SPECIALIZATION: PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS
SEMESTER-II
SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
621	Management Concepts – II	4	--	4	--
622	Good Manufacturing Practices	3	--	3	--
623	Pharmaceutical Validation	3	--	3	--
624	Good Laboratory Practices	3	--	3	--
625	Regulatory Affairs Practical - I	--	18	--	6
626	Drug Discovery and Development Process -Outline	2	--	2	--
627	Assignments/Seminars/Presentations	3	--	--	3
	TOTAL	18	18	15	9

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
621	Management Concepts –II	3	80	20	---	---
622	Good Manufacturing Practices	3	80	20	---	---
623	Pharmaceutical Validation	3	80	20	---	---
624	Good Laboratory Practices	3	80	20	---	---
625	Regulatory Affairs Practical-I	6	---	---	80	20
626	Drug Development Process -Outline	3	80	20	---	---
627	Assignments/Seminars/Presentations	---	---	---	---	100
	Total		400	100	80	120

SUBJECT : Management Concepts - II
SUBJECT CODE : 621
RATIONALE: The knowledge of this subject is required of all professional students who wish to choose Industry/field as their career. This course is designed to develop understanding of various Marketing mix areas, role of workers and providing knowledge about IT, International marketing and project management concepts.

COURSE OBJECTIVES:

1. To understand and apply some major marketing concepts in pharmaceutical Industry.
2. To provide an understanding on the research issues and to critically examine the recommendations.
3. To understand the role of IT in regulatory affairs of pharmaceutical industry.
4. To provide theoretical knowledge on international marketing issues.
5. To provide knowledge on various compensation techniques and other Human resource policies
6. To insist the importance on team building and other soft skills
7. To teach the importance of branding elements in marketing.

LEARNING OUTCOMES:

1. Shall understand and analyze the core concepts and role of marketing in pharma Industry.
2. Ability to develop marketing strategy based on place, promotional objectives.
3. Ability to collect and analyze consumer data to make marketing decisions.
4. Shall identify the legal loopholes in registering and processing online.
5. Shall analyze critically the performance appraisal techniques of companies.
6. Shall plan a project schedules and controls effectively.
7. Shall prepare an effective Brand plan for any product.

PREREQUISITES:

1. Management Concepts - I

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TOTAL HRS/ Week	CREDITS	EVALUATION SCHEME		TOTAL MARKS
				INTERNAL	EXTERNAL	
621	Management Concepts - II	4	4	20	80	100

CONTENT:

1	**Marketing concepts**:	15
	Core concepts of pharma marketing – Basis for market segmentation – Marketing of industrial and consumer goods[API, Prescription , OTC products, Medical equipments] – Product line and product mix – Managing a product in Product life cycle – New product development – Pharma pricing policies- Product recalls – Marketing audit and ethics- e-marketing-	
2	**product Management**:	10
	Factors affecting designing a pharma product– Product differentiation – Integration – diversification – extension –Brand elements -building a successful brand – reasons for failure of brands —brand strategies in OTC and FMCG market- Customer Relationship Management.	
3	**Market Research**:	10
	Research objectives – Types of researches -steps involved in market research –Market research techniques.	
4	**IT Role:**	15
	Project proposal concepts,-Preparing project proposal using software tool –Resources management and networks- Online registering and filing project proposals- precautions to be taken during online registering.	
5	**Business Environment** :	10
	Foreign Trade Policy – WHO – GATT-Money and capital market –Sale of goods act – consumer protection act –Negotiable instruments act – VAT – legal requirements related to labeling and packaging, food and drug adulteration.	
6	**International marketing** :	10
	Challenges –Foreign market entry strategies – International pricing – difficulties in framing distribution channels – Global advertising. - pros and cons of exports- preliminaries to start export –Documents needed for exports [bills of exchange , custom clearance, certificate of shipment, foreign exchange regulations] – EXIM policy and bank role – RBI facilities.	
7	**Finance:**	10
	Cost- Concepts, nature and elements –Types of costing. Budgeting –Concept and Types of budgets – Concept of Zero based budgeting **[Theory aspects only]**	
8	**HRM:**	10
	Career planning –compensation techniques –leadership qualities – Employee relations management –event management- team building- Attitude models.	
9	**Project management:**	10
	PERT/CPM – Work breakdown structure, critical path, float, negative float, crashing	

