CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ

Report of Validation Panel

Date of Meeting: 16-06-2016

Named Award:	Certificate
Programme Title:	Certificate in Cleanroom Manufacturing Practices
Award Type:	Special Purpose Award
NFQ Level:	6
Intakes Commencing:	01-09-2016
ECTS/ACCS Credits:	10

PANEL MEMBERS

Name / Function / External Institution OR CIT Academic Unit
Dr Hugh McGlynn, Head of School of Science and Informatics (Chair)
Mr Brian Nation, Master Distiller, Midleton Distillery
Mr Joseph Croke, Department of Biological Sciences

PROPOSING TEAM MEMBERS

Name / Function / Academic Unit
Mr Matt Cotterell, Head of School Mechanical and Process Engineering
Dr Michael J O'Mahony, Head of Department of Process, Energy & Transport Engineering
Mr Ian O'Sullivan, Department of Process, Energy & Transport Engineering
Dr Anne Toebes , Department of Process, Energy & Transport Engineering
Ms Mary Quirke , Department of Process, Energy & Transport Engineering

BACKGROUND TO THE PROPOSED PROGRAMME

This Special Purpose Award in Cleanroom Manufacturing Practices provides an accredited qualification in Contamination Control and Cleanroom Management for individuals working or wishing to work in production, quality assurance or validation roles within pharmaceutical, biopharmaceutical, medical device and food companies. Key topics addressed include identifying and measuring sources of cleanroom contamination, materials compatibility in controlling contamination, selection and use of cleaning agents, the classification of cleanrooms according to ISO14644-1, cleanroom design and construction, cleanroom garbing and behaviour, cleanroom monitoring and validation.

The proposed Certificate in Science in Cleanroom Manufacturing is a 10 ECTS credit offering at level 6 and is a response to Industry needs. The modules proposed are part of the Higher Certificate in Science in GMP and Technology. By offering groups of modules of the Higher Certificate in Science in GMP and Technology as Special Purpose Awards, it allows the part time students to gain a qualification within one academic year at a reasonable cost

There has been an $8 billion investment in new BioPharma facilities in Ireland in recent years and a requirement for 5,000 new personnel in this sector over the next 5 years to reflect this capital investment.

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, programme will attract both graduates and non-graduates who require upskilling in the workplace or who wish to gain new knowledge and skills to enter the pharma/biopharma/medical device industries.

Finding(s): Real demand from BioPharma sector in both small molecules and peptide sector.

Requirement(s): none

Recommendation(s): none

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

Overall Finding: Yes

Finding(s): Level 6 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 of necessary theoretical and practical skills in both know how and know why aspects of the Cleanroom Manufacturing Practices in both BioPharma and Medical Devices sectors.

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

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 learners form the BioPharma and Medical Devices sectors. This will add to the portfolio of offerings within the Institute and have a positive impact.

Requirement(s): none

Recommendation(s): none

2. Other Findings

Panel complementary of an excellent proposal.

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.

APPENDIX

Semester Schedules

Stage 1 / Semester 1

Mandatory								
Mod Code	**Module Title**	**Co-ordinator**	**Level**	**Credits**	**FT Contact Hours**	**PT Contact Hours**	**Course Work**	**Formal Exam**
BIOM6004	Contamination Control (Approved)	MICHAEL J O MAHONY	Fundamental	5.0	3.00	3.00	40.0	60.0

Stage 1 / Semester 2

Mandatory								
Mod Code	**Module Title**	**Co-ordinator**	**Level**	**Credits**	**FT Contact Hours**	**PT Contact Hours**	**Course Work**	**Formal Exam**
BIOM6003	Cleanroom Management (Approved)	MICHAEL J O MAHONY	Fundamental	5.0	3.00	3.00	100.0	0.0