**REPORT ON PROGRAMME REVIEW** **Q 3 report template**

## Part 1 Programme details

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| **Proposed title** | MSc in Pharmaceutical Quality Assurance and Regulation |
| **Existing titles and codes** | MSc in Pharmaceutical Quality Assurance and Biotechnology DT233<br>MSc in Pharmaceutical Quality Assurance and Regulation DT237. |
| **Mode and duration of programme** | 1 year full-time<br>2 years part-time |
| **ECTS** | 90 |
| **TU Dublin Award(s) sought** | Master of Science in Pharmaceutical Quality Assurance and Regulation<br><br>Postgraduate Diploma in Pharmaceutical Quality Assurance and Regulation<br><br>Postgraduate Certificate in Pharmaceutical Quality Assurance and Regulation |
| **Classifications of award(s)** | MSc:, Pass (50%) Distinction (70%)<br><br>PgDip and PgCert: Distinction, Merit Grade 1, Merit Grade 2, Pass |
| **School responsible** | Chemical and Pharmaceutical Sciences |
| **Professional body accreditation and relevant dates (where applicable)** | N/A |
| **External provider type (where applicable)** | N/A |
| **Delivery location** | On-line and City Campus –Grangegorman |

## Part 2 Programme approval information

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| **Date of initial approval (of Q1A) by SLT's Academic and Research Committee/SLT** | 2003 |
| **Date of validation/review event** | 20th May 2021 |
| **Date of approval by Academic Council and Governing Body** | |
| **Proposed date of re-commencement** | September 2021 |

## Part 3 Programme background/structure

***Background***

TU Dublin's MSc in Pharmaceutical Quality Assurance was first validated in 1999 as a part-time programme to up-skill graduates working in the pharmaceutical industry. Following this in 2000, a full-time option was developed to provide a bridge to recent graduates to meet the specific needs of the pharmaceutical industry.

In 2006, the programme was reviewed and the original four-module format was modified to become a twelve-module format to reflect the introduction of semesterisation in the (then) DIT. At this time, the full-time element was renamed the MSc in Pharmaceutical Quality Assurance and Biotechnology DT233 and the part-time element as the MSc in Pharmaceutical Quality Assurance and Regulation DT237.

***Stated aims and learning outcomes of the programme***

The aims of the programme is to provide a comprehensive technological education service for Irish society and industry having regard to the technological, commercial, social and cultural needs of the community it serves.

General programme objectives include:

(i) To provide a programme which allows science graduates and professionals develop the necessary knowledge and skills to integrate quickly into the role of Quality Assurance Specialist or Quality Manager in the pharmaceutical industrial environment,

(ii) To present to the student a body of knowledge, practical, technical and theoretical, that is relevant to the needs of the pharmaceutical industry in the area of Quality Assurance,

(iii) Provision of high quality industrially relevant education and training by experts from academia and industry,

(iv) The teaching of proposed modules and related topics designed to enhance the knowledge and skills of students in these areas,

(v) Provision of appropriate assessments and assignments to enhance, reinforce and test learning,

(vi) To deliver modules and topics suitable for continuing professional development.

(vii) To deliver a programme which will enable graduates to work effectively with scientists, engineers, managers and other professions in solving plant operating problems,

(viii) To enhance the students' ability to exploit work-based learning and self-directed learning,

(ix) To develop research skills,

(x) To provide sufficient academic knowledge and practical skills to allow the graduate to perform effectively within the pharmaceutical industry. The programme builds upon an undergraduate science degree to achieve this,

(xi) To provide students with sufficient knowledge to apply quality assurance principles within a pharmaceutical environment.

It is considered that as a result of the detailed content of each module, and the variety of assessments incorporating essays, literature reviews, case studies, design exercises, practical reports, problem sets and individual/team assignments that each module addresses some component of the programme objectives. Some examples of modules and related assignment work are provided in section 1.3 to demonstrate the link between the graduate attributes, the

module assignment work and the related assessment.

**Programme Learning Outcomes**

Upon successful completion of this programme, learners are expected to have:

- Demonstration of knowledge and understanding that is at the forefront of learning.
- Demonstration of the application of knowledge, understanding and problem-solving abilities in new or unfamiliar contexts related to the field of study.
- Demonstration of the ability to integrate knowledge, handle complexity and formulate judgments.

***Programme structure***

Stage 1 of the programme operates over one year on a full-time basis and over two years on a part-time basis with entry to the programme possible each year. It has been designed on a modular basis to incorporate a flexible structure into the programme. The current structure has 9 taught modules for stage 1 of the programme (2 years). Stage 2 of the programme is the dissertation element, which is carried out over a 6-month period on successful completion of Stage 1.