Reference Books:

Marketing Management – Karunakaran
Marketing Management – Philip Kotler
Product Management - S.A.Chunawalla
Human Resource Management – Gary Dessler
Project Management – Vasant Desai
Financial Management –I M Pandey
International Marketing – Philip Cateora
International Marketing – Subhash C.Jain.

SUBJECT : **Good Manufacturing Practices**
SUBJECT CODE : **622**

RATIONALE **:** Students to know the Various Aspects of Good Manufacturing Practice adopted Nationally & Internationally by Pharma. Industries to produce good quality of Drugs & how to maintaining documentation thereof.

COURSE OBJECTIVES **:** To provide the student with understanding of various facets of Good Manufacturing Practices adopted in Pharmaceutical Industries to produce the good quality of Drugs & preparation of various documents related to GMP.

LEARNING OUTCOMES: The basic understanding acquired by the student at the end of the course shall help him/her to produce the good Quality of Pharmaceutical Products by adopting Good Manufacturing Practices in Industry and to know how to maintain all types of GMP related records by industries**.**

PREREQUISITES: B.Pharm graduate

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
622	Good Manufacturing Practices	3	-	3	3	20	---	80	---	100

Contents:

1	Drugs & Cosmetics Act-1940 & Rules-1945(Sch. M)	
PART 1	GOOD MANUFACTURING PRACTICES FOR PREMISES AND MATERIALS 1.General requirements 1.1. Location and surroundings.- 1.2. Building and premises.- 1.3 Water System. - 1.4. Disposal of waste. - 2. Warehousing Area. - 3. Production area. - 4. Ancillary Areas. - 5. Quality Control Area.- 6. Personnel.- 7. Health, clothing and sanitation of workers. - 8.2. Precautions against mix-up and cross-contamination- 9. Sanitation in the Manufacturing Premises. - 10. Raw Materials. - 11. Equipment. - 12. Documentation and Records. - 13. Labels and other Printed Materials. - 14. Quality Assurance. - 15. Self-Inspection and Quality audit - 16. Quality Control System.	35

	17. Specification 18. Master Formula Records**.** 19. Packing Records. - 20. Batch Packaging Records. 21. Batch Processing Records 22. Standard Operating Procedures (SOPs) and Records, regarding. - 23. Reference Samples. - 24. Reprocessing and Recoveries. - 25**.** Distribution records: 26. Validation and process validation. - 27. Product Recalls. - 28**.** Complaints and Adverse Reactions. 29. Site Master File.	
Part I A	Specific requirements for manufacture of sterile products, Parenteral preparations (small volume injectable and large Volume parenteral) and sterile ophthalmic preparations.	10
Part I B	Specific requirements for manufacture of oral solid dosage Forms (tablets and capsules)	05
Part I C	Specific requirements for manufacture of oral liquids (syrups, elixirs, emulsions and suspensions)	05
Part I D	Specific requirements for manufacture of topical products i.e. External preparations (creams, ointments, pastes, emulsions, Lotions, solutions, dusting powders and identical products	05
Part I E	Specific requirements for manufacture of Metered-dose-inhalers (MDI)	05
Part I F	Specific requirements of premises, plant and materials for Manufacture of active pharmaceutical ingredients (bulk drugs).	05
Part II	**Requirements of plant and equipment for:** 1. External Preparations. - 2. Oral Liquid Preparations. - 3. Tablets 4. Powders 5. Capsules 6. Surgical Dressing 7. Ophthalmic Preparations. 8. Pessaries and Suppositories 9. Inhalers and Vitralle 10. Repacking of Drugs and Pharmaceutical Chemicals. 11. Parenteral Preparations	05
2	GMP guideline of WHO & various countries like USA, EU, TGA, Canada, MHRA.	15
3	GMP requirements regarding Ayurvedic, Siddha, Unani drugs (Schedule T)	10

