



Institute of Technology Sligo
INSTITIÚID TEICNEOLAÍOCHTA SLIGEACH

PROGRAMME VALIDATION REPORT

DATE OF EVALUATION 26th May 2016

PROGRAMME EVALUATED

SG_SBIOP_M09

Masters in Bioprocessing (90 credits)

SG_SBIOP_G09

Postgraduate Diploma in Bioprocessing (60 credits)

Panel of Assessors

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(Chairperson)

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Former Chairperson HETAC Collaborative Programme Board
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Declaration regarding any conflicts of interest:

The members of the Panel signed a form confirming that they did not have any conflict of interest.

Meeting with School Management

Attendees:

Registrar: Colin McLean
Head of School: Dr Jerry Bird
Head of Department: Dr James Brennan
Dr Sharon Barrett
Kieran Tobin

The Chair welcomed the Management team and introduced the panel.

Rationale

The Programme coordinator presented a brief overview of Department of Life Science and the programmes available. She highlighted:

- The absence of a Level 9 pathway for students
- Staff within the Department work closely with NIBRT, which has all the facilities for bioprocessing on a pilot scale
- IT Sligo has developed a number of minor awards in conjunction with NIBRT, which are mainly taught online
- The MSc in Biopharmaceutical Science has run since 2008. This has been very successful and helped staff to develop considerable experience
- Rationale for the new programmes comes from students and from employer demand for this type of graduates
- Aimed at L8 graduates rather than students in industry. The content reflects the cohort of applicants
- Programme to be delivered in blended format. Blocks of practical sessions to mimic real life industry. Some will take place in Sligo, some in NIBRT
- A variety of assessments included in the programme

The Registrar welcomed the Panel and commended the programme team on the development of this programme. He explained that the new Strategic Plan will take effect September 2016 and will take us up to 2020. This programme is in line with our CUA targets, which aims to increase research and upskilling of staff.

The panel asked management to elaborate on Programme design and its particular structure. They said they are responding to an industry need that has been identified in their last Programmatic Review. For example, IDA visited the Campus yesterday and commented that this is exactly what they need to be able to show companies coming to Ireland and the Northwest, which are keen to see the availability of skilled graduates. The Head of Department said staff is well versed in what is contemporary and meet regularly with industry representatives. This constant interaction with people in the field informs their teaching and programme design.

Resources

The Chair queried the additional staff resources alluded to in the documentation. The Registrar responded that the resource allocation has been signed off. The Head of School added that skills are available internally and he would not wish to tie down the skill set at this stage. The Department has a strong student cohort and a great knowledge depth in existing staff. When queried about additional facility resources, he said existing facilities were adequate however funding for further equipment has been made available.

Aims and objectives

The Chair referred to Page 6 and the statement “The course will provide the theoretical background, practical training and ancillary workplace skills that will equip graduates with the essential tools for a successful career in the biopharmaceutical and biotechnology industry” and wondered where the workplace skills come in. The programme coordinator said the facilities in NIBRT are as close as real life a student can experience. Students will do some labs, clean room and GMP in NIBRT. She acknowledged it is a not a long period of work experience but it will give students a good understanding of the environment. Students operate equipment in NIBRT for a total of three days. Other laboratory work is done in IT Sligo.

The Chair queried the design process of the Programme outcomes and who had written them. The programme coordinator explained that many were leveraged from the existing programme in consultation with the Programme team. Kathleen Love’s research contributed to this.

Learning outcomes

The panel referred to page 16 of the documentation and the Programme outcomes. The programme outcomes do not show that it is a L9 as it is not linked to QQI standards, explicitly showing the requirements. They are not there and will be a condition. The programme needs to conform to the QQI L9 Science indicators.

The panel looked at learning outcome 9. They felt this could apply to some other modules as well. They wanted to know how you tie it to the 3 day hands-on experience and how students would be assessed. Would they be taken out of their comfort zone and challenged? The programme coordinator responded that the learning outcome will apply to a lot of assignments and projects not just the time in NIBRT. Students are working as part of team, but they also have individual responsibilities and this is assessed too.

The panel found it hard to understand Learning outcome 7. The Programme coordinator explained it is an evolving area, and pointed to single use technology and regulatory affairs. The industry is not static and students need to stay current.

The panel pointed to different aspects of the Award Standards for Science from QQI.

- *Lead interdisciplinary team.* The Programme coordinator said the NIBRT experience involves specific team task, where they all have different functions and different professional responsibility.
- *A critical awareness of current problems and/or new insights, generally informed by the forefront of a field of learning.* Head of Department responded NIBRT is not just a training facility but they engage in work for industry and students will get to experience this. Staff also publishes at the leading edge. There is no book that can be recommended for finding this information, it is constantly changing and they also learn from the work in the L9 dissertations.

One panel member queried the lack of bioengineering in the programme. The programme coordinator pointed out that IT Sligo is more science based and other Institutions may be more engineering based.

The panel asked of the level of statistics. The programme coordinator explained this could be included in the research aspect of the programme, depending on the type of project students select. There is also statistical expertise among staff, and students have access to SPSS. It also features in Semester 1 modules such as Research methods.

