BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI

INSTRUCTION DIVISION

SECOND SEMESTER 2021-2022

Course Handout (Part II)

29/12/2021

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	**:**	**Akash Chaurasiya**
Instructor	**:**	**Akash Chaurasiya, Parameswar Patra, Kanan Panchal**

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 procedures are part of the course. This course also covers the regulatory procedures applicable in clinical trials and approval of new drug products.

3. Learning outcome:

- Complete knowledge about QA, QC, GMP and TQM
- Working in compliance to GMP and other regulatory requirements
- Able to validate various pharmaceutical process and analytical methods
- Acquainted with NDA, ANDA, patent process and applications

4. 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: Alfred H. Wachter and Robert A. Nash, "Pharmaceutical Process Validation" Marcel Dekker, New York, 2nd Edn., Vol. 129, 2014.

Reference Books (R):

R1: Richard A. Guarino, " New Drug Approval Process" Marcel Dekker, New York, 4th Edn., Vol. 139, 2008.

R2: Dale H. Besterfield, “Quality Control” Prentice Hall International Inc., New Jersey, 7th Edn., 2011

R3: Sandy Weinberg, “Good Laboratory Practices’ Marcel Dekker, New York, 4th Edn., Vol. 168, 2007.
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, 41st Edn., 2018.

5. Course Plan:

Lecture No.	Learning Objectives	Topic to be covered	Reference
1	Overview of regulatory affairs and regulatory bodies	Introduction	Lecture notes
2-12	Understanding the regulations, requirements, procedures and applications of new drug approval process	Introduction to requirement of filing of IND, NDA, sNDA, ANDA Chemistry, Manufacturing, and Control (CMC) requirement of the NDA and ANDA Clinical Studies requirement Dossier Preparation Common Technical Documents	R1 Ch 1, 3, 4, 5, 6, 7, 14, 18
13-16	Introduction to PDUFA, GDUFA-I & GDUFA-II	Introduction to Prescription Drug User Fee Act (PDUFA) & Generic Drug User Fee Act (GDUFA)	Lecture Notes
17-24	The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)	Introduction to various quality guidances	Lecture Notes
25	Overview of quality control and validation process in a pharmaceutical industry	Introduction	T1 Ch. 1 R2 Ch. 1 R3 Ch. 1
26, 27	Concepts and tools for effective implementation of TQM	Total Quality Management (TQM)	R2 Ch. 13
28, 29	Understanding the significance and implementation of Good Laboratory Practices	QC laboratory- Rules & Regulations	R3 Ch. 2
30-33	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	T1 Ch. 3-13

		f) Packaging & Labeling control g) Laboratory controls- Reports & Records h) Return Goods & Relabeling	
34-37	Pharmaceutical Process Validation	Concepts, tools, methods and statistical application in validation of various areas in a Pharmaceutical industry	T2 Ch. 2-9
38-39	Quality audit (means and mechanism) as a tool for manufacturing and quality control system development	Quality Audit Introduction to FDA audit at GMP areas	R1 Ch 16
40-41	Understanding the requirements of patents, copyrights, designs in relation to pharmaceutical industry and products	Introduction to patents, copyrights, designs Patenting process	Lecture notes
42	Process and significance of ISO certification	ISO certification	--

6. Evaluation Scheme:

Component	Duration	Weightage (%)	Date & Time	Remarks
Mid-semester Test	90 min	30		As announced in the timetable (100% CB if conducted offline/ 100% OB if conducted online or hybrid mode)
Seminars/Assignments	-	20		OB
Laboratory component	-	15		OB
Comprehensive exam	180 min	35		As announced in the timetable (85% CB if conducted offline/ 100% OB if conducted online or hybrid mode)

CB – closed book and OB – open book

7. Mid-semester evaluation: Will be announced after the Test.

Attendance: Regularity in attendance will be one of the criteria in deciding the borderline cases at the time of final grading.

8. **Grading Procedure:**
    1. It is not necessary that all the grades would be awarded.
    2. In borderline cases subjective judgment will be exercised for pull-up's (max. 1%). Basic guiding factors will be regularity, consistency in performance (above average) or/and steady improvement through out the semester.

9. **Make-up:** Make-up will be given only for genuine reasons. It is expected that students shall avoid misuse of this feature.

10. **Chamber consultation hours:** 2 – 3 pm; Monday to Thursday.

11. **Notices:** Notices pertaining to this course will be displayed only on Pharmacy Department Notice board.

12. **Academic Honesty and Integrity Policy**: 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 G532