Books Recommended:

1. Drugs & Cosmetics Act-1940 & Rules-1945 (Sch-M,T,U)
2. Good Manufacturing Practices (MDSeries,Vol-109,146,169)
3. cGMP for Pharmaceuticals-By Manohar A. Potdar
4. How to practice GMP-By P.P. Sharma
5. WHO guideline for GMP
6. GMP guideline of various countries like USA, EU, TGA, Canada, MHRA.
7. Guideline for Standard Operating Procedure-By D.H. Shah
8. Quality Assurance Manual-By D.H. Shah

SUBJECT : **Pharmaceutical Validation**
SUBJECT CODE : **623**
RATIONALE **:** To discuss the various methods of validation for instrument, equipments, processes, analytical methods, utilities etc. & maintaining records thereof.

COURSE OBJECTIVES **:** To provide the student with understanding of various facets & protocols of Pharmaceutical Validation used in Pharmaceutical Industries.

LEARNING OUTCOMES: The basic understanding acquired by the student at the end of the Course shall help him/her regarding various methods used for Validation & calibration of instrument, equipments, process, analytical method, utilities and to maintain all types of records by industries regarding validation.

PREREQUISITES: B.Pharm Graduates
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
623	Pharmaceutical Validation	3	-	3	3	20	---	80	---	100

Contents:

1	Types of validation. Regulatory considerations in validation	10
2	Basic concepts of process validation for Pharmaceutical dosage forms & its Validation	20
3	Basic concepts of calibration, Calibration of equipments and instruments	10
4	Validation of analytical & Bioanalytical methods	10
5	Validation of sterilization methods and equipments: Dry heat sterilization, autoclaving, membrane filtration, Validation of process (Sterile and non sterile products)	15
6	Validation of Air-handling equipments and facilities	05
7	Introduction to validation of manufacturing facilities D.Q./I.Q./O.Q/P.Q and certification, Preparation of validation protocols	10
8	Validation of water supply systems (purified, distilled and water for injection)	05
9	Validation and security measures for pharmaceutical data processing.	05
10	Validation of computer aided instruments.	10

Books Recommended:

1. B. T. Lofters, R. A. Nash, Pharmaceutical Process Validation, Marcel Dekker, Inc. New York. Volume 129, 3rd edition.
2. Carleton & Agalloco, Validation of Pharmaceutical Processes-sterile products, 2nd edition, 1995.
3. E. Joachim, Method Validation in Pharmaceutical Analysis, Willey-Vch Verlag Gmbh& Co, Kga, 1st Ed., 2005.
4. Indian Pharmacopoeia
5. British Pharmacopoeia
6. United states Pharmacopoeia.
7. Validation Standard operating procedures- By Haider
8. ICH guidelines for analytical method validation

SUBJECT : **Good Laboratory Practices**
SUBJECT CODE : **624**
RATIONALE **:** To discuss the importance of & various facets of Good Laboratory Practices adopted by Pharma. Industries & maintaining record thereof.

COURSE OBJECTIVES **:** To provide the student with understanding of various facets of Good Laboratory Practices used in Pharmaceutical Industries & to maintain record thereof.

LEARNING OUTCOMES: The basic understanding acquired by the student at the end of the course Shall help him/her to how Good Laboratory Practices can be maintain in the analysis of Raw materials, finished products and allied materials used in pharmaceutical industries and how all types of records are maintained by industries.

