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

Date of Meeting: 09-05-2014

Named Award:	Certificate
Programme Title:	**Certificate in Biopharmaceutical Manufacturing Operations**
Award Type:	Special Purpose Award
NFQ Level:	6
Intakes Commencing:	01/09/14
ECTS/ACCS Credits:	55

PANEL MEMBERS

Name / Function / External Institution OR CIT Academic Unit
Dr Hugh McGlynn, Head of School of Science and Informatics (Chair)
Dr Jim O'Mahony, Department of Biological Sciences
Mr Brian Nation, Master Distiller at Irish Distillers, Pernod Ricard

PROPOSING TEAM MEMBERS

Name / Function / Academic Unit
Mr Matt Cotterell, Head of School, Mechanical, Electrical and Process Engineering
Dr Michael J O'Mahony, Head of Department of Process, Energy and Transport Engineering
Dr Ann Toebes, Department of Process, Energy and Transport Engineering
Mr Cilian O'Suilleabhain, Department of Process, Energy and Transport Engineering
Dr Sandra Lenihan, Department of Process, Energy and Transport Engineering

BACKGROUND TO THE PROPOSED PROGRAMME

The Biopharmaceutical manufacturing sector has been identified as difficult to fill in the 'Vacancy Overview 2012' a report produced by the Skills and Labour Market Research Unit (SLMRU) in FÁS for the Expert Group on Future Skills Needs, February 2013. Skills recruitment difficulties being experienced mainly relate to: Validation and Quality (EGFSN/Forfás Report: Future Skills Requirements of the Manufacturing Sector to 2020) and Biotechnology skills for bioprocessing with a focus on formulation, cell culture, stem cell research and vaccine development (Guidance for Higher Education providers on current and future skills needs of enterprise, Springboard 2013)

This Special Purpose Award in Biopharmaceutical Manufacturing Operations provides an accredited qualification in Biopharmaceutical Manufacturing Operations for people wishing to work in production, quality assurance or validation roles within Pharmaceutical/ Biotechnology manufacturing companies. Key topics addressed includes GMP, QA, QC, Cleanroom management, Biotechnology, Mathematics, process equipment and process engineering laboratory skills.

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): Springboard initiative indicates need for skills in this area, course proposed meets this skills shortage.

Requirement(s): none

Recommendation(s): none

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

Overall Finding: Yes

Finding(s): modules are at appropriate level

Requirement(s): none

Recommendation(s): none

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

Overall Finding: Yes

The key topics (delivered in module mode) will serve to enhance the student's prospects when applying for employment as a process operator or process supervisor in the Pharmaceutical/ Biotechnology sector. This programme would also include a 2 day course at the National Institute for Bioprocessing Research and Training (NIBRT). NIBRT is a world-class institute that provides training and research solutions for the bioprocessing industry. It provides a unique learning experience for trainees in an environment that replicates the most modern industrial bioprocessing facility. This Special Purpose Award in Biopharmaceutical Manufacturing Operations also includes a 10 week, accredited work placement.

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): Panel indicated the need for such a course which will produce a pipeline of employees for Biopharmaceutical industry

Requirements: 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): Course will run using existing modules and instances of delivery, hence no additional resource requirement needed.

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 leaners through the Springboard initiative and provide opportunities for progression for learners onto the Diploma and BSc GMP programmes. 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.