De Montfort University

Course Template

1. Basic information

- Course Name: Pharmaceutical Quality by Design
- Course Code: SP077T
- Level (UG, PG): Postgraduate Taught
- Academic Period: 2015
- Faculty: HLS - Faculty of Health & Life Sciences
- Department: School of Pharmacy
- PMB PHAR
- Offered at:
- Type (single, joint.): SI
- Highest Award : Master of Science
- All possible exit awards : Postgraduate Diploma; Postgraduate Certificate; Institutional Postgraduate Credit
- Award notes :

Professional Body Recognition

- Accreditation by Professional/Statutory body:

No

- Exemption by Professional/Statutory body:

No

- Details

- Modes of attendance: Main MOA: Full-Time
  Other MOA:
- Mode Notes:

- Course leader: Geoff Smith

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.

If English is not your first language an IELTS score of 6.5 or equivalent when you start the course is essential. English language tuition, delivered by our British Council accredited Centre for English Language Learning, is available both before and during the course if you need it.

3. Course Description

Characteristics and Aims

This is a multidisciplinary programme which enables students to gain knowledge and develop their theoretical and practical 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 in understanding 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 in process.
The modular teaching is carried out in terms 1 and 2 with lectures, seminars, tutorials, practical sessions and independent study. Term X is devoted to the research and writing of the final dissertation with supervisors assigned to individual students.
Programme assessments include, oral presentations; group work assignment; case study reports; phase tests; 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
• **Knowledge & understanding**	Demonstrate critical knowledge and understanding of current developments in the area of pharmaceutical product development, manufacturing and materials processing, and quality by design philosophies. Develop experimental methods using SOPs and cGMP protocols and QbD principles Demonstrate a clear understanding of pharmaceutical industry regulations, pharmaceutical quality systems and risk management.
• **Cognitive skills**	Have ability to apply critical analysis when interpreting and processing information. Demonstrate ability in planning, constructing and developing an argument. Demonstrate ability to deal with complex scientific and regulatory issues. Demonstrate creativity in the application of knowledge and understanding.
• **Subject specific skills**	Have the ability to make relevant use of numerical and statistical information derived from primary literature sources. Demonstrate effective oral and written communication skills. Have ability to use a range of research tools to organise information and data.
• **Key Skills**	Undertake critical analysis of issues in the area of pharmaceutical product development and quality by design. Disseminate knowledge effectively.

5. Structure and Regulations

Relationship Details

Module	Credits	Level	Take/Pass		Semester	Locations
PHCO5301	**15.00**	**5**	**Both**	**1**	**DM**	

PHCO5302	**30.00**	**5**	**Both**	**1**		**DM**	
PHCO5303	**15.00**	**5**	**Both**	**1**		**DM**	
PHCO5304	**15.00**	**5**	**Both**	**1**		**DM**	
PHCO5305	**15.00**	**5**	**Both**	**2**		**DM**	
PHCO5306	**15.00**	**5**	**Both**	**2**		**DM**	
PHCO5307	**15.00**	**5**	**Must Pass**		**1**		**DM**
PHCO5308	**15.00**	**5**	**Must Pass**		**1**		**DM**
PHCO5309	**60.00**	**5**	**Both**	**X**		**DM**	

Structure

Structure notes

Course Specific Differences or Regulations

Numbers at sites, including partner institutions

Relevant QAA Subject Benchmarking statement(s)

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;
Implement of the 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