validation

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#### LEARNING OBJECTIVES

- Understand the basic principles of Design Validation.
- List the elements and requirements for Design Validation.
- Learn how to apply tools for completion of Design verifications.
- Understand the basic principles of Design of Experiment.
- Understand the pitfalls of not adequately addressing Design Validation.

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#### QUALITY RISK MANAGEMENT PRACTICAL

Quality Risk Management via a workshop on Failure Modes Effects Analysis and other basic QRM tools.

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#### LEARNING OBJECTIVES

- Understand when to use an FMEA and its role within Validation.
- Know how to execute an FMEA.
- Know how to execute a Fault Tree Analysis / Fish Bone Diagram.

### WEEK 4

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#### GOOD DOCUMENTATION PRACTICES

The principles and practices of Good Documentation Practices in Validation.

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#### LEARNING OBJECTIVES

- Understand the regulatory requirements and guidelines for Good Documentation Practices.
- Appreciate the importance of Good Documentation Practices.
- Identify the connection between Good Documentation Practices and data integrity.
- Be able to list examples of documents requiring Good Documentation Practices.
- Know how to record data and make corrections to Good Documentation Practice standard.
- Identify the “Do / Don’ts” of Good Documentation Practices.

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#### STERILIZATION VALIDATION

The principles and practices of the Sterilization process and its validation.

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#### LEARNING OBJECTIVES

- Understand the Validation requirements and guidelines for Clean Room Facilities.
- Understand the Validation Requirements and Guidelines for Sterilization Validation.
- To understand the principles and practices of basic microbiology applied to prevention and elimination of product and device contamination.
- Understand the validation practices used in all contemporary sterilization methods
  - Steam and Dry Heat
  - Gamma
  - E-Beam
  - EtO
- Understand how sterility is determined, what sterility assurance means, and how it is validated.
- Complete case study exercise for a terminally sterilized product within the medical device industry.

## Course Plan

### WEEK 5

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#### GENERATING AND EXECUTING PROTOCOLS

- Validation Documentation ( plans, protocols and reports).
- Technical Writing.

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#### LEARNING OBJECTIVES

- Understanding the basic principles and applications of technical writing in validation documents.
- Outline the components of a Validation Plan, Protocols and Reports.
- Learn how to develop and execute validation protocols to meet design requirements.
- Understand the adaptation and proper use of validation documentation.
- Appreciate how to document and manage deviations.
- Step by step guide to write effective validation documentation.
- Complete case study exercise on the generation of a Validation Plan / Protocol and Report, for a piece of equipment within the medical device industry.

### WEEK 6

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#### EQUIPMENT QUALIFICATION

- Regulatory Requirements and Guidelines for Equipment Qualification.
- Qualification stages required for equipment.
- Case Study based on manufacturing equipment.

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#### LEARNING OBJECTIVES

- Identify the validation lifecycle approach to Equipment Validation.
- Become familiar with the phases of Equipment Qualification.
- Understand Equipment Installation Qualification, Operational Qualification and Performance Qualification.
- Understand clearly the design specifications that are required to generate IQ, OQ and PQ validation protocols.
- Understand the implications of not adequately completing Equipment Validation and recent FDA warning letters.
- Understand the requirements to decommission equipment.
- Be able to apply the theory of IQ, OQ and PQ in a work scenario.



## Course Plan

### WEEK 7

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#### COMPUTER SYSTEM VALIDATION

- Computerized System Validation
- Software Validation
- A risk-based approach using GAMP 5
- Electronic record / Data integrity
- Electronic signatures
- Recent validation trends and expectations

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#### LEARNING OBJECTIVES

- The validation requirements and available guidance around computerized systems, including relevant aspects of 21CFR820, 21CFRpart 210/211, 21 CFRpart11, ISO13485, GPSV.
- The 'why' behind the regulations and judging 'when' they apply.
- Computerized System Validation in the context of Software Development Life Cycles and in the context of Process Validation, where applicable.
- Basic overview of the premise, background and contents of 'GAMP 5 - A Risk-Based Approach to Compliant GxP Computerized Systems'.
- Realize the prevalence and reliance on electronic data in industry today and understand the importance of data integrity.

