

University of Mumbai

Website - mu.ac.in
Email id - dr.aams@fort.mu.ac.in
aams3@mu.ac.in



Academic Authorities,
Meetings & Services (AAMS)
Room No. 128, M. G. Road, Fort,
Mumbai – 400 032.
Tel. 022-68320033

Re- accredited with A ++ Grade (CGPA 3.65) by NAAC
Category- I University Status awarded by UGC

No. AAMS_UGS/ICD/2024-25/464

Date : 24th March, 2025.

To,
The Director,
Garware Institute of Career Education
and Development,
Vidyanagari
Santacruz (East)
Mumbai – 400 098.

Sub : Post Graduate Diploma in Pharma Management (PGDPM).
(One year) (Sem – I & II).

Sir,

With reference to the subject noted above, this is to inform you that the recommendations made by the **Advisory Committee & Board of Management** of Garware Institute of Career Education & Development at its Meeting held on **4th September, 2023** & resolution passed by the **Board of Deans** at its meeting held on **9th August, 2023** vide Item No. 9.2 have been accepted by the **Academic Council** at its meeting held on **1st November, 2023** vide Item no. 9.3 (B) 8 (N) and subsequently approved by the **Management Council** at its meeting held on **14th August, 2024** vide Item No. 6 that in accordance therewith, in exercise of the powers conferred upon the Management Council under Section 74(4) of the Maharashtra Public Universities Act, 2016 (Mah. Act No. VI of 2017) the following program with Ordinance for Title of the Program, Eligibility and Regulation numbers for Duration of Program, Intake Capacity, Scheme of Examinations, Standard of Passing and Credit Structure along with syllabus of **Post Graduate Diploma in Pharma Management (PGDM)(Sem I & II)** (Appendix – 'A') have been introduced and the same have been brought into force with effect from the academic year **2023-24**.

The New Ordinances & Regulations as per NEP 2020 is as follows :-

Sr. No	Name of the Programme	Ordinance no. for Title	Ordinance no for Eligibility	Duration
A	P.G. Diploma in Pharma Management (PGDM)	O.GPA – 45 A	O.GPA – 46 A	One year

University of Mumbai

Website - mu.ac.in
Email id - dr.aams@fort.mu.ac.in
aams3@mu.ac.in



Academic Authorities,
Meetings & Services (AAMS)
Room No. 128, M. G. Road, Fort,
Mumbai – 400 032.
Tel. 022-68320033

Re- accredited with A ++ Grade (CGPA 3.65) by NAAC
Category- I University Status awarded by UGC

No. AAMS_UGS/ICD/2024-25/464

Date : 24th March, 2025.

: 2 :

Regulation Nos	
Duration	R. GPA – 106
Intake Capacity	R. GPA – 107
Scheme of examination	R. GPA – 108
Standard of Passing	R. GPA – 109
Credit Structure	R. GPA – 110 A
	R. GPA – 110 B


(Dr. Prasad Karande)
REGISTRAR

A.C/9.3(B) 8 (N) /01/11/2023
M.C/6/14/8/2024

Copy forwarded with Compliments for information to:-

- 1) The Chairman, Board of Deans
- 2) The Dean, Faculty of Interdisciplinary Studies,
- 3) The Director, Board of Examinations and Evaluation,
- 4) The Director, Board of Students Development,
- 5) The Director, Department of Information & Communication Technology,
- 6) The Co-ordinator, MKCL.

Copy forwarded for information and necessary action to :-	
1	The Deputy Registrar, (Admissions, Enrolment, Eligibility and Migration Dept)(AEM), dr@eligi.mu.ac.in
2	The Deputy Registrar, Result unit, Vidyanagari drresults@exam.mu.ac.in
3	The Deputy Registrar, Marks and Certificate Unit,. Vidyanagari dr.verification@mu.ac.in
4	The Deputy Registrar, Appointment Unit, Vidyanagari dr.appointment@exam.mu.ac.in
5	The Deputy Registrar, CAP Unit, Vidyanagari cap.exam@mu.ac.in
6	The Deputy Registrar, College Affiliations & Development Department (CAD), deputyregistrar.uni@gmail.com
7	The Deputy Registrar, PRO, Fort, (Publication Section), Pro@mu.ac.in
8	The Deputy Registrar, Executive Authorities Section (EA) eau120@fort.mu.ac.in He is requested to treat this as action taken report on the concerned resolution adopted by the Academic Council referred to the above circular.
9	The Deputy Registrar, Research Administration & Promotion Cell (RAPC), rapc@mu.ac.in
10	The Deputy Registrar, Academic Appointments & Quality Assurance (AAQA) dy.registrar.tau.fort.mu.ac.in ar.tau@fort.mu.ac.in
11	The Deputy Registrar, College Teachers Approval Unit (CTA), concolsection@gmail.com
12	The Deputy Registrars, Finance & Accounts Section, fort draccounts@fort.mu.ac.in
13	The Deputy Registrar, Election Section, Fort drelection@election.mu.ac.in
14	The Assistant Registrar, Administrative Sub-Campus Thane, thanesubcampus@mu.ac.in
15	The Assistant Registrar, School of Engg. & Applied Sciences, Kalyan, ar.seask@mu.ac.in
16	The Assistant Registrar, Ratnagiri Sub-centre, Ratnagiri, ratnagirisubcentar@gmail.com
17	The Director, Centre for Distance and Online Education (CDOE), Vidyanagari, director@idol.mu.ac.in
18	Director, Innovation, Incubation and Linkages, Dr. Sachin Laddha pinkumanno@gmail.com
19	Director, Department of Lifelong Learning and Extension (DLLE), dlleuniversityofmumbai@gmail.com

Copy for information :-	
1	P.A to Hon'ble Vice-Chancellor, vice-chancellor@mu.ac.in
2	P.A to Pro-Vice-Chancellor pvc@fort.mu.ac.in
3	P.A to Registrar, registrar@fort.mu.ac.in
4	P.A to all Deans of all Faculties
5	P.A to Finance & Account Officers, (F & A.O), camu@accounts.mu.ac.in

