SANKALCHAND PATEL UNIVERSITY
।। अथातो ज्ञानजिज्ञासा ।।

Ph. D. Program
(July-2019 Batch)

Subject Code: 1RI3000102	Subject Title: Essentials of Disciplinary Research Subject-1 Subject Sub-Title: Validation & Product Development
Pre-requisite Subject	

Objectives of course:

The objective of this course is to impart fundamental knowledge and concepts about validation and quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Learning outcomes:

At completion of this course it is expected that students will be able to understand the importance of quality, ISO management systems, tools for quality improvement, analysis of issues in quality, Quality evaluation of pharmaceuticals, stability testing of drug and drug substances, statistical approaches for quality

Teaching Scheme (Credit Distribution)				Assessment Scheme (Weightage)	
Lecture	Tutorial	Practical	Credit	Hall Exam	Continuous Evaluation
4	--	--	4	60%	40%

Continuous evaluation is based on assignments/quiz/presentation/small projects as per the supervisor instructions.

	Subject Content		
Unit	Topic	No. of Lecture	Weightage %
1	**Introduction to Pharmaceutical Validation:** Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Types of process validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities, Calibration Master plan, Validation Master Plan, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments such as Electronic balance, pH, meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC		20
2	**Analytical Method Validation**: General principles of analytical method validation, Method development and optimization in HPLC, LC-MS/MS **UPLC:** Detail Introduction, instrumentation and method validation of UPLC		20
3	**Quality risk management:** Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.		20
4	**Computerized system validation:** Electronic records and digital significance-		10

	21 CFR part 11 and GAMP		
5	**Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. **Quality systems:** Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, AnnualProduct Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.		20
6	**Statistical Process control (SPC):** Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.		10

List of References:

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.
9. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
10. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
11. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
12. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
13. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

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Ph. D. Program
(July-2019 Batch)

Subject Code: 1RI3000103	**Subject Title:** Essentials of Disciplinary Research Subject-2 **Subject Sub-Title:** Experimental Drug Design & Intellectual Property Rights
Pre-requisite Subject	

Objectives of course: This course aims to guide students for achieving competence and proficiency in the use of experimental drug design as well as intellectual property rights and patent.

Learning outcomes:

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

- To understand the fundamental methodology & importance of experimental drug design.
- To understand IPR and Patents

Teaching Scheme (Credit Distribution)				Assessment Scheme (Weightage)	
Lecture	**Tutorial**	**Practical**	**Credit**	**Hall Exam**	**Continuous Evaluation**
2	--	--	2	60%	40%

Continuous evaluation is based on assignments/quiz/presentation/small projects as per the supervisor instructions.

Subject Contents			
Unit	**Topic**	**No. of Lecture**	**Weightage %**
1	**Experimental Design:** Terminology and definitions related to experimental design Study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques Sampling Designs: Introduction, types of sample designs, steps, criteria of selection, characteristics, random sampling, drop outs. Advantage and disadvantage of conventional design over experimental design.		25%
2	**Basic steps in experimental design.** Screening Designs: Screening of factors, General properties for independent factor selected for experimental design, Fractional factorial design (FFD): Purpose advantage and disadvantage of fractional factorial design, Concept of Aliased Effects and Design Aliasing Structure and constructing FFD Analysis of fractional factorial design: Concept of Design Resolution for FFD Case study of factorial design Plackett–Burman designs: Purpose advantage and disadvantage and construction of matrix , Comparison between placket-Burman and FFD design, Case study Full factorial design		35%

	Optimization techniques and various method of optimization Introduction to contour plots Introduction of repose surface design: Classification Characteristic of design Matrix and analysis of design with case study Evolution of full and reduced mathematical models in experimental designs Central composite designs Taguchi and mixture design Application of experimental design in pharmacology for reduction of animal		
3	Patents: Patents definition, need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search, The essential elements of patents, Guidelines for preparations of laboratory notebook, non obviousness in patents, Drafting of patent claims, Patent Infringement, Important patent related websites.,		20%
4	Brief introduction to trademark protection and WTO patents, Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application		20%

List of References:

1. Lewis G.A., Mathiea D., Phan-Tan-Luu Roger, "Pharmaceutical Experimental Design", Marcel Dekker Inc., N.Y.
2. Armstrong N. and James L.K.C., " Pharmaceutical Experimental Design and Interpretation", Taylor & Francis.
3. Cochran W.G. and Cox G.M., "Experimental Designs", Wiley, 1957.
4. Fisher R.A., " The Design of Experiments", 8th ed., Hafner, 1966
5. Vogt F. G., Kord A. S.. Development of Quality by Design Analytical Methods. J. Pharm. Sci.. 2010; 100(3): 797-812.
6. Patent laws , By P. Narayan. Eastern law house publications
7. www. ipindia.nic.in,
8. www.uspto.gov
9. https://www.epo.org