### WEEK 8

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#### TEST METHOD QUALIFICATION

Test Methods and Measurements used within Validation

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#### LEARNING OBJECTIVES

- Know the regulatory requirements for Test Method Qualification and its role in Validation.
- Understand the importance of accurate data and measurements during Validation.
- Know how to determine if a test method is suitable for its intended use.
- Know how to prove that data is reliable, reproducible, accurate and specific.
- Understanding the basic principles of Measuring System Analysis such as Gauge R and R.

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#### SAMPLING

Sampling and use of sampling plans within Validation.

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#### LEARNING OBJECTIVES

- Appreciate the importance of sampling in validation.
- Understand the theory of sampling and sampling plans.
- Know how to apply statistics to data obtained during sampling.

## Course Plan

### WEEK 9

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#### PROCESS VALIDATION STATISTICS

Key statistical tools used in process validation

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##### LEARNING OBJECTIVES

- Use Minitab to analyse process data.
- Know the difference between descriptive and inferential statistics.
- Understand how to choose samples and associated sampling risks.
- Understand the basics of acceptance sampling plans for attributes.
- Learn how to use Minitab to test your data for normality.
- Understand the basics of Measurement systems analysis (Gauge R&R etc.).
- Understand how to assess process capability.
- Understand how to use control charts for continuous process verification.

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#### VERIFICATION AND VALIDATION

The basic principles of Validation and Verification

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##### LEARNING OBJECTIVES

- Know when to Verify and when to Validate
- Appreciate the regulations pertaining to verification and comparing it to process validation.
- Understand the basic principles of V &V testing.
- Understand the key factors supporting Software verification, validation and testing.
- Understand the various elements of dynamic and static testing.
- Learn how to develop a Software Test Procedure.

### WEEK 10

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#### PROCESS VALIDATION LIFECYCLE

Regulatory Requirements and Guidelines for Process Validation

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##### LEARNING OBJECTIVES

- Review the regulatory requirements and guidelines for Process Validation.
- List the elements of Process Validation as per the International Medical Device Regulators Forum (GHTF Quality Management Systems Process Validation Guidance).
- Understand the goals and activities for each element of Process Validation.
- Consider validation requirements for support processes e.g. Packaging.
- Appreciate the importance of the Operational Qualification stage.
- Appreciate the importance of linking in sampling, quality risk management, validation change control, documentation and deviation management in the validation lifecycle.
- Understand when to consider revalidation.

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#### CLEANING VALIDATION

Regulatory and expectations pertaining to cleaning methods and analysis

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##### LEARNING OBJECTIVES

- Appreciate the importance of cleaning medical devices and cleaning of manufacturing equipment and facilities.
- Understand the practical aspects of cleaning equipment and cleaning processes.
- Appreciate the consequences of not validating cleaning processes adequately.
- Understand the link between medical device design and cleanability.
- Consider the importance of validating analytical methods used to prove adequate cleaning.
- Understand the concept of acceptable levels of cleanliness.

## Course Plan

### WEEK 11

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#### SUPPLIER QUALIFICATION

##### The role of the supplier in the validation lifecycle

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#### LEARNING OBJECTIVES

- Understanding the Validation Requirements and Guidelines for Supplier Qualification.
- Understanding how change control and other quality programs feed into the supplier qualification programme.
- Understanding how to initially identify suppliers that meet your requirements prior to qualification.
- Understand how to develop adequate procedural and documentation controls for the selection, approval and qualification of vendors and suppliers.
- Understand that controls are not limited to materials and components but also apply to contract service providers such as calibrations, laboratories, maintenance, contract manufacturing/packaging and others including software vendors.
- Appreciate common pitfalls to avoid when qualifying suppliers.

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#### MAINTAINING A VALIDATED STATE

##### Maintaining validation after validation approval

Ongoing monitoring of processes and the importance of Quality Management support systems.

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#### LEARNING OBJECTIVES

- Understand the Validation Requirements and Guidelines for Validated Systems and Processes.
- Understand key factors supporting maintenance of the validated state.
- Understand the key factors that trigger Re-Validation.

- Understand specific activities to maintain the validated state which include:
  - Knowing the importance of timely process data monitoring and analysis.
  - How to use Statistical Process Control.
- Appreciate the role of Corrective and Preventative Action (CAPA).
- Appreciate the importance of Management Review.