PREREQUISITES: B.Pharm graduate

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
624	Good Laboratory Practices	3	-	3	3	20	---	80	---	100

Contents:

1.	Schedule-L-I of Drugs & Cosmetic Rules-1945	
2.	General Requirements	05
3.	Premises	05
4.	Personal	05
5.	Equipments	05
6.	Chemicals and Reagents	05
7.	Good housekeeping and safety	05
8.	Maintenance, calibration and validation of equipments	05
9.	Reference materials	05
10.	Microbiological Cultures	05
11.	Quality system	05
12.	Internal quality system audits	05
13.	Management review	05
14.	Standard Operating Procedures	10
15.	Protocols and specifications archive	05
16.	Raw data	05
17.	Storage and archival	05
18.	GLP Guidelines of USFDA, EA, UK, Canada, Australia, S.Arebia, Africa, Shrilanka etc	15

Books Recommended:

1. Drugs and Cosmetic Act 1940 & Rules-1945 (Sch-L-I)
2. Good Laboratory Practices Regulation. Fourth Edition(MDVol-124 & 168)
2. Laboratory Auditing for Quality & Regulatory compliance(MDVol-150)
3. Guideline for Standard Operating Procedures-By D.H.Shah
4. IP, BP, USP etc.
4. Pharmaceutical Analysis – By- Harpal Singh
5. Validation Standard Operating Procedures-By Haider
6. Validation of Pharmaceutical Process-(MDVol-129)
7. GLP Guidelines of USFDA, EA, UK, Canada, Australia, S.Arebia, S. Africa, Shrilanka etc.
8. Analytical Profile of Drug substances-By Florey

SUBJECT : Regulatory Affairs Practical - 1
SUBJECT CODE : 625
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
625	Regulatory Affairs Practical-I	-	18	18	6	---	20	---	80	100

Practical's cover under the following subjects
Good Manufacturing Practices
Good Laboratory Practices
Pharmaceutical Validation
Drug discovery & development Process

SUBJECT : Drug Discovery & Development Process
SUBJECT CODE : 626
RATIONALE : Student to know how Drug can be discovered and how the drug Process can be developed in Research and development in Pharma. Industry.

COURSE OBJECTIVES : To study the different methods used in process of drug discovery and drugs development in Prarma industry.
LEARNING OUTCOMES : At the end of the course the student will know how the drug discovered & how drug process can be developed in Research and development in Pharma Industry.

PREREQUISITES : B.Pharm Graduate
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
626	Drug Discovery & Development Process	2	-	2	2	20	---	80	---	100

Contents:

1	Overview of Drug Discovery and Development process:	15
	a) History of Drug Discovery	
	b) Flowchart of various processes involved	
2	Recent techniques used for the above processes: Miniaturization, Automation approaches such as HTS, microarrays, cellular assays, Bioinformatics, Chemo informatics.	25
3	Pharmacological Evaluation of Drug Molecules:	35
	a) Preclinical Pharmacodynamics, Pharmacokinetic and toxicological studies	
	b) Clinical Phase of Drug Development: Phase 0 to phase IV studies General Concepts.	
4	Development of pharmaceutical dosage forms and its applications	25

SUBJECT : Subject Seminar
SUBJECT CODE : 627
RATIONALE : This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES : At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: None
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
627	Subject Seminar	3	----	3	3	-----	100	-----	-----	100

SPECIALISATION: PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS
SEMESTER-III
SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
631	Management Concepts – III	4	--	4	--
632	Good Clinical Practices	3	--	3	--
633	Preclinical Safety and Efficacy Studies	2	--	2	--
634	Regulatory Aspects for Cosmetics, Nutraceuticals, Biotech Products and Medical Devices	3	--	3	--
635	Regulatory Submissions - National and International	3	--	3	--
636	Regulatory Affairs Practical - II	--	18	--	6
637	Assignments/Seminars/Presentations	3	--	--	3
	TOTAL	18	18	15	9

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
631	Management Concepts – III	3	80	20	---	---
632	Good Clinical Practices	3	80	20	---	---
633	Preclinical Safety and Efficacy Studies	3	80	20	---	---
634	Regulatory Aspects for Cosmetics, Nutraceuticals, Biotech Products and Medical Devices	3	80	20	---	---
635	Regulatory Submissions - National and International	3	80	20	---	---
636	Regulatory Affairs Practical - II	6	---	---	80	20
637	Assignments/Seminars/Presentations		---	---	---	100
	TOTAL		400	100	80	120

SUBJECT : Management Concepts - III
SUBJECT CODE : 631

RATIONALE:

This subject provides an important insight in the areas of Cybercrime, strategic planning, economics, services management and Banking which are inevitable for any regulatory affairs professional. After learning this, the student shall become proactive in decision making and planning.