To,

1	The Chairman, Board of Deans pvc@fort.mu.ac.in
2	<p>Faculty of Humanities,</p> <p>Dean</p> <p>1. Prof.Anil Singh Dranilsingh129@gmail.com</p> <p>Associate Dean</p> <p>2. Dr.Suchitra Naik Naiksuchitra27@gmail.com</p> <p>3.Prof.Manisha Karne mkarne@economics.mu.ac.in</p> <p>Faculty of Commerce & Management,</p> <p>Dean</p> <p>1. Dr.Kavita Laghate kavitalaghate@jbims.mu.ac.in</p> <p>Associate Dean</p> <p>2. Dr.Ravikant Balkrishna Sangurde Ravikant.s.@somaiya.edu</p> <p>3. Prin.Kishori Bhagat kishoribhagat@rediffmail.com</p>

	Faculty of Science & Technology Dean 1. Prof. Shivram Garje ssgarje@chem.mu.ac.in Associate Dean 2. Dr. Madhav R. Rajwade Madhavr64@gmail.com 3. Prin. Deven Shah sir.deven@gmail.com
	Faculty of Inter-Disciplinary Studies, Dean 1. Dr. Anil K. Singh aksingh@trcl.org.in Associate Dean 2. Prin. Chadrashekhhar Ashok Chakradeo cachakradeo@gmail.com
3	Chairman, Board of Studies,
4	The Director, Board of Examinations and Evaluation, dboee@exam.mu.ac.in
5	The Director, Board of Students Development, dsd@mu.ac.in DSW directr@dsw.mu.ac.in
6	The Director, Department of Information & Communication Technology, director.dict@mu.ac.in

As Per NEP 2020

University of Mumbai



Syllabus for Post Graduate Diploma in Pharma Management (Garware Institute of Career Education and Development)

Semester- Sem I & II

PG GR dated 16th May, 2023

(With effect from the academic year 2023-24)

UNIVERSITY OF MUMBAI



(As per NEP 2020)

Sr. No.	Heading	Particulars
1.	O: <u>GPA – 45A</u> Title of the Course	Post Graduate Diploma in Pharma Management(PGDPM)
2.	O: <u>GPA – 46A</u> Eligibility	Graduate in Science field only. Preference will be given to MBBS, B.PHARM/ M.PHARM / M. Sc. / BAMS/ BHMS/ Paramedical courses. OR Passed Equivalent Academic Level 5.5
3.	Duration of Program R: <u>GPA - 106</u>	1 Years
4.	R: <u>GPA – 107</u> Intake Capacities	60
5.	R: <u>GPA – 108</u> Scheme of Examination	50 Internal – Continuous Evaluation 50 External- Semester End Exam
6.	Standards of Passing R: <u>GPA - 109</u>	50% in each component
7.	Credit Structure R: <u>GPA – 110A</u> R: <u>GPA – 110B</u>	Attached herewith
8.	No. of Years / Semesters :	One year, Sem I & II
9.	Program Level :	PG 6.0
10.	Pattern :	Semester
11.	Status :	New
12.	To be implemented from Academic Year.	From Academic Year 2023-24

Keyurkumar

Dr. Keyurkumar M. Nayak,
Director,
UM-GICED

Prof.(Dr.) Anil Kumar Singh
Dean,
Faculty of Interdisciplinary Studies

PREAMBLE

Introduction:

Pharmaceutical industry is one of the largest industries in India; its demand for efficient manpower is continuously on the rise. This requires well prepared personnel to handle medical support to marketing, drug development, clinical activities of drug introduction and monitoring in markets.

- The Post Graduate Diploma in Pharma Management was started in 2006 by University of Mumbai.
- This is a 12 months full time program developed to cover knowledge-base in science, medicine, management, technological concepts and environmental factors involved in processes from drug discovery to marketing approval by regulatory authorities in diverse markets.
- The course is meant to train personnel for medical and research support departments in Pharmaceutical companies, CROs, Laboratories and Research institutions.
- Industrial Training is an exclusive two/three months training programme in Second Semester. It is an opportunity for the students to actually relate all the classroom discussions and theoretical deductions with the practical corporate arena.
- The course is reviewed & upgraded regularly through a panel of experts which comprises of Managers from Pharmaceutical industries.
- In an ever-changing business environment, the Post Graduate Diploma in Pharmaceutical Management equips you with the knowledge needed to stay ahead of the competition.

Aims and Objectives:

The objective of Post Graduate Diploma in Pharma Management course is to develop students, over the period of one year, by rigorous training and academics for positions in Product Management Department, Pharma Sales Department, Quality Assurance and Quality Control Department, Regulatory Affairs department, Medical services Department in Pharmaceutical Companies, CRO. Students spend 8 weeks of summer Internship with Pharmaceutical Companies.

- To demonstrate and apply sound domain knowledge and competence in environment management, sustainable development studies as well as use skills with respective techniques, methodologies and theories constructively in professional spheres.
- To develop and put into practice effective communication, reading and presentation skills in environment management and sustainability domains and use appropriate body language.
- To analyze, interpret and evaluate different data, emerging industrial trends and be an environmentally responsible individual able to take informed decision for his company and country.
- To identify, select, organize, and apply the research techniques to carry out research and value intellectual property rights as well as interpret the research data correctly on the professional front.
- To choose and use basic computer applications & domain specific tools along with core training in modern laboratory equipments for enhanced output.
- To understand, investigate and evaluate concepts from diverse areas such as social entrepreneurship and public governance and NGOs.
- To be prepared to face a situation or fulfil a requirement and arrive at a win-win solution – both commercially as well as technically through holistic thinking and problem solving approach.
- To serve and assist in socially/ environmentally useful and productive work and be prepared potential entrepreneurs to base their ventures on solid offerings for sustained greatness.
- To interact with people of diverse backgrounds and cultures respecting their beliefs and practices and while effectively engaging within a multicultural society and be able to empathies with the societal needs and be concerned and responsible to environmental issues and practice sustainability.
- To develop professionalism, organizational skills and employability skills, make decisions, put into practice self-, time- and change management and solve problems by following learnt ethical principles.
- To cultivate self-awareness, inner strength, creative and original thinking, attitude to continuously update and upgrade one's knowledge and expertise in alignment with the core Environmental

Sensitization.

Course Objective

- To demonstrate sound proficient knowledge of fundamental principles and their applications in the area of Pharmaceutical Sciences.
- To develop ability for in-depth analytical and critical thinking in order to identify, formulate and solve the issues related to Pharmaceutical Industry, Regulatory Agencies, Community Pharmacy and Hospital Pharmacy.
- To identify the rules and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines along with a sound knowledge of drug formulation technology and overview of medicines as per the requirement of Pharmaceutical sectors.
- To develop an understanding for the need of pharmaceutical sciences and technology towards giving quality life to people in society.
- To recognize the problems faced by the industry while handling Pharmaceutical concern and provide solutions which are ethically correct in the first place.
- Be employable/ Self-employed and future ready as there would be more emphasis on 'learning by doing' and introducing the student to the industry beforehand through internship, live projects, industrial visits and industry- academia interphase.

