

## **2.12.1 PHM 5407: PHARMACEUTICAL QUALITY CONTROL**

*Pre-requisites: PHM 4406;*

*Credit Units: 3*

### **2.12.2 Purpose of the course;**

This course is designed to be a continuation of PHM 4406 but which offers the student a real chance in the laboratory to learn the expertise of operating a Quality Control /Assurance laboratory.

### **2.12.3 Expected Learning Outcomes of the Course;**

At the end of the course, the student should be able to:

1. Develop and implement Standard Operating Procedures for all the critical steps in the operations of a Quality Assurance /Control Laboratory,
2. Explain the principles of Good Manufacturing Practices and Good Laboratory Practices

### **2.12.4 Course Content;**

**Total quality control;** Serious criteria for quality control; Quality control of drugs; Quality control of raw materials, production and supplement of drugs; Quality control of procedure; Quality test. **WHO's GMP and GLP.** Quality Assurance. Setting up and managing a Quality Control Laboratory. **ISO Certification** in a Pharmaceutical Set-up.

### **2.12.5 Mode of Delivery;**

**Lectures, power point presentations, and class discussions:** The instructor will give lectures in class to explain to the students various subjects that make up the field of pharmacy. The lectures will take a participatory approach where the instructor will involve students by frequently asking them questions that are meant to keep them alert in class and trigger class discussions. The instructor will also be free to answer questions from the students in the course of the lectures. **Video demonstrations and/or CD-Roms** in various Pharmacy settings will be shown in class when available after the relevant topic has been covered. **Assignment criteria:** Students will be given several individual or group research assignments on relevant topics.

### **2.12.6 Instructional Materials and/or Equipment;**

Lecture notes or power points for presentation; Video demonstrations; Tutorials; CD-Roms; Photos /charts

### **2.12.7 Course Assessment;**

#### **Distribution of Marks**

Attendance and participation	5%
CATS (minimum 2 sit in)	20%
Term Paper/group or assignment	15%
Mid-semester Examination	25%
End semester Examination	35%

**Total**

**100%**

**Grading**

90 – 100	A
87 - 89	A <sup>-</sup>
84 - 86	B <sup>+</sup>
80 - 83	B
77 - 79	B <sup>-</sup>
74 - 76	C <sup>+</sup>
70 - 73	C
67 - 69	C <sup>-</sup>
64 - 66	D <sup>+</sup>
62 - 63	D
60 - 61	D <sup>-</sup>
00 - 59	F

**2.12.8 Core Reading Materials for the Course**

Potdar, M. A. (2006). Pharmaceutical Quality Assurance for Students of Pharmacy. 1<sup>st</sup> Edition. Pragati Books Pvt. Ltd., Mumbai

[Skoog](#), D. A., [West](#), D. M., [Holler](#), F. J., [Crouch](#), S. R. (2013). Fundamentals of Analytical Chemistry. 9<sup>th</sup> Edition. Cengage Learning, Belmont, CA

**2.12.9 Recommended Reference Materials;**

[Donald Cairns](#), D., Ed. (2012). Essentials of Pharmaceutical Chemistry. 4<sup>th</sup> Edition. Pharmaceutical Press, London, UK.

**Watson, D. G. (2012).** *Pharmaceutical Analysis: A Textbook for Pharmacy Students and Pharmaceutical Chemists.* 3<sup>rd</sup> Edition. Churchill Livingstone, Oxford, UK

World Health Organization. Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials. Good Manufacturing Practices and Inspection, Volume 2. World Health Organization, Geneva