FIRST SEMESTER 2016-2017

Course Handout

Date: 02/08/2016

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 G532**
Course Title : **QUALITY ASSURANCE & REGULATORY AFFAIRS**
Instructor-in-charge : **Dr. Gaikwad Anil Bhanudas**
Instructor : **Mr.Satish S Reddi and Mr. Italiya Kishan Shamjibhai**

1. **Course Description:**

Quality control, assurance and management, various parameters for achieving quality pharmaceutical products, application of statistics in quality assurance, reliability, cGMP for pharmaceutical manufacturing , pharmaceutical process validation, drug regulatory affairs, clinical research protocols, new drug applications.

2. Scope and Objective of the course:

This course deals with the basic need of quality in the manufacturing of Pharmaceutical products and it's build up with the help of quality control and quality assurance management. Various current Good Manufacturing Practices (cGMP) to be followed in a pharmaceutical organization and its validation procedure are part of the course. This course also covers the regulatory procedures applicable in clinical trials and approval of new drug products.

3. Text Book (T):

T1: Sidney H. Willig, Murray M. Tuckerman and William S. Hitchings IV, " Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control" Marcel Dekker, New York, 4th Edn., Vol. 78, 1997.

T2: Bernard T. Loftus and Robert A. Nash, " Pharmaceutical Process Validation" Marcel Dekker, New York, 2nd Edn., Vol. 57, 1993.

Reference Books (R):

R1: Richard A. Guarino, " New Drug Approval Process" Marcel Dekker, New York, 2nd Edn., Vol. 56, 1993.

R2: Dale H. Besterfield, “Quality Control”Prentice Hall International Inc., New Jersey, 5th Edn., 1998.

R3: Sandy Weinberg, “Good Laboratory Practices’ Marcel Dekker, New York, 2nd Edn., Vol. 69, 1995.

R4: Leon Lachman, Herbert L. Lieberman and Joseph L. Kanig " The Theory and Practice of Industrial Pharmacy" Varghese Publn., Bombay, 3rd Edn., 1987.

R5: U.S. Pharmacopeia, U.S. Pharmacopeial Convention Inc., Rockville, MD, 23rd Edn., 1995.

4. Course Plan:

Lecture No.	Learning Objectives	Topic to be covered	Reference
1	Overview of quality control and validation process in a pharmaceutical industry	Introduction	T1 Ch. 1 R2 Ch. 1 R3 Ch. 1
2	Interrelation of factors influencing quality and customer acceptability of Pharmaceutical products	Quality & factors affecting Quality	T1 R2 Ch. 1, R3 Ch. 2
3, 4	Quality improvement techniques	Quality Control and Quality Assurance	R2 Ch. 2, 11, R3 Ch. 4
5, 6*	Application of statistical approaches for quality control	Quality Control Charts	R2 Ch. 3-9
7, 8	Concepts and tools for effective implementation of TQM	Total Quality Management (TQM)	R2 Ch. 13
9, 10	Understanding the significance and implementation of Good Laboratory Practices	QC laboratory- Rules & Regulations	R3 Ch. 2
11-20	Concepts and tools in the planning, implementation and control of current Good Manufacturing Practices in the Pharmaceutical industry	Good Manufacturing Practices a) Organization & Personnel b) Buildings & Facilities c) Equipment d) Components, Containers & Closures e) Production & Process control f) Packaging & Labeling control g) Laboratory controls- Reports & Records h) Return Goods & Relabeling	T1 Ch. 3-13
21	Quality audit (means and mechanism) as a tool for manufacturing and quality control system development	Quality Audit	T1
22	Process and significance of ISO certification	ISO certification	--
23-32*	Concepts, tools, methods and statistical application in validation of various areas in a	Pharmaceutical Process Validation a) Organization b) Pharmaceutical Products (Solid dosage forms and Sterile products)	T2 Ch. 2-9

	Pharmaceutical industry	c) Prospective validation d) Retrospective validation & Analysis e) Raw material validation f) Analytical method validation	
33-38*	Understanding the regulations, requirements, procedures and applications of new drug approval process	New Drug Approval Process a) Pre-clinical studies b) Brochure preparation for IND & ANDA c) Management of clinical studies	R1Ch.1-3, 5, 10, 11

* - Some of the aspects of the above topics will be covered during the laboratory hours.

5. Evaluation Scheme:

No.	Evaluation Component	Duration	Weight-age (%)	Date & Time	Nature of Component
1	Mid semester Exam	90 min	30	8/10 10:00 - 11:30 AM	CB
2	Continuous Assessment*		40		
5	Comprehensive Exam	180 min	30	13/12 FN	CB

*Continuous assessment will be based on theory covered in class. Topics and number will be announced in the class. It will be in terms of home assignments, tutorials, projects, laboratory, viva- voce and presentation/ seminars.

Attendance: Although attendance is not compulsory, regularity in theory classes will be decisive factor during grading, especially in borderline cases.

Chamber Consultation Hour: To be announced in the class.

Make-up policy: Generally make-up will be considered for regular students only (80% attendance in lecture classes). It is solely dependent on the "genuineness" of the circumstances. The make-up application should be personally given to instructor-in-charge.

Notices: Concerning this course will be displayed on Pharmacy Group notice board only.

Instructor-in-Charge

PHA G532