***Entry Requirements***

An honours degree (2.2) in a level 8 Hons Undergraduate Programme or equivalent in the area of chemistry, pharmacy, medicine, veterinary medicine, pharmaceutical chemistry and technology, biology, engineering or other equivalent scientific discipline as approved by the Programme Committee.

***Student assessment***

In accordance with TU Dublin City Campus General Assessment Regulations

***Derogations from the General Assessment Regulations, including rationale for derogation and view of the Panel:***

Derogation has been received previously from Academic council with regard to the pass mark of 50% on the MSc and the classification of the MSc award (Pass or Distinction).

Following the successful completion of the taught element of the programme (with a mark of 50% in a minimum of 7 of the 9 modules, including all three 10ECTS modules); students may undertake an industrial based research dissertation. Students must register for Stage 2 (dissertation) within two years of successful completion of Stage 1. Failure to do so will result in the automatic awarding of a Postgraduate Diploma.

Students have up to 2 attempts to complete each assessment.

## Part 4 Validation Details and Membership of Panel

**Schedule of meetings:** Thursday, 20th May 2021

***Venue:*** *MS Teams*

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| 9.30am | Introduction and Brief 10 minutes presentation by programme team |
| 9.45 am | Private Meeting of the Panel (Plan for the day) |
| 10.30am | Meeting with the representative students / graduates. |
| 11.15am | Private Meeting of the Panel |
| 11.30am | Panel Break |
| 11.45am | Meeting with the staff teaching on the programme |
| 13.00pm | Panel Break |

14.00pm Private Meeting of Panel to discuss outcome and highlight key areas for the report (Head of School / Programme Chairs to be available should the panel require any clarifications)
15.00pm Panel Break: QA Office during this time will circulate the draft report. Panel can send back any corrections via email
15.30pm Panel presents the report to School Management

**Panel Membership**

***Internal Members***

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| Dr Alan Hore (Chair) | School of Surveying & Construction Management, TU Dublin City Campus |
| Dr Niamh Gilmartin (Deputy Chair) | School of Biological & Health Sciences TU Dublin City Campus |
| Dr Claire McBride | School of Management TU Dublin City Campus |

***External Members***

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| Professor David Brayden | School of Veterinary Medicine & Conway Institute of Biotechnology University College Dublin |
| Ms Nichola Quinn | Vice President of Quality Operations Horizon Therapeutics, Dublin |

***Officer***

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| Ms Nicole O'Neill | Quality Assurance Officer |

**Documentation submitted:** Self Evaluation and Overview, Student Handbook, Q5 Annual Monitoring Reports, External Examiner Reports, Programme Committee Minutes

## Part 5 Summary of Panel findings against key questions

Note: the Panel's findings (ie yes/no) and any additional comments against each of the key questions should be recorded below. Where a 'no' is recorded, an associated condition or recommendation should be included in Part 6, Findings of the Panel.

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| Is the market demand and need for the programme clear and articulated? | Yes |
| Are the aims, objectives and learning outcomes of the programme well-founded and clearly formulated? | Yes, a recommendation to improve programme learning outcomes is included by the Review Panel. |
| Are the entry requirements clear and appropriate? | Yes, a recommendation to provide clarity in this regard is included by the Review Panel. |
| Are the arrangements for access, transfer and progression in accordance with Institute policy and NFQ? | Yes, a condition to provide clarity in this regard is included by the Review Panel. |

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| Are the programme learning outcomes at the appropriate level as set out by the NFQ requirements? | No, a condition to provide clarity in this regard is included by the Review Panel. |
| Do the individual modules 'add up' to a coherent programme? | Yes |
| Are Graduate Attributes embedded within the programme? | Yes |
| Will the accumulation of the module learning outcomes result in the attainment of the programme learning outcomes? | No, a condition to provide clarity in this regard is included by the Review Panel. |
| Is there appropriate use of student-centred learning, teaching and assessment strategies, including the First Year Framework for Success checklist, which recognise the needs of diverse student groups? | Yes |
| Do the curricula and teaching schemes in each module descriptor give realisable substance to the module's aims, objectives and learning outcomes? | Yes |
| Are the assessment methods and criteria aligned to the learning outcomes in each module? | Yes |
| Are facilities and resources, including staff, in place to support the delivery of the programme at the standard proposed? | Yes, see recommendation in relation to staffing |
| Is there parity between off-campus/on-campus delivery (if applicable)? | N/A |
| Are the roles and responsibilities of each partner clearly specified (if applicable)? | N/A |

## Part 6 Recommendations of the Panel

- **Overall recommendations of the Panel**

The panel commends the programme team on the quality of the programme and the relevance of the subject matter and the comprehensive range of modules that cover the industry requirements. The team have strong interaction with industry which informs the programme. The student outcomes and career progression reflect very well on the standard of the programme. The panel noted that the students with whom they met were very complimentary of the programme, positive about the on-line learning experience and the benefits of continuing on-line delivery, as well as being able to attend physical workshops and site visits.

