BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE PILANI
HYDERABAD CAMPUS
SECOND SEMESTER 2018-2019
Course Handout (Part II)

Date: 07/01/2019

In addition to Part-I (General Handout for all courses appended to the time table) this portion gives further specific details regarding the course.

Course No. : PHA F413
Course Title : Pharmaceutical Management and Quality Control
Instructor-in-charge : V. Vamsi Krishna Venuganti

1. **Scope & Objective of the Course**: It is a course designed to give the students a flavor of pharmaceutical quality control, standard industrial guidelines, pharmaceutical process scale up and validation aspects. The course is divided into various sections for easier assimilation and the last section deals with some basic aspects of pharmaceutical management. After completing this course, students will be familiar with pharmaceutical quality control aspects, scale up and validation procedures. The relevancy of this course to routine practices followed in the pharmaceutical industry makes it attractive and important to undergraduate students who wish to pursue their career in the pharmaceutical industry.

2. **Learning outcomes:**

- The student is expected to appreciate the importance of guidelines for current good manufacturing practices within pharmaceutical manufacturing.
- The student is expected to learn how to put the cGMP guidelines into practice.
- The student is expected to learn different validation steps for various manufacturing and analytical processes.
- The student is expected to learn to use statistical tools to perform product quality analysis.
- The student is expected to learn guidelines for changes made in pharmaceutical manufacturing processes post approval for marketing.
- The student is expected to learn the principals involved in scale-up operations for preparation of pharmaceuticals.
- The student is expected to learn the basics of marketing, production and financial management within the context of pharmaceutical industry.

3. **Text Book**s:

i. Industrial Engineering and Management by Khanna O.P.; Dhanpat Rai Publication, Rev. Ed., 1999

ii. Good Manufacturing Practices for Pharmaceutical: A Plan for Total Quality Control from Manufacturer to Consumer by Sidney H. Willing; Marcel Dekker, 5th Edition, 2001

4. **Reference Book**s:

i. Lachmann, Liebermann & Kanig: the Theory & Practice of Industrial, Pharmacy, K.M. Varghese, Third Edition, 1990. New Delhi.
ii. Sekhar Mukhopadhyay: Pharmaceutical Selling, Sterling Publishers.
iii. Bernard. T. Loftus, Robert A. Nash: Pharmaceutical Process Validation, Marcel Dekker.
iv. Good Manufacturing Practices for Pharmaceuticals; Edited by : Joseph D. Nally; 6th Edition; Marcel Dekker, 2007
v. Pharmaceutical Process Scale-up; Edited by: Michael Levin; Marcel Dekker, 2002

4. Course Plan:

Lecture No	Learning objective	Topics to be covered	Reference Chapter/Section
Section 1: Pharmaceutical Quality Control			
1	Scope & objective of course	Introduction	Class lecture
2-12	cGMP guidelines in pharmaceutical manufacturing processes	Importance of cGMP, General guidelines (Subpart A to Subpart K)	2(ii) Chapters 1-12 3(v) Chapters 1-12
Section 2: Pharmaceutical Process Validation			
13-17	Process validation	Introduction and Types (Prospective, Retrospective & Concurrent validation)	3(iv) Chapters 1-3
18-21	Statistical analysis for decision making	Statistical applications in validation and QC	3(i) Section II – Chapter 10 & Section IV - Chapter 27
Section 3: Pharmaceutical Process Scale up			
22-24	Pharmaceutical Process scale up	Requirements of pilot plant for scale up operations	3(i) Section IV – Chapter 23
25-27	Scale-Up of Tablet dosage form	Requirements for scale-up of Tablets	3(vi) Chapter 8 (1,2,3)
28, 29	Scale-Up of Parenteral dosage forms	Requirements for scale-up of Parenterals	3(vi) Chapter 2
30-32	SUPAC Guidelines	Essentials of guidelines for IR, MR, ER & Semisolid products	3(vi) Appendix: Guidance for the Industry (Pg No. 353-499)
Section 4: Pharmaceutical Marketing and Management			
33-35	Basics of Pharmaceutical Marketing Management	Knowledge & functions of Marketing Management	Class Notes
36, 37	Pharmaceutical Detailing	Various aspects of Pharmaceutical selling	3(iii) Chapter 4-7
38, 39	Basics of Financial Management	Balance Sheet, Profit and Loss account, Fund Flow	2 (i) Chapter 26, Section 26.1 to 26.49
40, 41	Basics of Production Management	Supply Chain Management, Production Management	Introduction to Production and Operations management (Class Notes) 3 (i) Section IV – Chapter 25

5. Evaluation scheme:

Component	Duration	Weightage (%)	Date & Time	Remarks
Mid-semester test	90 min	30	15/3 3.30 - 5.00 PM	CB
Surprise Quizzes*		10		CB
Seminar(s) / Assignment(s)		20		------
Comprehensive Exam	180 min	40	11/05 AN	OB (20%) + CB (20%)

*****Three quizzes will be held spread through the semester. Average of the three will be considered for the 10% weightage.

6. Mid-semester evaluation: To be done after the midsemester test.

7. Grading procedure:

1. Relative grading procedure will be followed.
2. It is not mandatory to award all the grades (i.e from A to E). Subjective judgment would be used in the award of A and E grades. Fine grading system (i.e. A, A-….) will be followed.

8. Make-up policy:

The facility of make-up test is meant to take care of 'Unavoidable' absence from scheduled tests. The instructor will decide whether a student should be considered for make up or not. No make-up will be given to surprise quizzes, seminars/assignments under whatsoever circumstances.

9. Chamber consultation hour: To be announced in the class

10. Notices: Notices, if any, concerning the course will be displayed on the notice board of Pharmacy and/ or course management system.

11. <u>Academic Honesty and Integrity Policy</u>: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

Instructor In-Charge
PHA F413