GMIT
INSTITIÚID TEICNEOLAÍOCHTA NA GAILLIMHE-MAIGH EO
GALWAY-MAYO INSTITUTE OF TECHNOLOGY

SCIE07010
Validation

Full Title	Validation		
Status	Uploaded to Banner	**Start Term**	2015
NFQ Level	07	**ECTS Credits**	05
Module Code	SCIE07010	**Duration**	Stage - (26 Weeks)
Grading Mode		**Department**	Physical & Life Sciences
Module Author	Ita Kelly		

Module Description

This module covers the science and practice of validation, as it applies within the pharmaceutical and medical device sectors. The use of risk management as part of the validation process is also covered.

Learning Outcomes
On completion of this module the learner will/should be able to:

1.	Explain the role of validation within Good Manufacturing Practice.
2.	Identify and apply the various validation guidelines and standards in use.
3.	Apply risk management tools as part of a validation exercise.
4.	Prepare a validation document in accordance with regulatory guidelines.
5.	Describe the major steps involved in the validation of critical pharmaceutical and medical device manufacturing operations.
6.	Describe the approach taken to analytical method validation.
7.	Complete various validation exercises.

Indicative Syllabus

Regulatory basis for validation

Risk management and its role in validation including review of ISO 14971

Equipment validation – DQ, IQ, OQ, PQ.

Pharmaceutical process validation

Analytical method validation and Good Automated Manufacturing Practice

Validation of medical devices including key processes including sterilisation

Change Control

Teaching and Learning Strategy

Delivery of the module will include lectures, group work, in class discussion and analysis. Guest industry speakers will be invited to present on specialist topics

Assessment Strategy

50% continuous assesment 50% final examination; Examples of assessment include validation documentation preparation, application of risk assessment tools, short in class quiz/exam, report preparation on specialist topics,

Repeat Assessment Strategies
repeat exam available

Indicative Coursework and Continuous Assessment:		50 %		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Assignment	Assignment	35 %	OnGoing	1,2,3,4,5,6,7
Assignment	Mid term examination	15 %	OnGoing	1,2,3,4,5,6,7

End of Semester / Year Formal Exam:		50 %		
Form	***Title***	***Percent***	***Week (Indicative)***	***Learning Outcomes***
Closed Book Exam	Final Exam	50 %	End of Term	1,2,3,4,5,6,7

Full Time Delivery Mode Average Weekly Workload:			1.50 Hours		
Type	***Description***	***Location***	***Hours***	***Frequency***	***Weekly Avg***
Lecture	Lecture	Lecture Theatre	1.5	Weekly	1.50

Recommended Reading Book List
(2007). *Validation of Pharmaceutical Processes, 3rd Edition*. CRC Press. ISBN 0849370558 ISBN-13 9780849370557
(2005). *Validating Pharmaceutical Systems: Good Computer Practice in Life Science Manufacturing*. Informa Healthcare.
(2003). *Pharmaceutical Process Validation: An International (Drugs and the Pharmaceutical Sciences)*. CRC Press. ISBN 8126541040 ISBN-13 9780824708382
Sofer, G., (2000). *Process Validation in Manufacturing of Biopharmaceuticals: Guidelines, Current Practices, and Industrial Case Studies (Biotechnology and Bioprocessing Series)*. CRC Press.
Haider, S., (2010). *Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries*. CRC Press. ISBN 1439826609 ISBN-13 9781439826607
(2004). *Analytical Method Validation and Instrument Performance Verification*. Wiley-Interscience. ISBN 0471259535 ISBN-13 9780471259534

Literary Resources
Andrews, J (2006) Validating pharmaceutical systems: good computer practice in life science manufacturing. CRC Publishing
Robert A. Nash and Alfred H. Wachter 2003, *Pharmaceutical Process Validation,* Marcel Dekker
A G Singh Rathore and Gail Sofer 2005, *Process Validation in Manufacturing of Biopharmaceuticals*, Taylor and Francis
Haider, SI & Syed AE 1010. Cleaning validation manual: a comprehensive guide for the pharmaceutical and biotechnology industries. CRC London.
Chan, C.C. 2004. Analytical method validation and instrument performance verification. Wiley Interscience, UK.

Online Resources
Food and Drug Administration www.fda.gov
Irish Medicines Board www.imb.ie
European Medicines Agence www.emea.europa.eu
International Council for Harmonization www.ich.org

Programme Membership
GA_SQRAG_S07 201500 Certificate in Science in Quality & Regulatory Affairs GA_SQUAG_B07 201400 Bachelor of Science in Quality for Industry