Learning Outcomes:

A Student Completing Post Graduate Diploma in Pharma Management will be able to:

1. Foster accountability and leverage expertise to form a highly functioning team and promote shared patient-centered problem solving.
2. Display preparation, initiative, and accountability consistent with a commitment to excellence.
3. Use effective interpersonal skills to establish rapport and build trusting relationships.
4. Deliver services in a manner that is legal, ethical, and compassionate and free of conflict of interest.
5. Demonstrate an awareness that one's professionalism is constantly evaluated by others.
6. Engage in the profession of pharmacy by demonstrating a commitment to its continual improvement.
7. Demonstrate knowledge of and an ability to use bioinformatics.
8. Utilize technology that is a component to or of the pharma use system.
9. Apply standards, guidelines, best practices, and established processes related to safe and effective drug use.
10. Understand and comply with central and state laws related to pharma.
11. Apply and assess the literature and other research resources to provide evidence-based drug information that meets the needs of patients and other health care providers.

CAREER SCOPE:

Pharma Management is a division of management that deals with chemical and health sciences and ensures the effective and safe use of pharmaceutical drugs. Pharma Management integrates business strategy with science and technology and the unique perspective of the industry. A management program in this area trains students on Management, Leadership, Advanced Business Concepts and Technology Management and Advanced Pharmaceutical Management.

Marketing & Sales:

- Medical Representative / Research Executive / Sales Executive / Product Executive / Business Development as a fresher.

- Zonal Manager / Sales Manager /Vice President of the company and other top positions with years of experience.
- Area Manager (AM) or District Marketing Manager (After 2 or 3 years)
- Regional Manager (After 5 to 6 years).

Marketing Management:

- Brand Management Executive
- Product Management Marketing Executive
- Market Researcher
- Business Development Manager

Clinical Research:

- Research Associate/ Project executive (Writing a protocol: Designing a study, format and focus on sample size and preparation of Statistical Analysis Plan).
- Research Executive (Bioequivalence studies: requirements, protocol, pharmacokinetics).
- Pharmacovigilance Associate/ Officer (detection, assessment, understanding and prevention of adverse effects, particularly long term and short term adverse effects of medicines).

Clinical Data Management (CDM)

- Trainee Junior Data Analyst/ Clinical Data Manager (Designing and validating clinical databases/Developing data management plans in areas such as coding, reporting, workflow or data transfer, etc)

Regulatory Affairs:

- **Regulatory Affairs** Executive/ Officer/ Project Associate (The drug approval process, in-licensing of the drugs, importing of drugs and registration of the manufacturing sites).

QA/QC:

Quality Assurance/ Quality Control Analyst/ Executive/ Officer (Responsible for all Production activities/ Maintenance of regulatory documentation/ Coding of new products in database)

Implementation of these aspects requires foundation and training of fresh graduates in industry, possibly in-house. The course has been designed by team of Pharma practicing experts from industry to provide this foundation.

5) Credit Structure –

R: _____

Level	Sem	Major			RM	OJT/FP	RP	Cum. Cr.	Degree	
		Mandatory		Electives						
6.0	Sem I	1.1: Principles of Management	TH	Credits 4	Credits 4 E1 : Marketing & Sales/ E2: Bio Statistics	4			22	PG Diploma (after 3-yr UG or PG Degree)
		1.2: Clinical Pharmacology	TH	Credits 4						
		1.3: Drug Development Process	TH	Credits 4						
		1.4: Overview of Medicine	TH	Credits 2						
	Sem II	2.5: Biochemistry, Genetics & Microbiology	TH	Credits 4	Credits 4 E3: Pharmaceutical Management/ E4: Communication skills		4		22	
		2.6: Clinical Trials & Pharmacovigilance	TH	Credits 4						
		2.7: Information Technology	TH	Credits 4						
		2.8: Finance	TH	Credits 2						
	Cr. For 1 YR Diploma		28			8	4	4		
Exit Option : PG Diploma (44 credits) after Three Year UG Degree										

Keyurkumar

Dr. Keyurkumar M. Nayak,
Director,
UM-GICED



Prof.(Dr.) Anil Kumar Singh
Dean,
Faculty of Interdisciplinary Studies

COURSE CONTENT BRIEF:

YEAR – 1: SEMESTER – I

Paper Code	Title of the Course	Scheme of Examination Assessment Pattern			Scheme of Instruction			Credits
		Internal Marks 50	External Marks 50	Total Marks 100	Theory Hours (L)	Practical Hours (P)	Total Hours	
GDPMMS1P1	Principles of Management	50	50	100	60	-	60	4
GDPMMS1P2	Clinical Pharmacology	50	50	100	60	-	60	4
GDPMMS1P3	Drug Development Process	50	50	100	60	-	60	4
GDPMMS1P4	Overview of Medicine	25	25	50	30	-	30	2
GDPMMS1P5	Marketing & Sales Or Biostatistics	50	50	100	60	-	60	4
GDPMMS1P6	Research Methodology	50	50	100	60	-	60	4
	Total	275	275	550	330	-	330	22

YEAR – 1: SEMESTER – II

	Paper Code	Title of the Course	Scheme of Examination Assessment Pattern			Scheme of Instruction			Credits
			Internal Marks 50	External Marks 50	Total Marks 100	Theory Hours (L)	Practical Hours (P)	Total Hours	
M	PGDPMMS2P7	Biochemistry, Genetics & Microbiology	50	50	100	60	-	60	4
	PGDPMMS2P8	Clinical Trials & Pharmacovigilance	50	50	100	60	-	60	4
	PGDPMMS2P9	Information Technology	50	50	100	60	-	60	4
	PGDPMMS2P10	Finance	25	25	50	30	-	30	2
E	PGDPMS2P11	Pharmaceutical Management or Communication skills	50	50	100	60	-	60	4
OJT/FP	PGDPMS2P12	On the Job Training	100	-	100	-	120	120	4
		Total	325	225	550	270	120	390	22

