Module Code	Pre-requisite Module codes	Co-Requisite Modules code(s)	ISCED Code	Subject Code	ECTS Credits	NFQ Level (CPD)#
CMPU4043					5	8
Module Title	Medical Software Development					

Medical Software Development

School Responsible:	School of Computing

Module Overview:
Students completing this module will be able to apply and critically evaluate best-practice software processes for the development and maintenance of regulatory compliant medical device software.

Learning Outcomes (LO):	
On Completion of this module, the learner will be able to	
1	Evaluate the need for following a particular standard when presented with a medical device software product that is to be marketed within a particular region
2	Explain the steps involved in taking a medical device software product from concept right through to delivery
3	Develop a best-practice process for a particular phase of the software development lifecycle
4	Apply the rules for determining if a software application is a medical device
5	Evaluate the suitability of adopting a particular lifecycle model to develop a medical device software product
6	Explain the importance of traceability when developing medical device software

Indicative Syllabus:
Evolution of Medical Device Software Why should medical device software be validated? Regulations within the different global regions. Classification of medical device software within different regions. Categories of medical device software. Standards required for regulatory compliance within different regions.

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Medical Device Software Development

Medical Device Software Processes. Medical Device Software Development Lifecycles. Different Phases of Development & Maintenance. Selecting a Lifecycle Model.

Supporting Activities

Quality Management Systems. IEC 62304 Standard. Medical Device Software Verification and Validation. Medical Device Software Risk Management Planning. Configuration Management. Defect Management. Reviews. Traceability. Supplier Selection. Handling 3rd Party Software.

Learning and Teaching Methods:	
The course delivery involves a combination of lectures and labs which may incorporate the use of blended learning techniques as appropriate throughout the delivery.	
Total Teaching Contact Hours	39
Total Self-Directed Learning Hours	61

Module Delivery Duration:
This module is delivered over one semester

Assessment		
Assessment Type	**Weighting (%)**	**LO Assessment (No.)**
Final Exam	60%	1,2,4
In Class Assessment	40%	2,3,5,6
Module Specific Assessment Arrangements (if applicable)		
(a) Derogations from General Assessment Regulations		

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(b) Module Assessment Thresholds	
(c) Special Repeat Assessment Arrangements	

Essential Reading: (author, date, title, publisher)

- Feltan, P. 2017, *Software Testing Basics: Software Verification Fundamentals for Dedicated testers in the Medical Device Industry*, CreateSpace Independent Publishin Platform
- Vogel, D.A. 2011, *Medical Device Software: Verification, Validation and Compliance*, Artech House
- Burton, J.; Richardson,I.; McCaffery, F. & Ó hAodha, M. 2009, *The Medical Device Industry: Developments in Software Risk Management*, Cambridge Scholars Publishing
- Fries, R.C. 2006, *Reliable Design of Medical Devices*, CRC Press
- Fries, R.C. 2006, *Handbook of Medical Device Design*, Marcel Dekker
- Cleland-Huang, J.; Gotel, O. & Zisman, A. 2012, *Software and Systems Traceability*, Springer [
- Laplante, P.A. 2011, *Encyclopedia of Software Engineering: Volume 1*, Taylor & Francis

Supplemental Reading: (author, date, title, publisher)

- Thompson, B. 2010, *FDA Regulations of Mobile Health*, Mobi Health News, Chester Street Publishing, 51-
- COCIR 2011, *Position Paper on the Privacy and Protection of Health Data*

Version No:		**Amended By**	
Commencement Date		**Associated Programme Codes**	

Modules that are to be offered as Stand-Alone CPD Programmes must have an NFQ level assigned

*Details of the assessment schedule should be contained in the student handbook for the programme stage.

Date of Academic Council approval ……

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