Responses to Panel Conditions & Recommendations

for

MSc in Pharmaceutical QA & Regulation TU258/TU288

Condition 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.

Response:

Part 1

The MSc in Pharmaceutical QA and Regulation (TU258/288) provides specific education at postgraduate level in 'Quality Assurance' and pharmaceutical regulatory requirements, to scientists and other professionals who operate in the 'Quality Environment' of the bio/pharmaceutical industry (accounting for up to 25% of graduates in this sector).

There are more than 85 pharmaceutical companies in Ireland with 9 of the world's top 10 pharma companies having substantial operations here. The programme is tailored to those who wish to work in this sector.

The programme provides an industry-relevant, broad-based curriculum which focusses on the Quality and Regulatory Framework for the bio/pharmaceutical industry.

The programme is flexibly designed to provide the knowledge, skills and competence required to work in the area of Quality Assurance. It is designed to provide a bridge for BSc (or equivalent) graduates to obtain quality roles in the pharmaceutical industry and also to up-skill graduates currently working in the pharmaceutical industry.

Part 2 - **In the table below, text in black relates to the purpose and objectives of the programme while text in blue outlines the programme learning outcomes.**

Title	MSc in Pharmaceutical QA and Regulation (TU258/TU288)
Purpose	The MSc in Pharmaceutical QA and Regulation (TU258/288) provides specific education at postgraduate level in 'Quality Assurance' and pharmaceutical regulatory requirements, to scientists and other professionals who operate in the 'Quality Environment' of the bio/pharmaceutical industry (accounting for up to 25% of graduates in this sector).

	There are more than 85 pharmaceutical companies in Ireland with 9 of the world's top 10 pharma companies having substantial operations here. The programme is tailored to those who wish to work in this sector. The programme provides an industry-relevant, broad-based curriculum which focusses on the Quality and Regulatory Framework for the bio/pharmaceutical industry. The programme is flexibly designed to provide the knowledge, skills and competence required to work in the area of Quality Assurance. It is designed to provide a bridge for BSc (or equivalent) graduates to obtain quality roles in the pharmaceutical industry and also to up-skill graduates currently working in the pharmaceutical industry.
Level	9
Volume	Large
Knowledge - breadth	Upon successful completion of the programme the learner will be able to: 1. Demonstrate the knowledge and understanding, and apply the skills necessary to integrate and operate effectively in Quality roles in the pharmaceutical industry. 2. Demonstrate in-depth knowledge of industry best practice focusing on Quality Assurance and the EU & US Regulatory Framework. This programme provides students with the opportunity to develop the knowledge and understanding, and the skills to integrate and operate effectively in roles ranging from Quality Assurance Specialist to Quality Manager in the pharmaceutical industrial environment. During stage 1 students are introduced to industry best practices through the programme teaching team, SMEs, members of the PRST and also through knowledge sharing in the class room setting (peer to peer learning)
Knowledge - kind	Upon successful completion of the programme the learner will be able to : 3. Demonstrate a comprehensive understanding of the Regulatory Framework that underpins a quality manufacturing environment. 4. Critically analyse and demonstrate an in-depth awareness of the key challenges associated with producing a quality product for the patient. This programme presents a body of knowledge, practical, technical and theoretical, that is relevant to the current and future needs and challenges of the pharmaceutical industry. Lectures, seminars and workshops with SMEs allows students to develop critical awareness and the ability to critically analyse the key challenges that industry faces including drug shortages, supply chain management, falsified medicines, pharma 4.0, lifecycle management and ICHQ12.

Know-how and skill - range	Upon successful completion of the programme the learner will be able to : 5. Apply advanced research skills in industry settings. This programme ensures students develop research skills that can be applied in an industry-based setting. These skills give them the confidence and competence to address knowledge gaps/challenges associated with quality aspects of the pharmaceutical industry (Stage 2 Dissertation).
Know-how and skill - selectivity	Upon successful completion of the programme the learner will be able to: 6. Apply the framework for quality and regulatory sciences to the emerging therapeutic areas of ATMPs and precision medicines. This programme provides students with the framework for quality and regulatory sciences and how to apply them to complex pharmaceutical modalities including ATMPs and other novel and emerging products.
Competence - context	Upon successful completion of the programme the learner will be able to: 7. Work and communicate effectively with scientists, engineers, managers and other professionals on addressing quality related issues This programme provides students with the theoretical framework and practical skills which enable them to work effectively with scientists, engineers, managers and other professionals (regulatory bodies) in addressing quality related issues across several complex sites e.g. CMOs, Virtual companies, API/FP, Bio/pharma.
Competence - role	Upon successful completion of the programme the learner will be able to: 8. Initiate and lead team-based activities in their work environment. This programme enables graduates to develop leadership skills and have the competence to initiate/lead team activities through industry relevant assignments.
Competence – learning to learn	Upon successful completion of the programme the learner will be able to: 9. engage in their continuing professional development to keep abreast of current developments in the areas of quality and regulatory sciences. This programme facilitates in enhancing the students' competence and ability to identify and exploit work-based learning and their own professional development opportunities (PDA, ISPE, RAPS).

