Report of Validation Panel
for a Special Purpose, Minor or Supplemental Award

Date of Meeting: 08-06-2018

Named Award:	Certificate
Programme Title:	Certificate in Validation Science
Award Type:	Special Purpose Award
NFQ Level:	7
Intakes Commencing:	01-09-2018
ECTS/ACCS Credits:	10

PANEL MEMBERS

Name / Function / External Institution OR CIT Academic Unit
Prof Hugh McGlynn, Head of School of Science and Informatics (Chair)
Dr Louise Keane, Quality Engineer at Sanmini
Dr Mary Lehane, Department of Physical Sciences

IN ATTENDANCE

Name / Function / External Institution OR CIT Academic Unit

PROPOSING TEAM MEMBERS

Name / Function / Academic Unit
Dr Matt Cotterell, Head of School Mechanical and Process Engineering
Dr Michael J O'Mahony, Head of Department of Process, Energy & Transport Engineering
Dr Eric Moore, Department of Chemistry, University College Cork
Dr Anne Toebes , Department of Process, Energy & Transport Engineering

BACKGROUND TO THE PROPOSED PROGRAMME

This Special Purpose Award in Validation Science provides an accredited level 7 qualification over one year for individuals who are seeking to up-skill or cross-skill in order to gain suitable employment in sectors such as biopharmaceutical, pharmaceutical and medical device industries.

This Special Purpose Award in Validation Science was developed in response to the requests from the industrial participants in the South Western Skills Forum. This forum has identified Validation Science as a key competence required in response to the Biotechnological developments in the South West region (MSD Brinny, Eli Lilly, Biomarin, Regeneron, Janssen Biologics and GE Biopark, LSC, PM Group, Boston Scientific, Alcon, Sanmina, Hovione and DPS).

The following were identified by industry representatives at the South West Validation Skills Group meeting in June 2017 as key areas requiring addition input by the academic partners, (Cork Institute of Technology, Institute of Technology Tralee, University College Cork). These all relate to the validation related functions.
  • Commissioning and Qualification (IQ/OQ/PQ)
  • Process Validation
  • Analytical and Method Validation.

The following companies were represented at this meeting; MSD, LSC, Hovione, Novartis, Astellas, DPS Engineering, PM Group, Pfizer & GSK.

This lead to the proposal that two modules would be developed to address the identified skills gaps.
Representatives from UCC, CIT and IT Tralee met in December 2017 to discuss a number of options in relation to the requests from industry. Ultimately, the following characteristics of the proposed 10 credits of learning was agreed.

  • Module level on National Framework of Qualifications (NFQ), Module bundling (Special Purpose Award, 10 credit minor award)
  • Level 7 on the NFQ framework (Ordinary degree standard)
  • Continuous Professional Development (CPD) delivery 10 Credit, two module Award

The Irish Business and Employers Federation (IBEC) and BioPharmaChem Ireland (BPCI) announced in February 2018 that MSD would create 350 jobs in Ireland, which bolsters the country's status as a thriving hub for the biopharmaceutical sector. BPCI have also highlighted opportunities for the pharma/life science sector in Ireland as a result of the pending BREXIT. The Irish Medtech Association has stated that as many of 9 out of the world's top 10 medical technological companies have a base in Ireland, employing 40,000 employees. The anticipated expansion rate and replacement demand in BioPharmaChem outlined in the Expert Report Group on Future Skills Needs (2016) highlighted projections of 8,400 trained personnel required over the next five years. Note in 2015, 41,500 people were employed in manufacturing in the South West and over 25% (10,000) were associated with "high-tech" in the pharmaceutical sector.

FINDINGS OF THE PANEL

*NOTE: In this report, the term "**Requirement**" is used to indicate an action or amendment which in the view of the Panel **must** be undertaken prior to validation and commencement of the Programme. The term "**Recommendation**" indicates an item which the Course Board (or other relevant Institute unit) should implement at the earliest stage possible, and appropriate implementation of which should be the subject of ongoing monitoring.*

On consideration of the documentation provided and discussion of the programme with the proposers, the Panel has arrived at the following Findings, Requirements and Recommendations:

1.   Validation Criteria

1.1   Is there a convincing need for the programme with a viable level of applications?

Overall Finding: Yes

Finding(s): Demand from BioPharmaChem and Medical Devices sector for pipeline of trained individuals in Validation Science to meet future planning projections and sector needs.