COURSE OBJECTIVES:

1. To provide knowledge on the cost reduction aspects in production and the materials management techniques.
2. To enable the learners to take right decisions at right time.
3. To create a basic understanding about cybercrimes.
4. To introduce the basic functions and activities of banks.
5. To provide an overview on importance of distribution and services in marketing.

LEARNING OUTCOMES:

1. Learners shall get enhanced skills on dealing with documents online.
2. Shall improve their decision making skills in marketing and product related aspects.
3. Shall connect the relationship between demand, supply, price and other non-price factors in a better way.
4. Shall able to analyze the market and sales potential in an efficient way.
5. Shall be quick in identifying and analyzing the critical factors affecting business.

PREREQUISITES:

1. Management Concepts I and II.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
631	Management Concepts - III	4	-	4	4	20	-----	80	-----	100

CONTENT:

1	**Operations management:** Types of manufacturing systems, capacity planning, production planning and control, Materials management – An introduction to materials management, Material requirement, Purchase Management, Inventory control, Material handling; Vendor selection, Make or buy decision. TQM and six sigma concepts.	10
2	**Strategic Management:** Concept of Strategy – defining strategy, characteristics and approaches to strategic decision-making; Strategic management process; Developing a strategic vision, mission and setting objectives Generic strategy alternatives – stability, expansion, retrenchment and combination strategies; variations strategy - Internal and external alternatives, related and unrelated alternatives, horizontal and vertical alternatives ; International level strategic alternatives; Challenges in strategic implementation.	20

3	**Sales and Retail Management:** Sales Management – concept, objectives and functions, concept of personal selling, sales organization, sales forecasting, sales budgeting, sales quotas and territories, sales meetings, Evaluating salesman performance, promotion tools. Retail management – concept, functions, importance and challenges in retail business ; theories of retailing ; classification of retail institutions on the basis – ownership, merchandise offered, store based and non- store based retailing ; strategic planning in retailing ; application of IT in retailing.	20
4	**Economics:** Pricing of products under various market conditions, Pricing under multiple products, Price discrimination and dumping. Business cycles, cost analysis- short and long run costs, Demand analysis and elasticity of demand, Demand forecasting.	10
5	**Security and Ethical Challenges** Ethical theories - Ethical responsibilities of Business Professionals – Business, technology; Computer crime –Hacking, cyber theft, unauthorized use at work; Piracy – software and intellectual property; Privacy – Issues and the Internet Privacy; Challenges – working condition, individuals; Health and Social Issues, Ergonomics and cyber terrorism	10
6	**Banking and finance:** Service and functions of bank, finance planning and sources of finance, short, intermediate and long term financing, tools of financial analysis, financial ratio analysis, funds analysis and financial forecasting, operating and financial leverages. General principles of insurance, Working capital management	10
7	**Marketing:** Distribution decisions: Importance and functions of distribution channels, distribution channel members. Problems in drug distribution. - Designing and selecting channels – Conflicts in channels- marketing generic drugs and selection of stockiest and distributors.	10
8	**Services marketing:** Service Strategy (7ps), Service failure & Recovery, Service Tax Provision Quality Issues and Models, Gap Analysis, SERVQUAL, Demand-Supply Management, Branding, Packaging, Pricing, Promotion, Service Research.	10

Books for Reference:

Production and materials Management – Shridhara Bhatt
Sales Management - Richard Still, Edward Cundiff, Norman Govani
Retailing Management - Michael Levy
Crafting and executing strategy – Arthur A.Thompson
Production and operations management –Ashwathappa
Financial Management – Prasanna Chandra
Marketing Management – Philip Kotler
Managerial Economics – Mithani
Sales and Distribution management –S.L.Gupta
Services marketing - Zeitham