The panel recommends continuing approval of the programme with the following awards at Level 9 on the National Framework of Qualifications:

- Master of Science in Pharmaceutical Quality Assurance and Regulation
- Postgraduate Diploma in Pharmaceutical Quality Assurance and Regulation
- Postgraduate Certificate in Pharmaceutical Quality Assurance and Regulation

The panel makes the following conditions and recommendations for the consideration of the programme team

### Conditions

1. The programme would be enhanced by a clearer statement on the unique vision and attributes of the programme and this should inform a review of the programme learning outcomes to better align with the level 9 award type descriptor and then revise the module learning outcomes to re-align to the revised programme learning outcomes.

2. Clarity should be provided in the documentation as to the requirements for the dissertation and whether it has to be embedded within industry and the options and supports available to students to develop industry relevant proposals or to do a peer – reviewed paper-based project. The flexibility demonstrated is welcomed and every opportunity should be afforded to students to facilitate their progression to stage 2 of the MSc programme.

### Recommendations

1. Review module learning outcomes to ensure that the terminology used reflects the level of the programme and the award.

2. A course schedule should be provided for the programme which clearly summarises the modules, semesters, Learning hours (contact and self-directed), and assessment breakdown.

3. Further details should be provided on the rationale for each derogation from the General Assessment Regulations to facilitate the University in considering the operation of the derogations.

4. The programme team should investigate the expertise across the University, for example Tallaght Campus, that would be valuable to this programme and encourage input from colleagues.

5. Make clearer in the documentation, that all applicants who meet the minimum entry criteria will be interviewed as part of the selection process.

6. Consider developing partnerships with industry to provide suitable research projects for students who are not in employment in industry.

7. The programme team needs to consider the future needs of the programme and consider providing more focus on emerging topics,such as, for example Gene Therapy, and Cell-Based Therapy and the implications of attracting industry experienced staff that will be required to teach these emerging topics.

8. Shipping Validation and Good Distribution Practices should be further emphasised within the programme.

9. In the programme documentation, expand on the competitive data provided with a comparative table which demonstrates the uniqueness of this programme from the other offerings.

10. The panel notes the requirement for industry experienced teaching staff on this programme and the difficulties of being able to competitively attract industry experienced lecturers and the administrative difficulties in relation to the payment of the same. The panel recommends liaising with colleagues in schools who have utilised the adjunct lecturer scheme and further explore this option for this programme.

11. The panel recommends that appropriate additional administrative support is provided for the programme.

12. Reading Lists should be refined and updated to ensure they reflect current global regulations and liaise with the library to ensure that adequate resources are made available to students.

13. Review the name of the ATMP 2 module to reflect the novel therapeutics content.

14. The programme management team are encouraged to utilise the university student feedback system, including Q6c and make available to the programme team the results and include this in the Annual Programme Monitoring Report.

15. The panel welcomes the move to on-line teaching, the mechanisms for co-delivery between full and part-time programmes should be clearly articulated in the Student Handbook. It should be clearly stated how modules will be delivered, the attendance requirements, the indicative timetable and provide links to the student resources for engagement with Brightspace. The module descriptors should clearly specify the different learning and teaching methods used for the delivery of the module on different programmes.

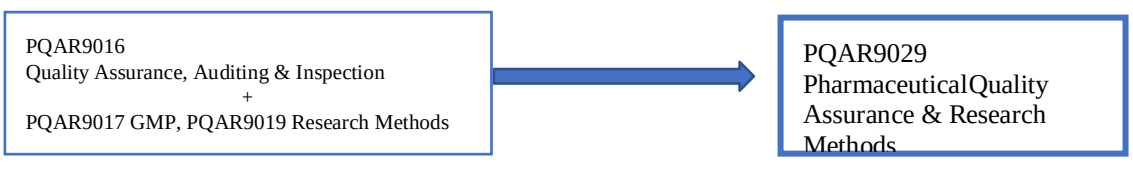
16. The dissertation handbook should be referenced in the module descriptor for the dissertation.

