L-Università ta' Malta
Faculty of Medicine & Surgery
Department of Pharmacy

Post-Graduate Course in Pharmaceutical and Regulatory Sciences

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INTRODUCTION

Pharmaceutical regulatory sciences evolved to ensure safe, quality and effective medicinal products. Features that are also becoming relevant today include access, resilience of supply and impact on the environment. Challenges for the implementation of pharmaceutical regulatory processes include capacity building and the increasing demand on workforce that is ready to embrace regulation of innovative technologies such as medical devices, biological drugs and non-biological complex therapies.

AIM

To develop a post-graduate course at Masters level that provides the opportunity to pharmaceutical graduates to develop competences that support regulatory sciences.

METHOD

Needs Analysis carried out through meetings with stakeholders:

- Pharmaceutical industry (manufacturing, batch release sites, regulatory offices),
- Strategy, policy and regulators (economic development, pharmaceutical competent authority, public health)

Programme development:

- Three year post-graduate course
- Offered as part-time studies
- Provides flexibility to address specific learning needs
- Elective courses to cover different aspects
- Leading to a Master degree

Course content elaboration:

- To meet needs of science graduates to develop competences required in pharmaceutical regulatory sciences
- To support pharmaceutical workforce to attain knowledge and skills required for Qualified Person position

RESULTS

- The course is in its fifth intake, N=48 students.
- In the first year, students choose 5 study units from 10 elective study units (5 ECTS each) in addition to the core study unit dedicated to research methodology.
- In the second year, a practical reflective placement is undertaken (10 ECTS) together with a choice of an elective specialisation study unit (20 ECTS).
- The third year is dedicated to the dissertation.

Table 1: Choice of elective study units

First Year Elective study units	Number of students (N=48)
Applied physiology, biochemistry and toxicology	47
Pharmacognosy	37
Pharmaceutical regulation	36
Pharmaceutical chemistry	36
Pharmaceutical technology	28
Industrial pharmacy	26
Pharmacovigilance	25
Pharmacoeconomics	10
Second Year Elective study units	**Number of students (N=34)**
Regulatory Sciences	23
Industrial Pharmacy	11

CONCLUSION

The course leading to a Master in Pharmaceutical and Regulatory Sciences contributes to pharmaceutical workforce capacity building by empowering graduates to develop specific skills and competences, and by meeting the needs of the evolving regulation of medicinal products. Graduates from the programme have taken up positions in the pharmaceutical sector as Qualified Persons in manufacturing and batch release sites, quality assurance departments, pharmacovigilance and pharmaceutical regulatory settings.