Sem.- I

SUBJECT-WISE SYLLABUS
SEMESTER I
MANDATORY SUBJECTS

Subject 1.1: Principles of Management	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives <ol style="list-style-type: none"> 1. To explain the evolution of Management and its principles. 2. To discuss the functions of management and their importance in business 3. To propose the application of the principles of management in an organizational setup. 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> 1. Absorb various management concepts such as planning, organizing, implementing, staffing, coordinating, controlling, motivating and Managerial Grid. 2. Recognize the human skills and conceptual skills as per industry requirements about basic management skills. 3. Diagnose various styles and qualities of efficient leadership, Coordination, Controlling, Management. 4. Assess the global situation, including opportunities and threats that will impact management of an organization. 5. Integrate management principles into management practices. 	
CONTENT	Total Hours
UNIT 1: Management: Science, Theory and Practice, Functions of Manager, Evolution of Management thought, Behavioral Sciences. International Management & MNCs.	6
UNIT 2: Purpose, steps, process, Objectives, MBO, Developing verifiable goals, Strategy, Policy, Decision Making.	6
UNIT 3: Organizing Structure, Departmentation, Span, Environment- entrepreneurial, innovation, Line, Staff, Authority, Decentralization, Delegation.	6
UNIT 4: Organizations in Pharma, R&D Labs, Hospitals, small scale Assessment of cost operation: Performance monitoring through Budgets and MIS Leading.	10
UNIT 5: Human Factor and Motivation: Motivational Theories, Strategic Approaches,	8

Special Motivational Techniques: Quality of life, Job enrichment, career advancement, management participation.	
UNIT 6: Team Building & Leadership: Definition, Leadership styles, Committees & Group Decision making, Controlling Process, Control points, Benchmarks, standards, Feedback system, Requirements of a good control system.	8
UNIT 7: Use of IT: Gantt Charts, Budgets vs Actual MIS, Preventive control, Social Responsibility Ethics.	8
UNIT 8: Startups- Overview success strategy. Game Theory.	8
Reference Books: <ul style="list-style-type: none"> • Koontz, Harold and Weijrich, Heinz : Essentials of Management : an Indian perspective. New Delhi, Tata McGraw-Hill Pub. Co. Ltd., • Weihrich Heinz and Koontz, Harold : Management : a global perspective. New Delhi, Tata Mc Grawhill Pub. Co. Ltd., • Koontz, Harold & others : Principles of Management New Delhi, Tata McGraw-Hill Pub. Co. Ltd., • Drucker Peter F : Management : Tasks, Responsibilities and Practice. New Delhi, Allied Publishers 	

Subject 1.2: Clinical Pharmacology	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives <ol style="list-style-type: none"> 1. To provide insight into fundamentals of pharmacokinetics and pharmacodynamics. 2. To acquaint yourself with drugs affecting various systems. 3. To understand the importance of selecting the right drug for treatment of cancer. 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> 1. Demonstrate a critical understanding of the basic principles of dose adjustment and pharmacokinetics/-dynamics, and factors contributing to individual variability 2. Recognise types of adverse drug reactions, why they occur, and their association with poor medication compliance 3. Appraise the effects and adverse reactions associated with common recreational drug use, and diagnose and formulate management plans for common presentations to a toxicology unit 4. Make informed judgements in situations in the absence of complete or consistent data/information. 	

CONTENT	Total Hours
UNIT 1: Pharmacokinetics: Absorption, Distribution, metabolism of drugs.	8
UNIT2: Pharmacodynamics: Mechanism of drug action, Dose response relationship, Antagonism, enhancement of drug effects.	8
UNIT3: Drugs affecting neurohumoral transmission, CNS, Anesthetic Agents, Cardiovascular Agents, Diuretic Agents.	8
UNIT 4: Drugs affecting Hematopoiesis and Hemostasis.	8
UNIT 5 : Analgesics, Anti inflammatory drugs	8
UNIT6: Hormones, Antagonists, and other agents affecting endocrine function	10
UNIT7: Chemotherapy: Cancer, sulphonamides, penicillins, other antibiotics, tetracyclines, antifungals, UTI, Aids, Tuberculosis, Malaria, Amoebiasis,	10
Reference books: <ul style="list-style-type: none"> Pharmacology and Pharmacotherapeutics: R.S.Satoskar, Nirmala N. Rege, S.D. Bhandarkar: Popular Prakashan Essentials of Medical Pharmacology : K D Tripathi Introductory Clinical Pharmacology : Lippincott Williams & Wilkins 	

Subject 1.3: Drug Development Process	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives	
1. To impart knowledge of regulatory framework including the concept of IPR. 2. To provide an overview of the drug discovery process. 3. To understand fundamentals of Regulatory Applications.	

<p>Course Specific Learning Outcomes (The students will be able to.....)</p> <ol style="list-style-type: none"> 1. Understand the role of intellectual property in drug discovery. 2. Critically evaluate the drug discovery process. 3. Discuss and place into context the use of high-throughput-screening in the drug discovery process. 4. Understand the importance of pharmacology in the drug discovery process. 5. Develop an understanding of how drug safety is assessed. 6. Understand the role of regulatory affairs and drug approval for use in the clinic. 	
CONTENT	Total Hours
<p>UNIT 1:</p> <p>Environment, Regulations & Standards Regulatory Environment: Patent Act, IPR.</p>	10
<p>UNIT 2:</p> <p>Regulatory Affairs:</p> <p>Authorities, Applications, Inspections, Toxicology. Early History of Medicine, Drug Discovery and Development in middle ages, Foundation of current process, Beginning of Modern Pharma industry. Evolution of Drug Products, Intellectual Property Rights. Drug Discovery and Development process: Overview, Economics, Trends. Targets and Receptors: Medical needs, Target Identification and Validation, Drug interactions with Targets or receptors, Enzymes, Signal Transduction, Assay development. Drug Discovery: Small molecule drugs. Rational approach, Antisense approach, Chiral drugs. Drug Discovery: Large molecule drugs. Biosimilars ,Biogenerics, Herbal Medicines. Introduction to monographs and official competence.</p>	20
<p>UNIT 3:</p> <p>Regulatory Authorities</p> <p>Drug Controller General of India, US FDA,European Agency for evaluation of Medical products, Japan's Ministry of Health, Labour and Welfare, China's State Drug Administration, African, Russian UAE Authorities, Authorities other than Drug Regulatory Agencies.</p> <p>International Conference on Harmonization(ICH), WHO, Pharmaceutical Inspection Cooperation scheme, Important links related to drug(literature).</p>	15
<p>UNIT 4:</p>	15

<p>Regulatory Applications</p> <p>FDA, European Union, Japan, China, Africa. Russia etc, GOOD MANUFACTURING PRACTICE: Regulatory Requirements. USA, Europe, ICH, Core elements of GMP, Systems, Modifications and reviews of Standards</p> <p>GMP: Drug Manufacturing. GMP Manufacturing, Inspection, Small molecule, large molecule APIs, Finished Dosage Forms. Future Perspectives. Past Advances and Future challenges(may be guest lectures/seminars), Dosage forms.</p>	
<p>Reference Books:</p> <ul style="list-style-type: none"> • Drugs from Discovery to Approval: Rick Ng Pub: Wiley-Leiss • Pharmaceutical Medicine, Biotechnology and European Law Richard Goldberg, Julian Lonbay: Cambridge University press. 	