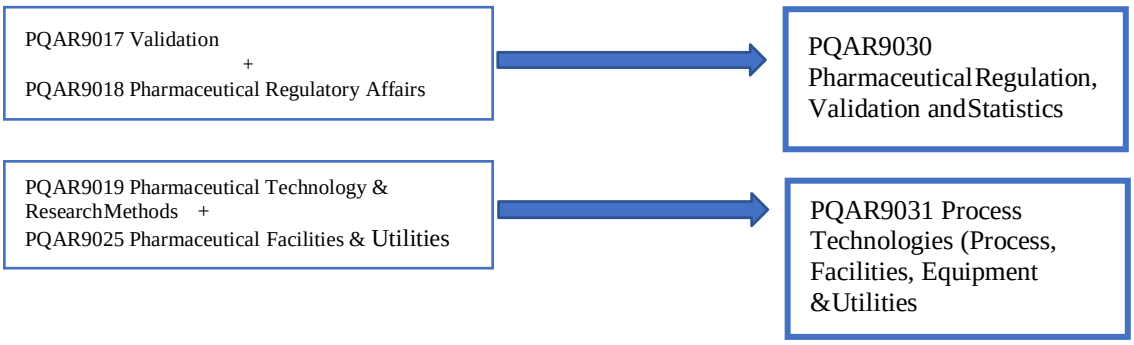
**Summary of Changes Approved**

There are a number of proposed modifications to the programmes:

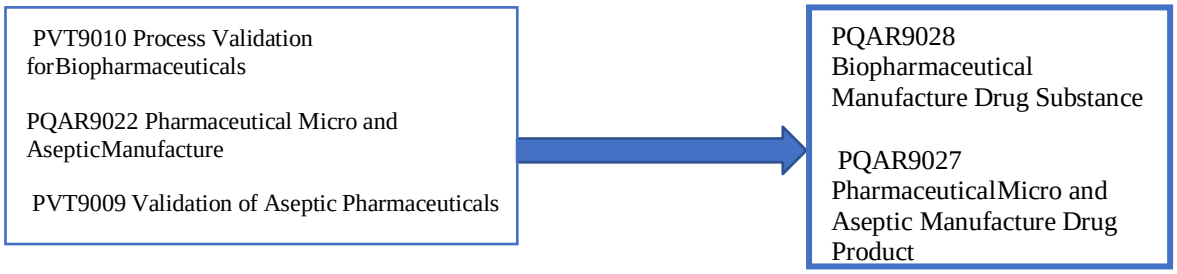
1. All modules were reviewed and updated.

2. 5 modules were combined to form three 10 ECTS modules and they are as follows:






Aspects of three modules were amalgamated forming 2 new modules developed specifically for this programme - PVT9010 Process Validation for Biopharmaceuticals and PQAR9022 Pharmaceutical Micro and Aseptic Manufacture will become PQAR9027 Pharmaceutical Micro & Aseptic Manufacture Drug Product and PVT9009 Validation of Aseptic Pharmaceuticals will become PQAR9028 Biopharmaceutical Manufacture Drug Substance.




The Programme Committee proposed that a number of existing modules will be discontinued, including PQAR9023 Pharmacology & Toxicology, PVT9017 Science and Knowledge Management across the Pharmaceutical Product Lifecycle, PQAR9014 Biotechnology and PQAR9015 Biopharmaceutical Analysis. The Programme Committee propose two new modules PQAR9032 -ATMP 1 and PQAR9033 - ATMP 2. These modules will provide the students with an opportunity to study topics relevant to the future skills-needs of the pharmaceutical industry including the regulatory environment of Advanced Therapeutic Medicinal Products (ATMPs), personalised medicines and combination products.

3. Move to online delivery for TU288

The move to online delivery for this programme will make the programme available to a wider audience. As mentioned, many students would like to do the programme but would have had difficulty in attending TU Dublin 3 times per week as per previous timetables. This move reflects feedback from current students, graduates of the programme, and prospective students. The programme has run smoothly over the last year as we have made the swift transition from face to face to online delivery. Therefore, it is not anticipated that this move will present additional challenges to the students or staff as appropriate.

4. Progression to dissertation for weaker students

The Programme Committee recommend that a mark of 50% be achieved in a minimum of 7 of the9 modules (including all three 10 ECTS modules) in order to progress to Stage 2. If student do not achieve these requirements they will be advised to exit the programme with a postgraduate diploma.

5. Realigning the MSc programmes

The Programme Committee would like to align the two MSc programmes and change the name ofTU258 to 'MSc in Pharmaceutical Quality Assurance & Regulation' to reflect this.