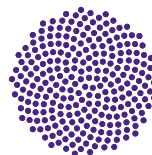


Connected
Health

Skillnet,

Medical Software Quality Assurance

Level 8 15 ECTS



Irish Medtech
Association
ibec

connectedhealthskillnet.ie

Introduction

The **Connected Health Skillnet** and contracting organisation, the **Irish Medtech Association**, and the University of Limerick (UL), are delighted to present the Medical Software Quality Assurance programme developed to meet the needs of member companies for qualified software quality professionals with knowledge of the Software Quality Standards and Regulations required for the medtech regulated environment.

Advancements in manufacturing technologies together with a move toward more connected solutions in healthcare is increasing the industry's requirements for software and other skillsets related to the Internet of Medical Things. This programme, funded by Connected Health Skillnet, is designed to provide those with a background in engineering, science, technology or technician-based roles with the skills to take up software quality positions and/or expand their knowledge and expertise in the Medtech and Digital Health sectors.

ABOUT IRISH MEDTECH ASSOCIATION

Irish Medtech Association is a business sector within Ibec that represents the Medical Technology sector. It works directly with government and policy makers nationally and internationally, to shape business conditions and drive economic growth.



Overview

ABOUT THIS COURSE

The programme will provide participants with fundamental theoretical and practical skills, abilities and knowledge for assuring the quality of medical software applications in accordance with relevant state of the art regulatory requirements and quality management systems. This includes standalone software which is a medical device, software which is part of a medical device, medical device apps and for software used in the Medtech regulated environment. Participants will be capable of creating and executing test cases and tracking software issues from their diagnosis to resolution and generally assuring the quality of developed software. This course has a proven track record of successfully delivering excellent content to participants who have included Testers, Software Engineers, Project Managers, QA Personnel, Quality Managers, Technical Consultants and Senior Managers.

CERTIFICATION

This course will be accredited by University of Limerick to Level 8 NFQ with 15ECTS.

Module 1: Foundations of Software Testing - 6ECTS

Module 2: Software Quality Assurance Standards - 9 ECTS

ENTRY REQUIREMENTS

3rd Level qualification (certification, diploma, degree) in Software, Engineering, Quality or a Science related discipline desired.

Experience in software Quality Assurance activities, such as software testing, will be taken into account in lieu of a third level qualification.

DELIVERY

The programme will be delivered virtually over 2 x 8-week modules through online classes, self-paced eLearning, and project work. Online classes will take place on Tuesday and Thursday evenings. The focus is on the reduction of theory to practice so there is a strong emphasis on developing practical skills. Upon completion, learners will be able to apply the theory behind what they have learned in their workplace.

Start date: 09th September 2022
Location: Online classroom & self-paced eLearning

DELIVERY SCHEDULE

Online Introduction: 09th September 2022

Module 1:
Self-paced eLearning:
09th September – 09th October 2022

Online Classes: (90 minutes)
11th, 13th, 18th, 20th October 2022

Module 2:
Online Classes: (90 minutes)
24th, 26th, 31st January 2023
01st, 07th, 09th, 14th, 16th, 21st, 23rd, 28th February 2023
02nd, 07th, 09th, 14th, 16th March 2023

Note* Approximately 30 hours will be required for online learning and project work.

COST

Members €2,280
Non-members €3,800



BOOKS / MORE INFORMATION

Visit the Connected Health Skillnet website to book your place online: www.connectedhealthskillnet.ie

Or contact: **Jennifer McCormack**, Network Manager

T: 01 605 1537 E: jennifer.mccormack@ibec.ie

In Association with:



MODULE ONE

Foundations of Software Testing

This module will enable professionals to demonstrate practical knowledge of the fundamental concepts of software testing.

Content:

- A background into Standard Operating Procedure (SOP) structure and purpose
- Software development lifecycle approaches in the development and quality assurance of medical software (e.g. Waterfall, V-Model, Agile, SCRUM)
- The relevance and appropriate use of Agile methods
- The process of adapting internationalized medical software for a specific region.
- A foundation in formal Software Quality methods and techniques as covered in **International Software Testing Qualifications Board (ISTQB) Foundations syllabus**
 - Fundamentals of Testing
 - Testing throughout the software lifecycle
 - Static Techniques
 - Testing Design Techniques
 - Constructing a protocol and test scripts from a requirements document
 - Bug Reporting
 - Test Management
 - Traceability
 - Tool Support for Testing and Test Automation
 - Testing tools and their uses within the organisation

Note*

Module One follows the ISTQB syllabus. In addition to sitting the UL exam, learners will also have the option to sit the official ISTQB exam, should they choose, to achieve the professional ISTQB qualification.

MODULE TWO

Software Quality Assurance Standards

This module will provide professionals with an understanding of the relevance and importance of state of the art Medical Device Software standards and regulatory requirements.

