

De Montfort University

Course Template

1. Basic information

- Course Name: Quality by Design for the Pharmaceutical Industry
- Course Code: SP077U
- Level (UG, PG): Postgraduate Taught
- Academic Period: 2015
- Faculty: HLS - Faculty of Health & Life Sciences
- Department: School of Pharmacy
- PMB PHAR
- Offered at: DM - DMU Leicester
- Type (single, joint.): SI
- Highest Award : Master of Science
- All possible exit awards : Postgraduate Certificate; Postgraduate Diploma; Institutional Postgraduate Credit
- Award notes :

This programme is available part time. The full MSc consists of 6 out of 7 modules totalling 180 credits, including a 60 credit dissertation. It is a highly flexible programme. The students can do individual modules without having to complete the full MSc programme, though the full course is highly recommended. The course can be studied as a three-year part time programme and has a modular structure with students studying modules running through terms 1&2. Most modules are available at the start of both terms. The modules PHCO5319 and PHCO5320 are an either/or option if the students chose to do the full MSc.

There will be two cohorts of students per year, one starting in October and another in March (subjected to student's numbers). The students are expected to complete 60 credits per year leading progressively to PG Cert, PG Dip and finally MSc award.

Module PHCO5316 is compulsory for all exit awards unless students are joining the programme having completed the PgCert Work-based Studies in Pharmaceutical QbD.

Students transferring with the PgCert Work-based Studies in Pharmaceutical QbD must complete module PHCO5323. This module is not available to other students.

Postgraduate Institutional credits - This option was design to capture the Continuous Professional Development (CPD) market where the students are not initially aiming for a full award. The students that accumulate 60 or 120 within the registration period will be allowed to gain a named award of PG Cert (60 credits) or PG Dip (120 credits). For the MSc award the students must complete modules PHCO5321 and PHCO5322 within the maximum of 6 years of registration.

For the MSc option, module PHCO5321 is pre-requisite for the dissertation module PHCO5322.

Professional Body Recognition

- Accreditation by Professional/Statutory body:

No

- Exemption by Professional/Statutory body:

No

- Details

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- Modes of attendance: Main MOA: Distance Learning
Other MOA:
- Mode Notes:

- Course leader: Walkira Schlindwein

2. Entry Requirements and Profile

A good Honours degree (minimum 2:2 or equivalent) in a chemical, biological or physical science, including (though not exclusive to) chemistry, biology, chemical engineering, engineering, pharmacy, pharmaceutical science, or physics (or equivalent)

Alternatively, we will accept a portfolio of professional and/ or academic qualifications of equivalent standing to an Honours degree Students should ideally be employed within the pharmaceutical or health sectors

If English is not your first language an IELTS score of 6.5 or equivalent is essential.

3. Course Description

Characteristics and Aims

This is a multidisciplinary programme which enables students to gain knowledge and develop their skills in pharmaceutical product formulation and manufacturing process development using quality by design principles. The content of the programme aims to enhance the ability of students to understand the variables which affect product quality. The training offered by the programme will assist students who want to work in the pharmaceutical industry. There is a balance between theory and practice within the whole programme as well as in each individual module. The programme requires that students apply theories to practice, in both taught modules and the dissertation.

Teaching, Learning and Assessment Strategies

The whole programme motivates students to be active, interactive, independent, evaluative and reflective in learning. The teaching provides opportunities for students to engage these learning strategies. Students are strongly encouraged to participate in interactive and reflective styles of teaching and learning in all modules. They are expected to search literature and information independently and share their knowledge and experiences. They need to take initiatives to clarify with lecturers and fellow students the issues they are unsure about and identify the relevance and their learning needs.

The modular teaching is carried out in terms 1 and 2 with recorded lectures, tutorials and independent study. The final dissertation will be carried out in the third year of their study with supervisors assigned to individual students.

Programme assessments include, presentations; case study reports; coursework assignments a research proposal and the dissertation. The assessments are in line with the aims and learning outcomes of the modules of this programme.

