RKUNIVERSITY

SYLLABUS

Course Title	**QUALITY ASSURANCE AND INTELLECTUAL PROPERTY RIGHTS**
Course Code	PH606
Course Credit	Lecture : 3
	Practical : 0
	Tutorial : 0
	Total : 3

Course Objectives

- This subject gives basic knowledge about Intellectual Property Rights, various concepts of copyrights, trade mark and geographical limitations.
- To explain the students about various concepts of validation, designing of validation protocol and validation documents. This course will provide students insight into validation of various equipments, methods, formulations and building, quality management system, quality audits, concept of total quality management etc.

Detailed Syllabus

Sr. No.	Name of Chapter & Details	Hours Allotted
	SECTION I	
1	**Intellectual Property Rights: -** Introduction, types, Scope and objectives of IPR in Pharmacy. Concept of property with respect to intellectual creativity. Tangible and Intangible property.	**03**

2	Definition, introduction, process of registration, term of registration and infringement of following IPR: copyrights, trade mark, geographical indication, industrial design.	**06**
3	**Introduction:** An understanding of the concepts of quality assurance, Good Manufacturing Practice and quality control as applied to the pharmaceutical industry. Organization and personnel, responsibilities, training, hygiene, personnel, records. Manufacturing Premises: Location, Design, plant layout, construction maintenance and sanitation, environmental control, utility services like gas, water, maintenance of sterile areas & control of contamination. Equipment, selection, purchase specifications, maintenance, clean-in place and sterilize- in place methods (TP and STP). Raw materials; purchase, specifications, stores, selection of venders & control of raw materials.	**10**
4	Good Laboratory Practices (GLP)	**03**
	SECTION II	
5	Good Clinical Practices (GCP)	**03**
6	**Introduction to Pharmaceutical Validation:** Definition, Approaches to validation and scope of validation, Advantage of Validation, importance of Validation, Limitation of Validation, Organization for Validation, calibration & verification.	**05**
7	**Validation of Building and facilities:** (DQ, IQ, OQ, PQ)	**03**

8	**Types of Process Validation** (prospective, retrospective & concurrent)	**02**
9	**Analytical Method Validation:** General principles of analytical method validation for dosage forms. (accuracy, precision, specificity, linearity, range, robustness etc.)	**03**
10	Concept of Total Quality Management, Six Sigma methodology, ISO 9000. Controls on four M responsible for Quality variation in Pharmaceutical products.	**05**
11	Quality Audits	**02**

Instructional Method and Pedagogy:

- Lectures will be conducted with the aid of multi-media projector, black board, OHP etc.
- Assignments based on course content will be given to the students at the end of each unit/topic and will be evaluated at regular interval.
- Surprise tests/Quizzes/Tutorials will be conducted.

Students Learning Outcomes:

At the end of the course the students will be able to:

- Know about Intellectual Property Rights, various concepts of copyrights, trade mark and geographical limitations.
- Know details about basic concepts of quality, quality assurance and validation.

Text books:

1. P. P .Sharma “How to practice GMPs”, 3rd edition, Vandana Publication
2. CGMP :Current Good Manufacturing Practices For Pharmaceuticals By Potdar Manohar A.,

CBS Publishers

3. P. P. Sharma “How to practice GLP” Vandana Publication.
4. Pharmaceutical Quality Assurance, M.A. Potdar, Nirali Prakashan, Pune.
5. Current Good Manufacturing Practices, M.A. Potdar, Pharma-Med Press, Hyderabad.
6. Good laboratory practice and regulations by Mohanan P.V.
7. J. R. Berry and R.A. Nash, Pharmaceutical process validation. 3rd Ed Marcel Dekker, 2003.
8. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
9. ISO 9000 and Total Quality Management – Sadhank G Ghosh
10. Total quality management, principles, implementation and Cases, Sharma D. D., Sulatan Chand and Sons, New Delhi, 2000.
11. Fundamentals of Total Quality Managemnt, process analysis and improvement by Jens. J Daulgard, Kai Kriestensen and Gopal K. Kanji. Taylor and Francis

Reference Books:

1. Intellectual property rights and biodiversity by Swansan T.
2. P. Warayan, Intellectual Property Laws, Eastern Law House.
3. Ira R. Bery, “Introduction to the Pharmaceutical Regulatory Process”, Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
4. Indian Pharmacopoeia, Vol. 1-3, 2007.The Indian Pharmacopoeia commission, Ghaziabad, Govt. of India.
5. The International Pharmacopoeia Vol 1,2,3,4,5 3rd Edition
6. A. C. Cartwright and Brian Mathews, “International Pharmaceutical Registration” Taylor and Francis Ltd. UK, 2002.
7. P. Warayan, Intellectual Property Laws, Eastern Law House.
8. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
9. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A.

Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay

10. Pharmaceutical Master Validation plan by S. Haiden, CRC press.
11. Validation of pharmaceutical process by Conleton F.
12. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.
13. GLP quality audit manual, Milton A. Anderson, Third edition, Informa Healthcare
14. Laboratory auditing for quality and regulatory compliance, by Donald C. Singer, Stefan and Stedan, Drugs and pharmaceutical sciences, Vol. 150
15. Laboratory auditing for quality and regulatory compliance, by Donald C. Singer, Taylor and Francis.
16. Total quality management, Dale H. Besterfield, Pearson Education, 3rd edn., 2003.

Additional Resources

- Soft copies of quality assurance and intellectual property right books are available on http://www.pharmatext.org, www.pharmacyebooks.com, and in www.pharmamirror.com.
- Latest information regarding quality assurance and intellectual property right are available on http://www.pharmainfo.net
- Study material of quality assurance and intellectual property right are available on mypharmaguide.com, pharmatutor.com, authorstream.com, slideworld.com and in scribd.com.