Competence - insight	Upon successful completion of the programme the learner will be able to: 10. Use the knowledge and learning gained through the programme to promote a quality culture in their role and actively engage in opportunities to foster this in the wider pharmaceutical industry. This programme enables graduates to play an active part in the maintainance and development of the quality culture across a pharmaceutical industry, informed by their learning and knowledge gained through involvement of regulatory subject matter experts from the PRST, regulatory bodies and industry guest lecturers.
Progression & Transfer	Progression to programmes leading to Doctoral Degree (Award-type **O**), or to another Masters Degree or to a Post-graduate Diploma (Award-types **m** or **n)**.
Articulation	N/A

Part 3

A table outlining the programme leaning outcomes mapped against the module learning outcomes for ten modules is available in an appendix.

Condition 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.

Response:

The following **updated text** is included in programme documentation:

On completion of Stage 1 of the programme, students who have achieved a mark of 50% in a minimum of 7 of the 9 modules (including all three 10 ECTS modules) are eligible to progress to Stage 2 which comprises of a research dissertation module.

The dissertation module comprises of a 6-month industrial/work-based project which allows the student the opportunity to undertake a detailed study of a quality assurance topic relevant to industry.

On successfully completing stage 1, the student can then progress to dissertation. For part-time students who have experience and competence in working in the pharmaceutical industry it is assumed that the dissertation will be carried out in their normal place of work. However, full-time students are expected to be employed in the pharmaceutical industry to gain the necessary experience, confidence and competence prior to embarking on their dissertation. Students are typically allocated up to two years to embark on stage 2 (dissertation) of the programme.

Under exceptional circumstances e.g. illness or disability, where it is not feasible for a student to undertake an industrially based dissertation, arrangements will be made for the student to carry out an in-house dissertation. Normal procedures with regard to dissertation approval, standard of work etc will apply.

Dissertation supervision is achieved through appointment of an internal supervisor and an industry-based mentor. The internal supervisor ensures that the industry-based mentor is aware of the standard required for the work. The standard expected for the final body of work is appropriate for a taught Master's degree and a degree of originality is desirable but not essential. The final report must be in a typed, electronic form, with typical length of 15,000 to 20,000 words (not including appendices etc.). A peer reviewed paper accepted for publication in lieu of the final report is also acceptable. Current TU Dublin regulations and procedures will apply to dissertations. (As regulations are updated, the most recent version will apply).

Supports provided to the students

At induction for stage 1 of the programme the supports available to students in carrying out their dissertation and the requirements for carrying out the dissertation are presented.

At the end of stage 1 of the programme, a workshop will be held to discuss the dissertation process, the supports available to students and to look at “hot topics” in the area of regulatory science that may help in choosing a suitable topic for dissertation.

Assistance is given to students with CV preparation and interview skills.

Electronic versions of previously published dissertations are available in the library and students complete a dissertation review as an assignment in PQAR9029

Students are invited to attend the Dissertation Presentations of the previous cohort before preparing their dissertation proposal to give them a sense of the level of research and the academic standard expected for a level 9 dissertation.

To encourage writing and report skills and in advance of dissertation cycles students are offered the opportunity to attend a writing workshop (essay/report writing, thesis statements, grammar and editing) conducted by Maria-Jose Gonzalez, Head of TU Dublin’s Academic Writing Centre.

Students also have access to one-to-one meetings with the team at the Academic Writing Centre.

Students will be invited to a Pre-Approval Meeting, held shortly before each Dissertation Proposal Approval Meeting. At this pre-approval meeting students are given more support and guidance on what is expected when presenting a topic for dissertation and for completion of the dissertation.

At the Dissertation Proposal Approval Meeting students are asked to present an outline of their proposed research objective, research questions and the methods to be used to answer these questions. This is reviewed by the programme team and if approved a supervisor is appointed.

On completion of the dissertation students are asked to prepare and deliver an oral presentation of the key details relating to their study to the programme team and student cohorts.

Additional comment:

To clarify a comment from the panel - once students have embarked on stage 2 of the programme they have the option to report their industry relevant research work in dissertation format **or** prepare and submit a peer reviewed paper for the award of MSc.

Recommendation 1:

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

Response:

The module learning outcomes have been revised to ensure that the terminology reflects these level 9 awards. Module Descriptors are included as an attachment.

Recommendation 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.

Response:

The programme schedules in the Student Handbooks have been updated to identify the modules delivered during each semester, the contact and self-directed hours, and the assessment breakdown.

Recommendation 3:

Further details should be provided on the rationale for each derogation from the General Assessment Regulations, the University should further consider the operation of the derogations based on the submission of this rationale.