### WEEK 12

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#### FINAL CASE STUDY / PROJECT AND ASSESSMENT

- Participants will be required to complete a validation case study as discussed during the course.
- Participants must be capable of answering questions on the case study.
- A dissertation of approximately 4,000 words supporting the case study (or agreed equivalent topic) will be required within 2 weeks of final week.



## Programme Team



**Siobhán Dillon**

Siobhán Dillon has twenty years' experience in the Life Science Industry coupled with ten years lecturing.

Working independently, trading under Pacina Ltd, clients include medical device and pharmaceutical companies such as Pfizer, Alcon Laboratories, Stryker, Beckman Coulter, Lifewave, Zimmer Orthopedics, Phillips Medisize, Bio Medical Research, Merck as well as Irish Medtech Association and GetReskilled.

Industrial experience focuses on design, development and delivery of Quality and GMP training, Training Management and working with Quality Management systems. Academic experience includes working with DIT and Get Reskilled supporting their BSc in Validation.



**Alan Dillon**

Alan has worked in the Pharmaceutical, Medical Device and Bio-Pharma industry since 2004, working in QA, Validation and Engineering roles in both manufacturing and capital project environments and is an expert in ISO, FDA and EU cGMP regulations. Alan has attended numerous international conferences and validation training events and is a member of the ISPE, PDA and PHSS.

Alan holds a B.Sc in Applied Maths and Biology from NUI Maynooth, M.Sc in Pharmaceutical Science (eligible EU Qualified Person) from RCSI and a Professional Diploma in Education (PGDE) from NUI Galway.

Alan has extensive regulatory inspection exposure experience, including FDA, TGA, TUV, Health Canada and HPRA and has played significant roles on the planning, implementation and execution of Commissioning and Qualification programs for Allergan Pharmaceuticals, Boston Scientific and Baxter Healthcare including implementation of Quality Risk Management principles from concept design phases to product Process Validation.



**Simon Jegg**

Simon is a Lead trainer on the Irish Medtech Certificate of Quality Engineering, another UL Level 8 accredited course. He is a Director of Global Business Institute (GBI), an ASQ Global Partner and International Examination Centre for the American Society for Quality (ASQ). GBI provides Online, Onsite and public training in ASQ Certified Reliability Engineer, Certified Quality Engineer, Certified Quality Technician, Lean Six Sigma Yellow Belt, Green Belt, Black Belt and Microsoft Office Applications.

## Programme Team



### Carmel McGrath

Carmel McGrath is CEO of AlphaMed Consulting Ltd. A medical device validation affairs, quality and training contractor. She is a highly motivated, competent professional with significant experience (25+ yrs) in the Medical Device Industry.

Carmel has held varying roles of management incl. Medtronic, Life Care Medical Devices, Covidien and currently supports Creganna Medical along with Advotek International. Carmel has considerable experience dealing with Global Validation 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 validation inspections.

She has represented industry on the Post Market Surveillance task force in developing the initial Med Dev. Vigilance guidance document and worked in the role of Authorized Representative for a number of facilities. Carmel has conducted extensive field training throughout Europe, U.S. & China with electronic post market feedback systems introduced.



### Rita Woodings

Rita has over 18 years' experience in the Pharmaceutical, Medical Device and supporting service industries.

Rita has held engineering and management roles in areas of automation, software quality and project management. She has extensive compliance, quality systems and audit management experience coupled with deep technical knowledge in system development life cycles, electronic data systems, risk management, metrology, automation, and validation. Rita holds a B.Sc in Applied Physics and Instrumentation from GMIT, along with qualifications in Industrial Technology and Software Engineering and is a highly effective trainer with a drive for simplicity and an ability to connect with trainees to ensure a positive and successful learning experience.

Rita has held lead auditor and audit manager roles for large multinational organisations throughout her career.

### About Reidh Consulting and Martin Reddington

Martin Reddington, Managing Director of Reidh Consulting, is a highly experienced Business Management Consultant and Mentor specialised in Customer Experience Management. 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 Though People, Quality Service System Standards, Root Cause Analysis & CAPA techniques.

## Programme Enquiries

This programme can be booked online at  
[www.irishmedtechskillnet.ie](http://www.irishmedtechskillnet.ie)

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Irish Medtech Association is a business sector within Ibec