Content:

- Risk Management in the Medical domain e.g. ISO 14971 and ISO/TR 24971
- Quality Management System (QMS) and the role of software Quality Assurance in this.
- FDA 21 CFR Part 820, Subpart C – Design Controls
- EN ISO 13485 Quality Systems - Medical Devices
- FDA EU MDR and MDD regulations from a software development and software Quality Assurance perspective: e.g. IEC 62304, IEC 82304-1, IEC 62366-1 and ISO 14971
- The role and importance of Harmonized and Consensus Medical Device Standards
- Relevant Technical Reports and Guidance Documents
- Change Management in a Medical Device context
- The Medical Device Single Audit Program (MDSAP)
- Current 'state-of-the-art' in medical software standards - including FDA, IEC, ISO, ERES, and GAMP standards

ASSESSMENT

Module 1: 40% - 1 hour exam
60% - Project 1

Module 2: 50% - Project 2
50% - Project 3

Learning Outcomes

- 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) Construct a protocol and test scripts from a requirements document
- 8) Verify that user manuals are regulatory and standards compliant
- 9) Participate in localisation teams
- 10) Review design documentation
- 11) Acknowledge the professional and ethical responsibility of medical software practitioners to produce safe and reliable software



Biographies



Dr Valentine (Val) Casey

UL Dept. of Computer Science and Information Systems

Dr Val Casey is a lecturer, researcher and internationally recognised expert in key aspects of software development at UL. His expertise includes Software Quality, Software Testing, Regulated Software Development, and Software Process Assessment and Improvement. He is a CMMI assessor and ISO/IEC 15504 expert in software quality.

Dr Casey has spent over 12 years undertaking research into all aspects of Medical Device Software Development and Quality. Based on his results he has published extensively on Medical Device Software Verification and Validation, Traceability, Risk Management, the use of Agile and Lean Methods, Usability, International Standards, Regulations and the design, development and implementation of a medical device specific Software Process Assessment and Improvement Model. As a result of his work in these areas he is an internationally recognized expert in this field.

A key factor in the success of Dr Casey's work is that it deals with relevant industry topics and offers practical solutions to real issues and problems. Over the last 18 years he has held academic and research positions at UL, Bournemouth University, Dundalk Institute of Technology and Lero – the Irish Software Research Centre. In addition, he has over 16 years' professional experience in the software industry where his previous roles include Software Quality/Test Manager, Software Project Manager, Software Quality Specialist and Software Engineer. In addition, he also provided Software Consultancy Services to national and international organisations. He also has a proven track record of successfully developing and delivering courses at undergraduates, postgraduates and for industry professionals.



Prof. Ita Richardson

Lero and UL Dept. of Computer Science and Information Systems

Prof Ita Richardson, Department of Computer Science & Information Systems, University of Limerick, is a Principal Investigator within Lero – the Irish Software Research Centre, with responsibility for research projects worth over €2million. The focus of her research is on software process and assessment and the quality of use of software in a variety of domains, including hospitals and clinics, medical device and financial services. She also studies Connected Health – how the introduction of technology changes processes and care pathways. She has undertaken research within Medical Device companies such as Boston Scientific, HomeSafe Care and Vitalograph, and within Private and Public Hospitals. In University Hospital Limerick, her team have developed both a Hospital Quality Assurance Program and a Radiology Quality Assurance Program. Current projects include the introduction of Connected Health solutions in Clinical situations and for older adults in the community.

Prof Richardson has graduated 15 PhD students and 1 Habilitation student to completion, is currently supervising 7 PhD students, some of whom are part-time and industry-based and has supervised Senior Research Fellows and Research Fellows for the past 20 years. Prof Richardson has over 200 publications in refereed journals and conferences, book chapters and edited books.



Lero

Irish Software Research Centre

Lero brings together leading software research teams from Irish Universities and Institutes of Technology in a coordinated centre of research excellence with a strong industry focus. Lero has raised the level and profile of Irish software research with such effect that it is now one of the best known and most highly regarded software research centres in the world, collaborating with researchers globally. The centre has the proven capacity to attract and retain global research leaders and to make a substantial contribution both to software research and to the Irish economy.

Lero is supported by a Research Centre grant from Science Foundation Ireland, by other state grants, particularly the European Union's research programmes. Outside of education programs at primary, secondary and third-level, Lero's outreach program includes presenting training courses for employee upskilling and industry workshops



Connected Health Skillnet

The Connected Health Skillnet is a cross-sectoral learning and development network established to address the current and future skill needs arising from the convergence of the medtech, pharma, ICT and software sectors in the field of connected health. We do this through the delivery of niche training, up-skilling and cross-sectoral networking opportunities.

The Connected Health Skillnet is a not for profit network with Ibec as Contracting Organisation and operates in collaboration with three Ibec sector's, **Irish Medtech Association, Technology Ireland** and **BioPharmaChem Ireland**.



GET IN TOUCH



Connected Health Skillnet

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Irish Medtech Association is a business sector within Ibec

Irish Medtech Skillnet is co-funded by Skillnet Ireland and network companies. Skillnet Ireland is funded from the National Training Fund through the Department of Further and Higher Education, Research, Innovation and Science.



An Roinn Breisoideachais agus Ardoideachais,
Taighde, Nuálaíochta agus Eolaíochta
Department of Further and Higher Education,
Research, Innovation and Science