SUBJECT : **Good Clinical Practices**
SUBJECT CODE : **632**
RATIONALE **:** The subject discusses regulatory aspects of practicing clinical trials and other protocols.
COURSE OBJECTIVES **:** The roles and responsibilities of key players, as well as regulatory requirements. The elective subject consists of lecture and exercises. Participants will be placed in several real life situations such as reviewing pre-study documents and informed consent forms for completeness and compliance; conducting drug accountability; reviewing case report forms for accuracy and adherence to protocol and performing source document verification
LEARNING OUTCOMES: Understanding of GCPs requirements for Sponsors, Monitors, and Investigators. Significance of protocol and case report form development for all phases of clinical research. Information regarding in-field and in-house auditing. Investigational Review Boards (IRBs) and Informed Consent (IC) as required by regulations.

PREREQUISITES: B.Pharm graduate

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
632	Good Clinical Practices	3	-	3	3	20	---	80	---	100

Contents:

1	Basic concepts and introduction to Clinical Drug Development. • How drugs are discovered and developed for marketing approval • The four different study phases of clinical research • BA- BE Study • PK-PD study • IVIVC • ICH- Guidelines for Efficacy and Safety study	20
2	Clinical Trials • Introduction to the fundamentals of the design and analysis of clinical trials. • Ethical considerations intention-to-treat versus efficacy trials, • What constitutes Good Clinical Practices (GCP) • The principles of ICH- GCP • The IRB/IEC's composition and role/responsibilities • The IRB study review & approval process • Essential Documents • The role and responsibility of the sponsor • The role and responsibilities of the investigator & study site staff • Clinical Research study Protocol, ICF and CRF content and importance • The requirement and process for Informed Consent • Site monitoring and selection • The different types of study Monitoring visits & tasks for each	70

	• How to perform Drug Accountability & compliance • How to manage study supplies • How to detect and deal with Fraud • How to review study documents & determine compliance • How to review Case Report Forms and determine adherence to protocol • How to perform Source Document Verification • Auditor and audit report • Adverse Events - the types and reporting requirements	
3	Case studies and model protocols to understand above concepts Amendments and latest information related to regulatory aspects for clinical research.	10

Books Recommended;

1. ICH-GCP Guidelines
2. Gupta S K, Basic Principles of Clinical Research & Methodology (2007). Jaypee Brothers Publication.
3. Woodin K E, Schneider JC, The CRA's Guide to monitoring Clinical Research (2003), Thomson Center Wath, Boston, USA.
4. Stephen Beny, Crossover trial in Clinical Research (2002), John Wiley Pub, USA
5. Gallin John, Principles and Practice of Clinical Research (2002), Academic Press pub, USA.
6. New Drug Approval Process, Third Edition by Richard A. Guarino, Volume 100, Marcel Decker Inc.
7. IND and NDA Guidelines of Various Regulatory Authorities.
8. Updated GCP Guidelines

SUBJECT : **Preclinical Safety and Efficacy Studies**
SUBJECT CODE : **633**
RATIONALE **:** The subject discusses the use of in vitro testing methods and models. The suitability and choice of models with detailed methodology of evaluation of therapeutic effect of drugs and drug products are also discussed.

COURSE OBJECTIVES: At the end of the course the student should be able to know about:

1. Regulatory aspects of CPCSEA.
2. Factors affecting choice of correct model for particular activity.
3. Pharmacodynamics models.

LEARNING OUTCOMES: At the end of the course student will be able to:

1. Prepare protocols for CPCSEA.
2. Know about committee forum.
3. Regulatory requirements of animal handling for therapeutic activity.