Subject: 1.4: Overview of Medicine	Credits: 2
Total contact hours: 30	Theory Hours = 2/week
<p>Course Objectives</p> <ol style="list-style-type: none"> 1. To provide fundamentals of epidemiology of diseases. 2. To comprehend Health scenario globally as well as locally. 3. To gain knowledge of basics of hematology. 4. To know the programmes by international bodies for better health scenario. 	
<p>Course Specific Learning Outcomes (The students will be able to.....)</p> <ol style="list-style-type: none"> 1. Determine the cause of a disease. 2. Enlist various diseases 3. Identify the symptoms of various diseases. 4. Acquaint with international regulations for a better Health scenario 5. Participate in various programs launched by national and international bodies to improve health in the country. 	
CONTENT	Total Hours
<p>UNIT 1:</p> <p>Important diseases, Epidemiology and Treatment scenario. Clinical and Radiological Investigations and Diagnosis.</p>	6
<p>UNIT 2:</p> <p>Malaria, Tuberculosis, HIV, Influenza, Diarrhea Diseases, ARI / Pneumonia, Fevers and Systemic signs, Cardiology, Chest Medicine, Renal Disease, Gastroenterology Neurology, Dermatology, Endocrinology, Cholera, Diphtheria, Encephalitis, Mumps, Leptospirosis, Viral hepatitis</p>	12

UNIT 3: Hematology: Anemia, Thalassemia, bleeding disorders, leukemia.	4
UNIT 4: Gynecology, Immunization Schedule.	4
UNIT 5 : Health scenario in different countries/continents, races. Programmes of international bodies like WHO, NGOs, ICMR, Govt health programmes	4
Reference Books: <ul style="list-style-type: none"> ● Clinical Medicine: Praveen Kumar & Michael Clark ● Clinical Diagnosis : Hutchinsons (Handbook) 	

Subject: Research Methodology	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives: <ol style="list-style-type: none"> 1. To understand the basics of research designs and methodologies. 2. To identify research tools applicable to examine a research problem 3. To use the right research techniques to interpret the data. 4. To carry out research in an ethical manner. 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> 1. Propose appropriate research designs and methodologies to apply to a specific research project in a business function. 2. Determine the relevance of research tools and techniques for analyzing and evaluating research problems. 3. Develop a comprehensive research methodology for a given research question. 4. Analyze qualitative and quantitative data as a part of a defined research project. 5. Evaluate literature for a given research problem from the global and national perspectives. 6. Prioritize ethical research practices in conducting a research study. 7. Justify the chosen research orientation and methodology for a given research problem. 8. Construct an effective research proposal for a given study in a management function. 	
CONTENT	Total Hours
UNIT I: Business Research Fundamentals:	12

Research – meaning and types of business research –basic, applied, comparative, absolute, problem solving, problem identifying, qualitative, quantitative, characteristics of good research. Hypothesis, Types of hypothesis – Descriptive, Relational – Correlational and Causal, null and alternate. Brief Introduction to Business Research Process	
UNIT II: Steps in Business Research Process - I: Problem Identification / Problem statement. Review of Literature (including citation and bibliography / references). Research Questions & Research Objectives. Hypothesis formulation. Research Design: Exploratory Research Design. Difference between Qualitative and Quantitative Research. Qualitative Research: Observation, Focus Group, Depth Interview, Projective Techniques.	12
UNIT III: Conclusive Research Design: Quantitative Research: Descriptive research – survey, survey methods. Causal research – Experimentation – labs v/s field experiments, with & without control, before & after. Steps in Business Research Process - II: Sampling Design – Probabilistic and non- probabilistic sampling. Sources of data – primary and secondary. Measurement and Scaling. Validity and reliability. Questionnaire designing.	12
UNIT IV: Steps in Business Research Process - III: Data Preparation – preliminary questionnaire screening, editing, coding and data entry (using statistical software). Research Writing: - Research Proposal, Synopsis, Research Report.	12
UNIT V: Practical: A group of two students (Maximum) has to work on a Minor Research Project on the topic selected from the beginning of the semester in line with all the steps of Research Design starting from Identification of Research Problem to Findings & Conclusion and has to submit a Report to the concerned faculty member.	12
Reference books: <ul style="list-style-type: none"> ● Business Research Methods by Naval Bajpai. ● Marketing Research – An applied orientation by Naresh Malhotra and Satyabhusan Dash ● Business Research Methods by Donald R. Cooper and Pamela S. Schindler. ● Business Research Methods by ZikmundWilliam ● Research methods for business: A skill building approach by Uma Sekaran. ● Business Research Methods by Panneerselvam R. ● Research Methodology by D. K. Bhattacharyya. ● Business Research Methodology by J. K. Sachdeva. ● Research Methodology for Management and social Science by AdithanBhujange. ● Business Research Methods by Alan Bryman ● Journal of Indian Business Research 	

1. International Journal of Statistics and Analysis
2. Sankhya – Indian Journal of Statistics
3. Economic Times
4. Financial Express
5. Business Standard
6. Economic & Political Weekly
7. Vikalpa

