

Medical Software Quality Assurance programme

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



Introduction

The Irish Medical Devices Association Skillnet is delighted to present a new **Medical Software Quality Assurance programme** to meet the growing need of member companies in software quality roles.

The programme, funded by IMDA Skillnet, is designed to provide out of work computer, science, engineer, technician graduates or equivalent with software background with the skills to take up new work in the Medtech sector. The training takes place two - three days per week over 8 weeks in University of Limerick. A one day process validation workshop will also be included to provide the students with a background in Quality Management System for the medical technology industry.

On successful completion of the training programme, the participants receive a Medical Software Quality Assurance, NFQ Level 8 award and ISTQB qualification. After completion of the pilot course in January 2015, 71% of the graduates have managed to obtain an internship or full time employment.

Medical Software Quality Assurance

About this Course

The programme will provide graduates with fundamental theoretical and practical skills, abilities and knowledge for assuring the quality of medical software applications in accordance with regulatory requirements and quality management systems. Graduates 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.

Entry Requirements

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.

Certification

Level 8 15 Credits NFQ award and ISTQB qualification.

Delivery

The programme will be delivered in a workshop format based around two modules from the Computer Science degree.

MODULE ONE: Foundations of Software Testing

MODULE TWO: Software Quality Assurance Standards (Medical Devices)

2-3 days per week for 8 weeks

How will this affect my Social Welfare Entitlements?

During the 8 weeks directed training portion of the programme candidates will be in a position to retain any social welfare entitlements they are entitled to. If selected for a six month internship programme, eligible candidates may receive an additional allowance of €50 per week on top of their social welfare entitlements, in accordance with the eligibility criteria set out under Job bridge - the National Internship Programme. www.jobbridge.ie/InternEligible.aspx

" I think it is a very good course if you want to start a career in the Medical Device Industry, as it introduces you to all the relevant Standards and regulations. "

Cathal Kinane, Co Tipperary, 2015 graduate

" 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



Syllabus

MODULE ONE

Foundations 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 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 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
 - > Test Management
 - > Traceability
 - > Tool Support for Testing and Test Automation
- Testing tools and their uses within the organisation

MODULE TWO

Software Quality Assurance Standards (Medical Devices)

Problem Based Learning focused on Medical Device Software standards. This module will include an experiential element delivered over 12 days. Participants will produce a number of reports based on their experience in a medical device software context. This will happen as part of IMDA Skillnet supported placement or University of Limerick project work.

Content:

- Risk Management in the Medical domain: ISO 14971
- Quality Management System (QMS) and the role of software Quality Assurance in this e.g.
 - > FDA 21 CFR Part 820, Subpart C – Design Controls
 - > EN ISO 13485 Quality Systems – Medical Devices
- FDA and MDD regulations from a software development and software Quality Assurance perspective: IEC62304 and ISO 14971
- Change Management
- Current 'state-of-the-art' in medical software standards - including FDA, IEC, ISO, ERES, and GAMP standards

Learning Outcomes

Cognitive (Knowledge, Understanding, Application, Analysis, Evaluation, Synthesis)

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

Affective (Attitudes and Values)

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

- 1) Acknowledge the professional and ethical responsibility of medical software practitioners to produce safe and reliable software

Delivery Schedule

Location: University of Limerick

Module 1

Thurs	15-Oct 2015	Group 1	08:45	17:00
Fri	16-Oct 2015	Group 1	09:00	17:00
Mon	19-Oct 2015	Group 1	09:00	17:00
Tues	20-Oct 2015	Group 2	08:45	17:00
Wed	21-Oct 2015	Group 2	09:00	17:00
Thurs	22-Oct 2015	Group 2	09:00	17:00
Thur	29-Oct 2015		09:00	17:00
Fri	30-Oct 2015		09:00	17:00

Process Validation

Wed	04-Nov2015		09:00	17:00
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Module 2

Thur	05-Nov2015		09:00	17:00
Fri	06-Nov2015		09:00	17:00
Thur	12-Nov2015		09:00	17:00
Fri	13-Nov2015		09:00	17:00
Thur	19-Nov2015		09:00	17:00
Fri	20-Nov2015		09:00	17:00
Thur	26-Nov2015		09:00	17:00
Fri	27-Nov2015		09:00	17:00
Thur	03-Dec2015		09:00	17:00
Fri	04-Dec2015		09:00	17:00
Thur	10-Dec2015		09:00	17:00
Fri	11-Dec2015		09:00	17:00

Biographies



Dr Valentine (Val) Casey

Dr Val Casey is a lecturer, researcher and internationally recognised expert on key aspects of software development. These include software quality, software testing, regulated software development and software process assessment and improvement. As part of this work he has spent over three years carrying out specific research into all aspects of medical device software development. 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 and design and the development and implementation of a medical device specific software process assessment and improvement model.

Academic positions held include Senior Researcher in the Regulated Software Research Centre at Dundalk Institute of Technology, Senior Lecturer in Software Testing and Quality at Bournemouth University, Research Fellow with Lero - The Irish Software Research Centre at the University of Limerick where he also lectured. In addition he has over 16 years professional experience in the software industry. Previous roles in this context include Software Quality/Test Manager, Software Project Manager, Software Quality Specialist and the provision of consultancy services focusing on software testing, software quality, global software development and software process assessment and improvement.



Dr Ita Richardson

Lero and UL Dept. of Computer Science and Information Systems

Dr Ita Richardson is Senior Lecturer in the University of Limerick and a Principal Investigator within Lero – the Irish Software Engineering Research Centre (www.lero.ie) where she is the Competence Leader for Software Process Improvement and Global Software Development research. She is also Principal Investigator with the Applied Research on Connected Health (ARCH) Competence Centre. Within Lero and ARCH, Dr. Richardson leads a number of major projects where 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 currently leads a team of 14 researchers. When she graduated with a B.Sc. in 1983, Dr. Richardson joined Wang Laboratories, where she developed and maintained Information Systems. She graduated from the University of Limerick with a M.Sc. in 1992, and a PhD in 1999.

As Head of Department, Computer Science and Information Systems, Dr. Richardson was instrumental in the instigation of Lero. At that time, she received a 5-year grant to work on a problem posed by industry regarding Global Software Development problems which they were experiencing. Further funding within Lero allowed her research team to develop a training course for industry on Global Software Development, and to derive a Global Teaming Model for use in industry. She has since extended this process-focused research into the Medical Device Industry and Healthcare sector. Dr. Richardson has collaborated with a number of companies in her research, including Siemens Corporate Research, Boston Scientific, Fineos Corporation and small companies such as Data Display. She is currently involved in projects with Vitalograph, Cook Medical, Intel, ADA-Security and the Health Services Executive, specifically within Limerick Public Hospitals, where her team have developed H-QAP – a Hospital Quality Assurance Programme.



Lero

Irish software engineering research centre

Lero is an Irish software engineering research centre which brings together leading software engineering (SE) teams from 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 engineering research with such effect that it is now one of the best known and most highly regarded SE research centres in the world. The centre has the proven capacity to attract and retain global research leaders and to make a substantial contribution both to software engineering research and to the Irish economy.

Lero is supported by a Centre for Science Engineering and Technology grant from SFI, by other state grants, by industry contributions and by external funding (particularly the EU'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.



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IMDA is a business sector within Ibec