PREREQUISITES: B.Pharm graduate.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
633	Preclinical Safety and Efficacy Studies	2	--	2	2	20	---	80	---	100

Contents:

1	Laboratory animals, maintaining and handling of animals, basic laboratory animal data, breeding of lab animals, animal strains and their applications, knock out and transgenic animals	15
2	CPCSEA guidelines for use of animals in teaching and research.	10
3	ICH guidelines, oecd guidelines and schedule y for evaluating efficacy and safety of drugs.	10
4	Toxicokinetics methods	10
5	General principle of screening	10
6	Pharmacological screening model for: A. Central nervous system diseases B. Cardiovascular diseases C. Diabetes mellitus D. Gastrointestinal diseases E. Asthma F. Pain and inflammation G. Anemia H. Wounds and burns	45

SUBJECT: **Regulatory Aspects for Cosmetics, Neutraceuticals, Biotech Products and Medical Devices.**

SUBJECT CODE: **634**

RATIONALE: Students to know about
1) License and product approval procedure for manufacturing of Cosmetics, Neutraceuticals, Biotech Products, Medical Devices in India and Globally.
2) Product registration & approval procedure in India & Globally for above products.

COURSE OBJECTIVES: Students shall learn about
1) License and product approval procedure for manufacturing of Cosmetics, Neutraceuticals, Biotech Products, Medical Devices in India and Globally.
2) Product registration & approval procedure in India & Globally for above products.

LEARNING OUTCOMES: At the end of semester student will be able to understand regarding
1) License and product approval procedure for manufacturing of Cosmetics, Neutraceuticals, Biotech Products, Medical Devices in India and Globally.
2) Product registration & approval procedure in India & Globally for above products.

PREREQUISITES: B.Pharm Graduates

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
634	Regulatory Aspects for Cosmetics, Neutraceuticals, Biotech Products and Medical Devices.	3	-	3	3	20	---	80	---	100

Contents

1	As per D & C Acts and Rules 1945. (For Cosmetics) A. - Authorities and their powers. - Definition - Standards-(Sch-S) - Requirements for License and its procedure (import and manufacturing) - conditions of licenses - Labeling requirements - storage and distribution - Prohibition for cosmetics - Export of cosmetics - Cosmeceuticals & its approvals globally	20
2	B. For Biotech products and Medical devices - Authority and its powers	35

	- Definitions - Standard of biotech products and medical devices. - Requirements of licenses and its procedure. (import , manufacturing and sale) - Conditions of licenses and its validity - Labeling and storage - Distribution (cold storage if required) - Prohibitory section.	
3	Neutraceuticals - Definitions - Requirements in India- - Food safety and Standard Act-2006 or D & C Act – if therapeutic claim license is required - Requirements of licenses/permission for different country like USA. - Procedure for registration - Labeling requirements - Storage and distribution and procedure for registration.	15
4	Regulatory requirement of USA. Europe, Australia, etc. for Biotech products and Medical devices. - Classification of medical devices - Registration procedure for different countries	30

References:

1. Drugs and Cosmetics Acts and Rules 1945- Government Notification
2. Pharmaceutical, Cosmeceuticals, Neutraceuticals, and Medical devices.- An overview of regulations By-N. Udupa, Harvinder Popli (Career Publication)
3. FDA Regulatory Affairs- A guide for Prescription Drug, Medical devices and Biologics By Douglas J. Pisano (CRC Press)
4. Guide book for Drug Regulatory submission By Sandy Weinberg (Wiley Publication)
5. Regulatory Policies of different countries like..- USA, EU, Australia, Canada etc.
6. Food Safety and Standard Act 2006- Government notification
7. Different ICH Guidelines.

SUBJECT : **Regulatory Submissions - National and International**
SUBJECT CODE : **635**
RATIONALE **:** Students to know about

1 Discussion of stages of product development in context with drug approval process in India & Globally. The unit involves the discussion about approval authorities, documents and data required for approval process , Preclinical and clinical studies, NDA contents and guidelines for INDA, NDA and ANDA, Orphan Drug approval process as per CTD format.
2 License and product approval procedure for manufacturing of Cosmetics, Nutraceuticals, Biotech Products, Medical Devices in India and Globally.
3 Product registration & approval procedure in India & Globally for above product as per CTD format.