ELECTIVES

Subject E1 : Marketing & Sales	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives <ol style="list-style-type: none"> 1. To develop an understanding of the basics of marketing management. 2. To apply the acquired knowledge to analyze opportunities in market for profit. 3. To understand the influence of various factors upon consumer decision-making. 4. To acquire skill to market products digitally. 5. To demonstrate the understanding of international trade and its boundaries. 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> 1. Explain the basic concepts, principles, theories and models which apply to marketing. 2. Analyze the key concepts of strategy, planning, implementation and control through a range of tools and techniques to analyze and evaluate markets, market opportunities and market segments. 3. Demonstrate an understanding of who an organisations' customers are and explain the factors that influence consumer behavior. 4. Analyze the key concepts of the marketing mix to develop an integrated marketing mix that markets products, services and experiences. 5. Demonstrate an understanding of the boundaries of marketing and its integration with other business functions. 6. Understand the importance and need for Social Marketing and ethics in marketing. 7. Understand and know the various approaches to entering International markets along with relevant limiting factors. 	
CONTENT	Total Hours
UNIT1 Concepts of present day marketing, developing strategies and plans, gathering	10

information and scanning environment. Marketing Environment for consumer, Ethical and business products.	
UNIT 2 Market Research: Secondary, Primary. Analyzing Business Markets. Demand Forecasting, Analyzing markets, Segmentation in Business and consumer markets	10
UNIT 3 Product Management: Creating Brand Equity, Competition and Strategy, Product Strategy, Pricing Strategies, Distribution, Channel Management Decisions, Supply Chain Management.	8
UNIT 4 Marketing Communication: Advertising, Promotion, Publicity, Personal Selling, Direct Marketing, Event Marketing, Digital Marketing, Product Planning: Marketing plan.	8
UNIT 5 Introducing New Markets: Tapping Global markets, Social Responsibility of Marketing and Ethical Marketing, Marketing Budgets: investments, recurring, MIS.	8
UNIT 6 INTERNATIONAL MARKETING Regional Economic Size: GDP, Trade Patterns, Development of Trade in international scenario. Opportunities in Developing and Developed countries, Strategy for entry in international markets: Joint ventures, mergers Acquisitions, B2B sales, Budget Marketing, Research and information needs and methodology, Examples of local controlling authorities, regulations and laws.	16
Reference books: <ul style="list-style-type: none"> • Marketing Management - Kotler, Keller, Koshy & Jha –14th edition • Marketing Management – M. Altaf Khan, Wisdom Publications • Professional Sales Management – Anderson, Hair & Bush Tata McGraw Hill 	

Subject E2: Biostatistics	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives <ol style="list-style-type: none"> 1. To introduce student to basics of biostatistics 2. To acquaint with measures of central tendency and dispersion 3. To understand the fundamentals of Probability 4. To create an awareness of Statistical Testing methods 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> 1. Collect and compare the data. 2. Illustrate skills to measures of central tendency 3. Utilize Probability concept for apt decision making. 4. Select the right method for Hypothesis testing. 5. Apply the gained knowledge for Statistical techniques in Pharmaceutics. 	
CONTENT	Total Hours
UNIT 1: Biostatistics: Introduction, its role and uses, Raw data , attributes and variables , Collection of Primary and Secondary Data, Classification and Tabulation, Frequency Distributions cumulative frequency distributions and their graphical representation - Histogram , Frequency polygon. Diagrams - Multiple bar, Pie, Subdivided bar.	8
UNIT 2: Measures of Central Tendency and Dispersion : Criteria for good measures of central tendency, Arithmetic mean, Median and Mode for grouped and ungrouped data, combined mean. Concept of dispersion, Absolute and relative measure of dispersion, Range, Variance, Standard deviation, Coefficient of variation, Quartile Deviation, Moments, Measures of Skewness and Kurtosis.	8
UNIT 3 : Probability : Introduction ideas (probability rules, statistical independence, statistical dependence, joint probability, marginal probability). Additive and Multiplicative rules; Conditional Probability and Baye's Theorem. Random Variable, Mathematical Expectation, Binomial, Poisson and Normal probability distributions.	8
UNIT 4 : Sampling:	8

Methods of Sampling; Sampling and Non- Sampling Errors; Law of Large Numbers and Central Limit Theorem (without proof) Estimation, Point & Interval Estimates, Confidence Intervals.	
UNIT 5 : Statistical Testing A] <u>Testing Of Hypothesis Parametric Tests:</u> Hypothesis testing: one sample and two sample tests for means and proportions of large samples (z-test), one sample and two sample tests for means of small samples (t-test), F-test for two sample standard deviations. ANOVA one and two way. B] <u>Non Parametric Tests:</u> Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskalwallis and Friedman two way ANOVA tests. Spearman rank correlation, Chi-square as a test of Independence and as a test of Goodness of Fit.	10
UNIT 6 : Correlation, Regression and Time Series Analysis: Correlation analysis, Estimation of regression line, Time series analysis (Variations in time series, trend analysis, cyclical variations, seasonal variations and irregular variations, forecasting errors).	9
UNIT 7: Statistical techniques in Pharmaceutics: Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.	9
Reference Books: <ul style="list-style-type: none"> ● Richard I. Levin, David S. Rubin, Statistics for Management, Pearson Education. ● Fundamentals of Biostatistics by Bernard Rosner. ● Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bo. ● Business Statistics by J.K.Sharma. ● Business Statistics by S. P Gupta. 	

Sem.- II

SEMESTER II
MANDATORY SUBJECTS:

Subject 2.5: Biochemistry, Genetics & Microbiology	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives <ol style="list-style-type: none"> 1. To provide knowledge of the basics of biochemistry and biochemical methods. 2. To gain an insight into the fundamentals of genetics and inheritance related diseases. 3. To understand basic introduction of scope, potential and achievements in biotechnology. 4. To correlate the diseases with their microbiological origin. 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> 1. Recognize biomolecules on basis of their structure, classification and functions 2. Apply the knowledge of biochemical methods to identify various diseases. 3. Understand the New concepts of Biotechnology, Genetic engineering techniques and recombinant DNA technology. 4. Display awareness of bioethical aspect of medical genetics. 5. Classify the microorganisms into categories based on diseases caused by these. 	
CONTENT	Total Hours
UNIT 1: Biochemistry Basics of Biomolecules and Biochemical methods (PCR, Chromatography), Biochemistry and Disease. Chemical constituents of Blood and body fluids. Structure and Functions of Proteins and Enzymes. Introduction to hormones and steroids. Various metabolism pathways– Assays. Common Lab Tests used in Medicine for Diagnosis	18
UNIT 2: Genetics Cell Biology: Structure and function of genes and chromosomes: DNA, RNA and Proteins: Heredity at molecular level. Structure of Genes and Genome. Genetic Variation: Source of variation: mutation, Detection and variation of genetic variation. Overview of basic genetics and inheritance related diseases. Multifactorial inheritance. Clinical Cytogenetics, Biochemical Genetics, Pharmacogenetics, Gene Mapping and Cloning, Immunogenetics, Major Histocompatibility complex, Population screening for genetic diseases, tools for screening and diagnosis, prenatal diagnosis of congenital defects.	22