Entry requirements

The panel asked about selection of students for the programme as they could come from diverse backgrounds and different cultures. The programme coordinator pointed to another MSc programme which has international students. There was some uncertainty over the requirement for English proficiency but it was thought it was at least level 6. The eligibility requirement could include RPL and e-portfolio. They expect to take an intake from broader backgrounds as programme is a mixture of both science and engineering. The panel wanted to know what if someone comes from a strict engineering back ground and someone comes from biology background how would they fare on the programme and how would they be facilitated. The programme coordinator pointed out the process engineering element and that additional resources and content was made available to students on Moodle.

There is some support for overseas candidates where language might be a barrier in the use of assistive technology, e.g. recorded lectures can be viewed at slower pace. Staff said that they have to be firm on language requirement when selecting students.

A panel member suggested the use of a module in writing skills, as student could be very bright, but academic writing can be their biggest barrier.

The Head of Department said there are some modules in the Department of Business which could benefit these students. There are also modules in report writing which students can avail of. The selection of students with different backgrounds would have to be assessed on a case by case basis.

Assessment

The panel had some concerns of the use of MCQ (multiple choice questions) for a Level 9 Programme. The programme coordinator said the design of MCQ can be very sophisticated and is used on the current L9. It can include negative marking and it is strict on timing for online MCQs. MCQs would account for about 20-30% of assessments. The panel asked about integrity. The programme coordinator answered that you build from a bank of question and there are various ways to ensure integrity. Terminal supervised or open book exams are another type of assessment and account for approx. 30-35% marks. Projects and vivas typically account for the

remaining 45-50% of the marks. Turnitin is used for all modules. We have good controls in place and students can use remote proctoring facilities for examinations.

Meeting with the programme development team

Attendees:

James Brennan
Stephen Daly
Sharon Barrett
Kieran Tobin
MacDara Bodecker
Tony McCabe
Mary Heneghan
Ailish Breen
Margaret Doherty
Eadaoin Tyrrell

The Panel Chair welcomed the additional staff and introductions were made.

The panel was interested in hearing about the PhD research carried out by Kathleen Love (on the design, development, implementation and evaluation of Industry focused on-line Biopharma courses developed for the purposes of up-skilling individuals working in the Industry) and how it may have impacted on the design of the programme. The research includes a case study on the online MSc. The experience was that it was possible to study a Masters while working in industry and demonstrated that Industry focused online education benefits both the employer and employees. The programme had a transformative effect on the individuals and they attributed promotion to the completion of the programme. Another effect was the development of teams within company and barriers of communications were broken down. Students were in favour of the flexible on-line delivery and have indicated that they would have found it very difficult to travel to complete the MSc whilst working. It has proved that blended learning is beneficial and it has fed in to the new programme design.

General

The panel asked staff to demonstrate how the programme met QQI Award standards for Science in the following three areas.

- 1) *Critical awareness of current problems and /or new insights, generally informed by the forefront of field of learning.* Staff pointed to the modules Dissertation and Legislation. The Dissertation topics would aspire to be at the forefront of technology in the industry. The Legislation module ensures students are fully aware and up-to-date with current legislation in the field both domestically and internationally.
- 2) *Select from complex and advanced skills across a filled of learning; develop new skills to a high level, including novel and emerging techniques.* The Bioanalytics module focuses on new and emerging technologies both theoretically and practically. In Formulations students are exposed to what is coming down the line in areas such as drug delivery and nano technology.
- 3) *Act in a wide and often unpredictable variety of professional levels and illdefined contexts.* Students are challenged with incomplete information and enquiry based assessment. They would work in a team environment where they are given a problem with some missing

information to encourage independent research. The NIBRT modules have deliberate faults built in.

Discussion on specific modules

BIO09066 Bioprocessing manufacturing

Panel believed there was an excessive amount of learning outcomes. They queried if PAT was included. Staff said it was included in Real time monitoring, multivariate, non-destructive methods and USP. The concept of PAT is included in the quality and design as well as drawing on PAT in several other modules.

Assessment: If all outcomes are assessed it could be difficult for students achieve the outcomes. There could be reason to be cautious and focus outcomes more. Staff said as it was a 10 credit module it was appropriate and the module deals with both upstream and downstream. Students are assessed through a VIVA, which will be done person to person where the student will demonstrate their knowledge. If done online they will be recorded. The panel recommends more than one reader for protection of staff and students. It is also prudent to normalise questions and time given to students so that a lecturer's decision will not be questioned. Staff finds MCQs very effective. They put considerable effort in to them and they can be scenario based to encourage students to think. The lecturers write their own MCQs. There are no guidelines but there is a great experience among staff. Disposable design is used.

SCI09004 Leg Reg Biopharma

This module prepares students for how do you develop a drug and bring it to market. The panel believed the module descriptor should be updated. They queried if the following aspects were included; regulation framework, quality control, quality assurance GMP control and change control. Staff responded that it is included in this module and both the QA and QC concepts are brought in. It is also covered in the Validation module. IT Sligo undergraduates have strong background in quality systems. The panel asked about the inspection process, staff said auditing was not included but they would consider the inclusion of this. Some aspects are included in the Biocontamination module. The majority of the learning resources are from websites, e.g. those of the main regulatory institutions, to ensure the most current information is used.