Response:

In 2006 the following derogations were approved:

'Candidates achieving a minimum mark of 40% in each module with an overall average mark of 50 % in Stage 1 will be allowed to progress to Stage 2 of the programme (dissertation). Candidates failing Stage 2, having passed Stage 1 at 50%, will be awarded a Postgraduate Diploma with the relevant classification'

'One resubmission of assignment is permitted'

The updated derogation submitted for this programme review is:

'On completion of Stage 1 of the programme, students who have achieved a mark of 50% in a minimum of 7 of the 9 modules (including all three 10 ECTS modules) are eligible to progress to Stage 2 which comprises of a research dissertation module.'

A review of stage 1 results for students who needed very significant additional support* to complete stage 2 shows that although an average mark of 50% was achieved over the 12 modules delivered, the students have a significant number of marks in the 40-50 range (see table below). This has been a recurring observation noted by the external examiners over the last 5 year.

Student	No. modules between 40-50%	Grade for Stage 1	Dissertation Grade*
1	5	50-55	55-60
2	5	50-55	50-55
3	5	50-55	50-55
4	5	50-55	60-65

A more recent student presented to the external examiners did not meet the pass mark of 50% in stage 2 dissertation, see the external examiner comment below.

The principle suggestion that both external examiners agreed on was that the qualifying grade threshold for progression to the MSc dissertation phase of the programme should be reviewed (currently 50%). The situation outlined above (candidate not achieving the MSc award standard) related to a candidate who barely achieved this standard, and subsequently struggled significantly. We would recommend considering raising this grade threshold if deemed appropriate by the programme team.

External Examiner Craig Slattery 2020

Rather than changing the overall progression grade threshold, the programme committee would like to address the issue by amending the existing derogation to require students to achieve a mark of 50% in a minimum of 7 of the 9 modules (including all three 10 ECTS modules) in order to progress to Stage 2 (dissertation).

Recommendation 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.

Response:

The programme team will investigate expertise across the University and engage with other Schools to explore the possibility of accessing relevant input.

Recommendation 5:

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

Response:

This information will be detailed explicitly in programme information and application pages on TU Dublin website.

Recommendation 6:

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

Response:

The Programme Committee will look at the possibility of exploring existing relationships such as the HPRA and NIBRT to develop the above.

Recommendation 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.

Response:

The Programme Team have already engaged with industry experts to support the delivery of these modules and will continue to source suitable expertise from industry and NIBRT.

Recommendation 8:

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

Response:

Shipping Validation & GDP are now included in the indicative syllabus for PQAR9029 and PQAR9030.

Recommendation 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.

Response:

Programme	Institution	Duration	Part-time	Full-time	Mode of delivery	Student Profile	Graduate Profile
MSc Pharm QA& Regulation TU258	TU Dublin	1yr + 6 months' industrially relevant dissertation	No	Yes	Blended	BSc (Hons) in science or related area	Early stage Quality Roles
MSc Pharm QA& Regulation TU258	TU Dublin	2yrs + 6 months' industrially relevant dissertation	Yes	No	On-line	Working in Pharma Industry	Quality Managers
MSc in (Bio)Pharmaceutical Manufacturing Technology	TU Dublin	1.5 yrs	Yes	No	Blended	BSc/BEng(Hons)	Manufacturing roles in Biopharma, Finished Dose, Small molecule manufacturing and Medical device sectors
MSc in Pharmaceutical Technology and Quality Systems	UCC	2 Yrs	Yes	No	On-line	Working in Pharma Industry	QP
MSc in Science in Pharmaceutical Regulatory Affairs	IT Carlow	1 yr full time 2 yrs part-time	Yes	Yes	F2F	Working as regulatory affair personnel	RA in pharmaceutical sector
MSc in Pharmaceutical Business Technology	Griffith College Dublin	1 Yr full time 2 yrs part-time	Yes	Yes	Blended	BSc(Hons) science or related	Business roles in pharmaceutical sector

Postgraduate Diploma in Pharmaceutical Manufacturing Technology	TCD	2 yrs	Yes	No	On-line	Working in Pharma Industry	QP

Recommendation 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.

Response:

We currently access industry expertise through our alumni and PRST however the Programme Committee acknowledges that industry experienced teaching staff are required for the continued success of the programmes. We will work with TU Dublin to explore the possibility of using adjunct lecturers or other mechanisms to resource the future requirements of the programmes.

Recommendation 11:

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

Response:

The Programme Team endorses this recommendation.

Recommendation 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.

Response:

The Programme Team will review reading lists on annual basis.

Recommendation 13:

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

Response:

The title of ATMP2 has been changed to Innovative Medicines.

Recommendation 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.

Response:

The programme team will encourage students to engage with the university student feedback system, make the results available to the programme team and include the outcomes in the Q5.

Recommendation 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.

Response:

The Student Handbooks have been updated to reflect the above points.

Recommendation 16:

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

Response:

The dissertation handbook has been referenced in the relevant module descriptor.