COURSE OBJECTIVES: Students shall learn about

1 License and product approval procedure for manufacturing of Cosmetics Nutraceuticals, Biotech Products, Medical Devices in India and Globally.
2 Product registration & approval procedure in India & Globally for above products as per CTD format.
3 How to file INDA, NDA, ANDA, Orphan drug registration & approval procedures.
4 Understand importance of development stages, Preclinical and clinical phases of drug product.
5 How to use toxicity data and Pharmacokinetic data for approval process.
6 Derive all necessary data for new drug application.

LEARNING OUTCOMES: At the end of the unit student will be able to

1. Describe current requirements for filling INDA, NDA and ANDA to different approving authorities
2. Demonstrate use of Stability data, Toxicity data and pharmacokinetic data in drug approval process as per ICH guidelines.
3. Define Bio-waiver requirements in ANDA, Para I, II and III and IV approvals
4. Explain contents of INDA, NDA and ANDA in accordance with current guidelines.
5. License and product approval procedure for manufacturing of all types of Drugs, Cosmetics,
6. Nutraceuticals, Biotech Products, Medical Devices in India and Globally.
7. Product registration & approval procedure in India & Globally for above products as per CTD format.

PREREQUISITES: B.Pharm Graduates.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
635	Regulatory Submissions - National and International	3	-	3	3	20	---	80	---	100

Course Contents:

1	Regulatory Submission Nationally -As per Drugs & Cosmetics Act &Rules -Preamble of Drugs Cosmetics Act -Definition of -Drug(M.D.) ,Ayurvedic drug ,Homeopathic Medicine, New Drugs -Licensing Authorities -DCI, Delhi -State Authorities-Comm.-Jt. Comm. -District authorities-Asstt. Comm. -Detail procedure for obtaining licenses -condition of licenses -WHO GM certificate and COPP -labeling requirement -storage and distribution -special provision if any	50
2	Regulatory Submission Internationally(For USA, Canada, EU, Australia & other Countries) Ten Rules for Drug Regulatory submissions FDA Meeting Requests Orphan Drug Application(Fast track Application) Investigational New Drug Applications(INDs) New Drug Applications(NDAs) 505(b)2 New Drug Applications(NDAs) Abbreviated New Drug Applications(ANDAs) Annual Reports International Regulatory Submissions Future Issues in Regulatory Submissions Submission as per CTD & eCTD.	50

Books Recommended:

	1. Drugs and Cosmetics Acts and Rules 1945- Government Notification **2.** Pharmaceutical, Cosmeceuticals, Neutraceuticals, Biotech product and Medical devices. - An overview of Regulations- By-N. Udupa, Harvinder Popli (Career Publication) **3.** FDA Regulatory Affairs- A guide for Prescription Drug, Medical devices and Biologics By Douglas J. Pisano (CRC Press) **4.** Guide book for Drug Regulatory submissions- By Sandy Weinberg (Wiley Publication) **5.** Drug Regulatory Policies of different countries like..- USA, EU, Australia, Canada etc. **6.** Different ICH Guidelines.	

SUBJECT : Regulatory Affairs Practical - II
SUBJECT CODE : 636
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
636	Regulatory Affairs Practical - II	-	18	18	6	---	20	---	80	100

1. Practicals related to Good Clinical Practices.
2. Practicals related to Preclinical Safety and Efficacy Studies.
3. Practicals related to regulatory aspects for Cosmetics, Nutraceuticals, Biotech product and Medical devices.
4. Practicals related to Regulatory submissions National and International.

SUBJECT : Subject Seminar
SUBJECT CODE : 637
RATIONALE : This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES : At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: None
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
637	Subject Seminar	3	-	3	3	-----	100	-----	-----	100

SPECIALISATION: PHARMACEUTICAL MANAGEMENT AND REGULATORY AFFAIRS
SEMESTER-IV

SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK	CREDITS
641	Dissertation (Project Work)	36	12
642	Viva- Voce	----	12

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	UNIVERSITY LEVEL EVALUATION
641	Dissertation	100
642	Viva- Voce	100
	TOTAL	200