Assessment

The assessment should be updated to read 60-40%.

BIO09067 Biocontamination monitoring and Control

The panel queried whether this module incorporated Facility Design. Staff confirmed it covers all ISO documentation, USP water, microbial control, neurotoxins and containment versus protection Descriptor to be changed. Sterilisation is included in the Biocontamination Monitoring and Control module and freeze drying is covered in Formulation. The panel could like staff to review the descriptor and the number of outcomes.

BIO09069 Bioanalytical techniques

The panel asked for the rationale of introducing theory without lab and why they were divided between the semesters. This module is delivered online where students are given some problem based learning. Student need to know the techniques and theory before practising in a lab. The panel suggested that a dry lab could be run as part of the assessment to bridge the gap.

BIO09062 Research Methods Biopharma

The panel queried staff on how this module was structured. Staff explained that students would learn how to put a proposal together, they present this and the online presentation would be graded. The qualitative data, how they conducted surveys, analysis and reports was also graded.

Students learn how to analyse research papers, create abstracts and identify peer reviews. Ethics is not included however it is taught to current undergraduates, although discussions take place on topics such as animal replacement, remove preservatives and bio contamination in some modules. The panel suggested that further encouragement for ethical debates should be considered possibly through forums such as seminars.

BIO09063 Bioprocessing Manufacturing Laboratories

Panel queried the number of learning outcomes that students would have to achieve. Staff responded that outcomes were all appropriate but they could be joined

BIO09065 Formulation and Delivery

Staff explained that during the workshop days in NIBRT students were broken in to smaller groups to ensure full engagement and participation from all students. They also highlighted the close relationship IT Sligo has with NIBRT and the existence of broad spectrum MOUs.

BIO09065 Formulation and Delivery

The panel commended staff on this module. They asked staff about how this module was assessed and was there any practical component. The module is mainly delivered online but there are some face to face time and group work. This module brings all modules together. They were asked if it covered potential of ingredients in formulating products, for example, problems for diabetics, how this might have a biochemical effect on patients. Staff answered that some of these aspects were covered but further consideration of the effect on the patients could be included.

SCI09005 Lean Six Sigma and Operation Management

Panel commended this module and believed it very relevant with its focus on reducing waste, streamlining processes and forecasting.

BIO09068 Bioanalytics Practical Module

Panel queried the content in terms of practical design and how it would be assessed. Staff responded that it would depend on the labs. and there are various forms of assessments and problem solving/troubleshooting. The reference to BIO09069 should be corrected. The students do get exposed to the scenario of incorrect results through in-house practicals were they learn to proactively troubleshoot. OOS guidelines are included.

VALD09005

The panel asked if clean validation was included and if students write validation programmes. Staff welcomed this suggestion for a Level 9. Dual projects have been done between this and Bioanalytical Techniques on the on-line MSc.

DISS05001

Staff explained the schedule of this module, which consists of nine weeks in semester 2, students then sit their exams and afterwards work in laboratories commences. Students can access the labs 5 days a week. They have free technical support 9-6 and they can apply for out of hours support. Students also have adequate academic support with an allocation of 2 hours per week. There is a protocol in place for supervision.

General

The panel asked about progression if, for example, a student fails a semester 1 module. Staff responded that students can progress with a failed element and they would have to repeat the

project in the autumn. If a student defers the programme they could re-join the following year as the expectation is to run the programme on a yearly basis. The projected number of students for the first intake is 16.

Summary of Findings

The Panel recommends to Academic Council that it approve the Programme.

Panel Commendation

The panel find this an exciting new programme. A key need has been identified and the Programme has direct relevance to the economic developments of the country. The programme reflects a strong interaction with industry.

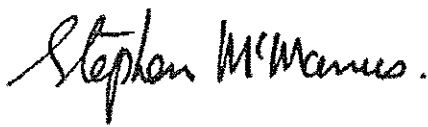
Panel Conditions

1. Match Programme Learning Outcomes to the QQI indicators for Science L9. Useful for staff to meet and discuss these outcomes.
2. Rewrite syllabi where necessary to include quality assurance as part of quality systems.

Panel Recommendations

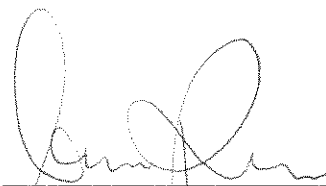
1. Periodically evaluate MCQ and the effectiveness of this assessment model for a L9 programme.
2. Review induction process and ensure that students, which come from diverse backgrounds where there could be deficit, are given access to academic direction and tutorials
3. Ethical issues that might arise in the industry should be discussed in lectures or seminars
4. Learning outcomes and assessments need to be updated where errors made.
5. All learning outcomes have to be achieved for a student to be successful. If not achievable, learning outcomes need to be reduced and reformulated.

Signed on behalf of programme validation Panel



Mr Stephen McManus
Chairperson

Date: 26th May 2016



Ms Annica Rasmak
Recording Secretary

Date: 26th May 2016