Requirement(s): none

Recommendation(s): none

1.2   Are the level and type of the proposed award appropriate?

Overall Finding: Yes

Finding(s): Level 7 modules are appropriate

Requirement(s): none

Recommendation(s): none

1.3   Is the learning experience of an appropriate level, standard and quality?

Overall Finding: Yes

Modules offered allow learners to acquire the relevant and necessary knowledge and skills at Level 7 in the area of Validation Science

Finding(s): Learning experience at appropriate standard and quality

Requirement(s): none

Recommendation(s): none

1.4   Is the programme structure logical and well designed (including procedures for access, transfer and progression)?

Overall Finding: Yes

Finding(s): Modules proposed are fit for purpose at the appropriate level and content and assessments were appropriate.

Requirement(s): none

Recommendation(s): none

1.5   Are the programme management structures adequate?

Overall Finding: Yes

Finding(s): Course Boards will be convened for this programme and course coordinator appointed

Requirement(s): none

Recommendation(s): none

1.6   Are the resource requirements reasonable?

Overall Finding: Yes as modules will be shared with other programmes within the Department of Process, Energy & Transport Engineering. Resource required for coordination and induction programme but this met by Springboard funding.

Finding(s):

Requirement(s): none

Recommendation(s): none

1.7   Will the impact of the programme on the Institute be positive?

Overall Finding: Yes.

Finding(s): Course will attract new learners form the BioPharmaChem and Medical Devices sector. This will add to the portfolio of offerings within the Institute and have a positive impact on existing programmes offered within Department of Process, Energy & Transport Engineering

Requirement(s): none

Recommendation(s): none

2.   Other Findings

Panel complementary of the excellent proposal, offering learners a blended approach to their learning and the positive engagements with the BiopharmaChem and Medical Devices sector.

CONCLUSION

Based on the above findings, the Panel recommends to Academic Council:

That the Programme be validated for five academic years, or until the next programmatic review, whichever is soonest, subject to implementation of the Requirements above, and with due regard to the Recommendations made.

Certificate in Validation Science

Awards	Certificate
Programme Code:	**Mode of Delivery:** Part Time, ACCS
No. of Semesters: 2	**NFQ Level:** 7
Embedded Award: No	

Programme Credits:	10
Valid From:	Semester 1 - 2018/19 (September 2018)
Next Review Date:	May 2019
Department:	PROCESS, ENERGY & TRANSPORT ENGINEERING
Programme Sponsor:	MICHAEL J O MAHONY

Educational Aim of Programme:

This programme will provide students with a knowledge of validation as applied in industry. It aims to deliver a broad scope of industry relevant validation topics that will give students valuable insight and raise their awareness of the importance, implementation and impact of validation in the pharmaceutical, biopharmaceutical and medical device industries.

Programme Outcomes

Upon successful completion of this programme the graduate will be able to demonstrate:

PO1 Knowledge - Breadth
(a) A knowledge of the principles of Validation Science in the context of current Good Manufacturing Practice.

PO2 Knowledge - Kind
(a) An understanding of the science behind the techniques and procedures in Validation Science.

PO3 Skill - Range
(a) Prepare validation documents, follow approved validation and quality procedures.

PO4 Skill - Selectivity
(a) Demonstrate the ability to apply a range of risk management tools in making regulatory based decisions to meet specified needs in a GMP environment.

PO5 Competence - Context
(a) Use technical knowledge to contribute effectively to a validation project.

PO6 Competence - Role
(a) Exercise personal responsibility, contribute constructively in a team across core scientific disciplines and communicate effectively.

PO7 Competence - Learning to Learn
(a) Experience and integrate learning through various virtual formats involving online webinar and case studies.

PO8 Competence - Insight
(a) N/A

Stage 1 / Semester 1

Mandatory

Mod Code	Module Title	Co-ordinator	Level	Credits	FT Contact Hours	PT Contact Hours	Course Work	Formal Exam
No Code Yet	Introduction to Validation (Draft)	MICHAEL J O MAHONY	Intermediate	5.0	1.50	0.80	100.0	0.0

Stage 1 / Semester 2

Mandatory

Mod Code	Module Title	Co-ordinator	Level	Credits	FT Contact Hours	PT Contact Hours	Course Work	Formal Exam
MANU7007	Validation Science (Draft)	MICHAEL J O MAHONY	Intermediate	5.0	3.00	3.00	100.0	0.0