INDUSTRIAL PHARMACY

PHR 4446 (20 credits)

Handbook

Module co-ordinators and tutors

A. Anastasi
L.M. Azzopardi
A. Serracino-Inglott
C. Shoemake

Department of Pharmacy
University of Malta

October 2011
1. **RATIONALE**

Fourth year pharmacy students that opt to follow this area of specialization will be assigned for an attachment to experience application.

The objective of this module is that pharmacy students are presented with a continuous industrial experience in pharmaceutical product design and manufacture, by taking part in research and continuous practice development activities within a multidisciplinary team.

1.1 *Learning Outcomes*

At the end of the placement, students should have experienced hands on practice on industrial processes including interaction with multidisciplinary team and developed the following skills:

i. Experience in quality assurance and quality control in the pharmaceutical industry.

ii. Application of pharmaceutical sciences to product development, process validation and in-process control.

iii. Development of the ability to integrate pharmaceutical skills in pharmaceutical production processes.

iv. Exposure to pharmaceutical pre-formulation and product development.

v. Maintenance of documentation systems.

vi. Experience in data handling and statistical applications

vii. Exposure to the application of GMP.

viii. Development of skills in management skills pertaining to industrial pharmacy

ix. Ethical and behavioral skills.

2. **STRUCTURE AND COURSEWORK**

- This handbook is intended to present the basic framework for the industrial attachment period.
A Record Sheet) is provided for students to record their daily activities.

- Students should fill in the Record Sheet on a daily basis.
- The Record Sheet should be signed by the preceptor assigned for the supervision of the industrial attachment or his/her delegate.
- The Record Sheets will be presented regularly in a tutorial within the Department of Pharmacy for review and discussion as per issued timetable.
- At the end of the industrial attachment, the Record Sheets should be submitted to the Department of Pharmacy as per deadline issued.
- Students are expected to attend the practice site for 30 hours per week. The schedule will be determined by the assigned preceptor. Any discrepancy in the hours of attendance should be discussed with the module co-ordinators.
- Any sick leave absence has to be reported to the Pharmacy Practice Lab at the Department of Pharmacy on contact number: 23402902 and the industrial attachment preceptor and/or delegate should be informed.

2.1 The Daily Record Sheet

The record sheet has 3 main sections namely:

i. Summary of activities
The student is expected to record a brief summary of the daily proceedings within the industrial pharmacy attachment.

ii. Interventions observed
This section lists a few interventions which are commonly encountered within an industrial pharmacy placement and that essentially form the main components of industrial pharmacy. The student is expected to daily tick the relevant interventions observed.

iii. Focus on intervention (s) observed
This section allows the student to undertake a focused analysis of a choice of one or more interventions observed. The student is expected to be able to document and discuss and reflect upon the rationale behind the chosen
interventions observed. Additional reference literature may be attached to this section for the student’s future reference only.

2.2 Tutorials

Students will be allocated to groups and group tutorials will be held as per scheduled time-table with the module co-ordinators and tutors. During these tutorials the students will have the opportunity to discuss any problems they are encountering within the attachment, present a case for discussion and also discuss the varying aspects and scenarios of industrial pharmacy practice. This is a learning experience and no mark will be allocated for the case discussions, however attendance will be logged.

3. THE WORKPLACE

3.1 Dress code

- The attire should reflect the professionalism of pharmacists and hence attire which is **strictly not allowed** includes halter or low cut tops and dresses, tops and dresses with straps or sleeveless, miniskirts and shorts, see through clothing, jeans, clothing with adverts, written statements and faded bleached or torn clothing.
- Shoes are to be clean and appropriately comfortable. No flip flops are allowed.
- Hair should be tied at the back.
- Clean shave is a mainstay.
- Make up and perfumes can be worn as long they are subtle and not overly done. In some placements no make-up should be worn.
- Nail polish and artificial nails are not allowed.
- Jewellery worn must be discrete and subtle and only one pair of earrings is allowed. In some places eg. production facilities jewellery will not be allowed.
• The preceptor or the delegate may ask students to go back home if they present to the placement not in line with the above dress code.

3.2 *House keeping points*

• A clean lab coat or specific work attire may be required to be worn.
• Students should wear the Department of Pharmacy Identification Tag at all times during the placement.
• Hand Hygiene is essential
• Valuable items such as car keys, money and mobile phones should be carried at all times by the student themselves unless a locker is provided.
• Mobile phones should be put on silent mode and calls should not be taken unless extremely important.

3.3 *Data Protection Act*

Students may be asked to complete the Data Protection Act form and abide by the said form. Security of data and confidentiality are an essential part of the industrial pharmacy placement.

4.  **FAMILIARISATION**

Industrial pharmacist positions are found in large pharmaceutical companies, smaller support organizations and government agencies. Industrial pharmacists participate in the research and development, production, testing, analysis and marketing of medicinal products.

4.1 *Job Description*

• Contribute to all aspects of drug production
• Review the drug manufacturing process
• Work with chemists, biologists, toxicologists and scientists on a regular basis
• Must stay up to date on all industry related topics and trends by attending seminars, reading industry related journals and magazines and networking with other pharmacy and medical professionals

• Conduct lab work during production, testing and analysis of the new or enhanced drug

• Prepare documents and presentations

• Participate in quality assurance reviews of process and product

4.2 Placement plan
The student will be introduced by the preceptor to person(s) who are responsible in the respective areas within the work environment where the student will be practising. In some instances rotation in different settings may be proposed. Students may be asked to undertake in-house training including self-training through Standard Operating Procedures prior to being exposed to hands-on experiences in the company.

5. GUIDELINES FOR CASE PRESENTATION
The presentation need not be an original idea or issue. However, it should not solely be a literature search. Rather, the student should identify a process or an activity and reflect on his/her experience. General steps that may be useful include:

a) presentation of activity or scenario

b) information currently available;

c) practical aspects;

d) summarizing and critical analysis

g) recommendations