Genetic Testing and Gene Therapy. Bioethics in medical Genetics. Introduction to Biotechnology in pharma.	
UNIT 3: Microbiology Lifestyle of Microbes: Bacteria, Fungi, Virus, Parasites. Diseases caused by these. Infection and Immunity. Microbiology tests and results, Infection Control and Sterilization techniques.	20
Reference Book: •Medical Genetics: LB Jorde, JC Carey, MJ Bamshad, RL White •Biochemistry: Debajyoti Das •Fundamentals of Biochemistry: Dr AC Das •Microbiology by Pelczar	

Subject 2.6: Clinical Trials & Pharmacovigilance	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives <ol style="list-style-type: none"> 1. To introduce to the fundamentals of clinical trials 2. To acquire knowledge of how clinical trials is conducted. 3. To know the different stages in drug development. 4. To comprehend the concept of pharmacovigilance. 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> 1. Understand the need of clinical trials. 2. Comprehend the compliance guidelines requirement for all clinical studies 3. How to think and apply learnt principles in real world studies 4. Get acquainted with the safety reporting to be considered. 5. Apply legal, ethical, and professional standards within a medication use system. 	
CONTENT	Total Hours
UNIT 1 : Drug Discovery and Development: Basic principles – Bioavailability, Bioequivalence, Pharmacokinetics, Phases of trials.	4
UNIT 2 : Regulations- History of Ethics and Evolution of Laws, Declaration of Helsinki, Schedule Y in detail should be covered as it law regulating clinical research in India, ICH-GCP, Indian GCP, ICMR guidelines, Brief overview of US FDA- CFR and EMEA	6

UNIT 3 : Ethics: Institutional Review Board- Composition, Functioning, Submissions, ethical issues, Informed consent process, Compensation	4
UNIT 4 : Clinical trials Part –I - Introduction to CLINICAL TRIALS, Ethical Considerations, Regulatory requirements for Clinical Trials, Role of regulatory authorities, Gene therapy and clinical trials Part –II- Study design, Randomization, Blinding, Placebo, To cover breaking of blind, simultaneous use of blinded and unblinded groups, Elements of protocol, protocol writing, CRF designing Part-III -Quality control and Quality Assessment Overview, Essential documents, Study files, Source documentation, Monitoring, Audits and Inspections including preparation, Training records, Standard Operating Procedures, CAPA.	12
UNIT 5 : Roles and Responsibilities (other stakeholders): Investigator, Sponsor, CRA/CRC/Monitor.	6
UNIT 6 : Safety Reporting: Adverse event / SAE reporting, Data Monitoring and Interim Analysis.	4
UNIT 7 : Investigational Product Management: Storage, Temperature, Accountability, Destruction.	6
UNIT 8 : Good Quality Control Practices	4
UNIT 8: Introduction to Pharmacovigilance	14
Reference book: <ul style="list-style-type: none"> • Apothecaries White Book for Clinical Research by Apothecaries Foundation, New Delhi. Second Edition • Textbook of Clinical Trials by John Wiley & sons Ltd. • Fundamentals of Clinical Trials by Lawrence M Friedman and others. • Foundations of Clinical Research: Applications to Practice by Leslie Gross Portney • Textbook of Pharmacovigilance: Ensuring the Safe Use of Medicines by SK Gupta , Sushma Srivastava. • Textbook of Pharmacovigilance: Concept and Practice by Guru Prasad Mohanta & Prabal Kumar Manna. 	

Subject 2.7: Information Technology	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives <ol style="list-style-type: none"> 1. To impart knowledge for operating MS office for better results at the work-place. 2. To understand the importance of cloud computing. 3. To provide an overview of various digital marketing tools used in pharma industry. 4. To utilize the softwares for better management of data in the industry. 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> 1. Get the tasks done quicker at work place with use of MS. Office tools. 2. Know the different communication devices 3. Understand various aspects of Project Management 4. Comprehend the cloud computing concept. 5. Operate various software for better management of clinical data. 6. Get acquainted with how digital marketing operates in pharma industry. 7. Develop an understanding of benefits of Artificial Intelligence in Pharma industry. 8. Explore the field of bioinformatics. 	
CONTENT	Total Hours
UNIT 1: Introduction of Information Technology Understand in detail office automation system <ol style="list-style-type: none"> 1. Ms word 2. Ms Excel (Advance level) 3. MsPowerpoint 4. Macro 	6
UNIT 2: Understand different types of Networks / communication devices <ol style="list-style-type: none"> 1. Wired 2. Wireless 3. Business network 4. IOT 5. Different technology Commonly used communication devices	6
UNIT 3: Enterprise Resource Planning <ol style="list-style-type: none"> 1. Vendor selection (Software / Hardware) 	8

2. How to implement ERP 3. Extended ERP (Supply Chain Management / Customer Relationship Management) 4. Implementation 5. Case study	
UNIT 4: Cloud computing	4
UNIT 5: Database management system 1. Concept 2. Data mining / data warehouse 3. MS Access 4. Statistical software 5. Latest Clinical Data Management systems 6. Patient Management	12
UNIT 6: Understanding of e-Commerce and basics of digital marketing 1. Various search engine 2. Social media 3. Mobile apps.	6
UNIT 7: Understanding of Project Management 1. What is project management 2. How to handle the project Understanding of various knowledge area specially Scope, Cost, Time and Quality	6
UNIT 8: New trend and development of software in pharma industry, Regulatory information Management (RIMS), Clinical Data Management (CDM), Artificial Intelligence in Pharma, Data Analysis	6
UNIT 9: An introduction to Basic Bioinformatics.	6
Reference Book: <ul style="list-style-type: none"> ● Courter G & Marquis A : Mastering MS Office XP, New Delhi, BPB Publishers, 2001 ● Sanders, D. H. : Computers in Business: An Introduction (McGraw Hill) 	
Subject 2.8: Finance	Credits: 2
Total contact hours: 30	Theory Hours = 2/week
Course Objectives	
1. To gain insight into the basics of accounting.	

2. To understand what is the return on investment.
3. To demonstrate the fundamentals of a balance sheet.
4. To utilize acquired knowledge of inventory management in work scenarios.

Course Specific Learning Outcomes (The students will be able to.....)

1. Get acquainted with how accounting practices are followed at a workplace.
2. Calculate monetary value of an investment versus its cost.
3. Analyze a balance sheet and connect it with the profit/ loss concept.
4. Comprehend the concept of ratio analysis.
5. Acquire knowledge of various financial aspects of the pharma industry.

