

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

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**Date of Meeting:** 06-06-2013

**Named Award:** Diploma

**Programme Title:** Diploma in Biopharmaceutical Manufacturing Operations

**Award Type:** Special Purpose Award

**NFQ Level:** 7

**Intakes Commencing:** 02-09-2013

**ECTS/ACCS Credits:** 60

### PANEL MEMBERS

Name / Function / External Institution OR CIT Academic Unit
Dr Hugh McGlynn, Head of School of Science and Informatics (Chair)
Mr Harvey Makin, Department of Applied Physics and Instrumentation
Mr Ronan Curtis, Janssen Biologics, Carrigtwohill
Mr Dermot O'Brien, Director of Process Development & Commercialisation, MSD Ireland

### IN ATTENDANCE

Name / Function / External Institution OR CIT Academic Unit

### PROPOSING TEAM MEMBERS

Name / Function / Academic Unit
Mr Matt Cotterell, Head of School of Mechanical 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
Dr Sandra Lenihan, Department of Process, Energy and Transport Engineering

### BACKGROUND TO THE PROPOSED PROGRAMME

The EGFSN/Forfás Report: Future Skills Requirements of the Manufacturing Sector to 2020 has identified specific skill shortages and gaps across the Biomedical and Biopharmaceutical industries and in particular in the areas of production, quality assurance and validation within the pharmaceutical, medical device and food industries.

The proposed Diploma in Biopharmaceutical Manufacturing Operations is a 60 ECTS credit offering at level 7 and is a response to the Springboard Initiative to address this skills shortage. The target audience would be those considering upskilling to Technician or team leader in all areas of the Biopharma sector, who would have come from the construction or civil engineering sector. Most of the modules on the proposed Diploma are derived from the HC in Science in Good Manufacturing Practice and the add-on BSc in GMP.

## 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

Suite of modules offered allow learners to acquire of necessary skills in Manufacturing Operations within the Biopharmaceutical sector

**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, but were mindful of the fact that course may run risk of being ‘everything for everybody’ and proposers to manage the expectations of the stakeholders.

**Requirements:** none

**Recommendation(s):** none

**1.5 Are the programme management structures adequate?**

Overall Finding: Yes

**Finding(s):** Course Board 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 learners through the Springboard initiative and provide opportunities for progression for learners onto the BSc in GMP programme. 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 complimentary 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.

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