4. Outcomes

Generic outcome headings	What a student should know and be able to do upon completion of the course
<ul style="list-style-type: none"> • Knowledge & understanding 	<p>PgC understand key concepts and theories of pharmaceutical product development apply to pharmaceutical industry</p> <p>PgD identify issues of pharmaceutical product design, control and quality research the current theories and concepts and to be able to critically evaluate them by debating in their written assignments.</p> <p>MSc understand key concepts and theories of pharmaceutical product development apply to</p>

	<p>pharmaceutical industry identify issues of pharmaceutical product design, control and quality research the current theories and concepts and to be able to critically evaluate them by debating in their written assignments.</p>
<ul style="list-style-type: none"> Cognitive skills 	<p>PgC plan, search, construct and develop abstract concepts and intellectual arguments engage in analysing real quality by design issues by working through scenarios and real case studies</p> <p>PgD acquire critical and analytical thinking skills by evaluating relevant literature on theoretical and practical perspectives and by processing information into knowledge engage in analysing real quality by design issues by working through scenarios and real case studies</p> <p>MSc acquire critical and analytical thinking skills by evaluating relevant literature on theoretical and practical perspectives and by processing information into knowledge plan, search, construct and develop abstract concepts and intellectual arguments engage in analysing real quality by design issues by working through scenarios and real case studies demonstrate originality or creativity in the development of pharmaceutical products in order to formulate safe medicines</p>
<ul style="list-style-type: none"> Subject specific skills 	<p>PgC identify in examples, cases and scenarios issues of pharmaceutical product formulation in different modules and apply this ability to real case situations have effective interactive skills to explain the importance of critical quality attributes, design of experiments, risk assessment and quality risk management in the development of pharmaceutical products</p> <p>PgD and Msc identify in examples, cases and scenarios issues of pharmaceutical product formulation in different modules and apply this ability to real case situations analyse and evaluate product quality issues in order to find a solution to enhance and promote safe products and efficient processes have effective interactive skills to explain the importance of critical quality attributes, design of experiments, risk assessment and quality risk management in the development of pharmaceutical products</p>

	demonstrate that they are able to draw knowledge and skills from different academic and professional perspectives offered by this programme to apply to their practice in case/scenario analysis
<ul style="list-style-type: none"> Key Skills 	<p>PgC</p> <p>develop analytical, evaluative and reflective thinking skills</p> <p>achieve academic and effective oral and written skills</p> <p>have organisational skills for academic and professional practices</p> <p>practise problem-solving skills in coursework and working experience sessions</p> <p>PgD and MSc</p> <p>develop analytical, evaluative and reflective thinking skills</p> <p>achieve academic and effective oral and written skills</p> <p>use a range of research and study tools to achieve independent study skills</p> <p>have organisational skills for academic and professional practices</p> <p>practise problem-solving skills in coursework and working experience sessions</p>

5. Structure and Regulations

Relationship Details

Module	Credits	Level	Take/Pass	Semester	Locations
PHCO5316	30.00	5	Both	1, 2	DM
PHCO5317	30.00	5	Must Pass	1, 2	DM
PHCO5318	30.00	5	Must Pass	1	DM
PHCO5319	15.00	5	Must Pass	2	DM
PHCO5320	15.00	5	Must Pass	2	DM
PHCO5321	15.00	5	Must Pass	1, 2	DM
PHCO5322	60.00	5	Must Pass	X, 1, 2	DM
PHCO5323	30.00	5	Must Pass	1, 2	DM

Structure

Structure notes

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2 For a PgCert compulsory modules are PHCO5316 and PHCO5317

For a PgD compulsory modules are PHCO5316, PHCO5317, PHCO5318, PHCO5319 and PHCO5320.

For an MSc compulsory modules are PHCO5316, PHCO5317, PHCO5318, PHCO5319 or PHCO5320, PHCO5321 and PHCO5322.

Course Specific Differences or Regulations

1
2

Numbers at sites, including partner institutions

1
2

Relevant QAA Subject Benchmarking statement(s)

1
2

6. Quality Assurance Information

QA of Workbased Learning

Liaison with Collaborative Partners

Procedures for Maintaining Standards

Student progress and achievements in this programme are monitored and evaluated in line with the standards of the QA procedures. All rules and regulations follow De Montfort University Generic Quality Assurance guidelines.

These include:

Monitoring of the programme content and syllabus to meet students' needs;

Discussion of the programme content at programme team meetings for improvement;

DMU module evaluation form for completion by students at the end of the delivery of each module;

Sample of assignments for internal moderation and external examining;

Implementation of feedback from external examiner(s);

PG board approval of the assessment outcomes;

Performance Enhancement Plans to implement changes required or suggested in the above processes.

Course Handbook Descriptor