CONTENT	Total Hours
UNIT 1 : Introduction to Accounting Practices	6
UNIT 2 : Capital Investments, ROI	6
UNIT 3 : Balance Sheet and Profit & Loss Account, Ratio Analysis	6
UNIT 4 : Miscellaneous <ol style="list-style-type: none"> 1. Process and Batch Costing 2. Inventory Management 3. Credit in Business 4. Working Capital Requirements 5. Maintenance of Accounts 	12
Reference Books: <ul style="list-style-type: none"> ● Khan M. Y. & Jain, P. K. : Financial Management : Text, Problems & Cases. New Delhi, Tata McGraw Hill Pub. Co. ● Prasanna, Chandra : Financial Management ● New Delhi, Tata McGrawHill Pub. Co. Ltd 	

Subject: On Job Training	Credits: 4
Total contact hours: 120	Theory Hours = 4/week

Course Objectives: <ol style="list-style-type: none"> 1. To impart eight weeks rigorous training to the students in any one industry/ organization/ institution in the field of Pharma. 2. To provide the students with hands-on physical work experience in a professional-life working scenario. 3. To aid students to pursue careers in the private, public, and nonprofit sectors where there is an increasing demand for Pharma professionals. 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> 1. Explore different organizations involved in manufacturing and applications. 2. Undergo practical training for at least 4 weeks of intensive training in the industry to correlate theoretical knowledge with practical work. 3. List objectives of training with specific instructions on code of conduct while on training. 4. Be provided an opportunity to use the knowledge and acquired skills in execution and conduction of the project. 5. Acquire a training completion certificate from the one industry/ organization/ institution as an added credential. 6. Understand how and why people behave in organizations as they do, either as individuals or in groups and how their behaviors affect their performance and performance of the organization as a whole. 7. Understand and address the barriers to personal effectiveness. 8. Apply clear and effective communication skills. 9. Develop effective time management skills and the ability to cope with stress. 10. Recognize how to adapt your leadership style to effectively lead and influence others. 11. Know the importance of working in a team. 	
CONTENT	Total Hours
<ul style="list-style-type: none"> ● Intensive Practical training for atleast 4 weeks in any one industry/ organization/ institution in the field of Sustainability / Environment to correlate theoretical knowledge with practical work is a mandatory part of the curriculum. ● Students will be given a detailed briefing on objectives of training with specific instructions on code of conduct while on training. ● Students should prepare their resumes and should be advised to go on training placements as planned by the faculty in-charge/ placement officer. ● A weekly update regarding learning outcomes during the training period is compulsory. ● The students will submit a report after completion of the inplant training having the certificate of completion duly signed and stamped by the authorized personnel and on the training industry/ organization/ institution letter-head. 	90

<ul style="list-style-type: none"> There will be an assessment based on presentation and viva-voce exams. Placement Grooming <ul style="list-style-type: none"> Elements of Personal Grooming Personal Grooming & Hygiene - Hair care, Nail care & Foot care, Dental care, Body odour care Benefits of Grooming Habits to maintain personal Hygiene Importance of Corporate / Business Office Environment Importance of Dressing Professionally Why Perceptions of other People about Us matters Basic Etiquettes at work Good manners at office Table manners & Dining Etiquettes Social Etiquettes Role play of Personal Management & Placement Grooming 	30
--	----

ELECTIVES

Subject E3: Pharmaceutical Management	Credits: 4
Total contact hours: 60	Theory Hours = 4/week
Course Objectives <ol style="list-style-type: none"> To provide insight into the Total Quality Management System. To impart knowledge of basics of ISO systems. To comprehend the latest trends in pharma industry through various case studies. To make the students aware about the various fields/functions that they can get into in the Pharma industry (for e.g. QA/QC, Regulatory Affairs, Business Development, Clinical Research, Clinical Data Management, Pharmacovigilance, etc.). To give an overview of the clinical/product life-cycle of drugs in the industry. To make students know about various management theories that exist - such as scientific, administrative, bureaucratic and behavioral theories. To explain various management strategies that used on day to day basis by pharma companies. 	
Course Specific Learning Outcomes (The students will be able to.....) <ol style="list-style-type: none"> Develop an understanding and associate the knowledge of various concepts in Total Quality Management. 	

<p>2. Recognize the importance of compliance of laws in the industry.</p> <p>3. Gain an insight into the ISO auditing systems.</p> <p>4. Comprehend the knowledge of various latest trends in the pharma industry.</p> <p>5. Understand how human resource management is done in the pharma industry.</p> <p>6. Discuss about the common problems faced by sales force in pharma industry.</p>	
CONTENT	Total Hours
UNIT 1: Total Quality Management: Introduction and evolution of quality movement. Contributions of Shewhart, Deming, Juran, Feigenbaum, Crosby Contributions of Japanese pioneers: Ishikawa(Ishikawa Matrix), Shigeo Shingo. Statistical quality control basics. Basics of sampling & reliability Quality tools and techniques. Quality Improvement and Total Employee Involvement. JIT manufacturing and Lean manufacturing through waste elimination. Six Sigma tools, quality circles. Statistical Process control, process capability studies. Cost of quality – Juran / Crosby. Legal aspects of Pharma Industry.	15
UNIT 2 : ISO Quality Systems .	15
UNIT 3: Recent Development in Pharmaceutical Industry with case studies: Biopharmaceuticals/ Advanced Bioinformatics/ Nutraceuticals/Medical Devices	15
UNIT 4: Advance Human Resource Management in Pharmaceutical industry: An introduction to the concept, case studies.	15
Reference Book: <ul style="list-style-type: none"> • TQM in this Service – By R.P.Murthy, R.R.Lakhe • Total Quality – By Institute of Directors • Human Resource Management: K Aswathappa, 5th edition TMG, 2009 	

Subject E4: Communication skills	Credits
Total contact hours: 60	Theory Hours = 4/week
Course Objectives	

- 1.To learn the steps taken to complete the project with respect to time, cost, scope and quality.
- 2.To be able to apply the acquire knowledge in communication technology for effective communication in personal as well as professional life.
- 3.To introduce the students to modern tools for effective communication.

Course Specific Learning Outcomes (The students will be able to.....)

1. Develop an understanding of relevance of good communication skills in business.
2. Debate on various topics in a group.
3. Comprehend group dynamics for effective communication.
4. Gain confidence through mock interview sessions.
5. Comprehend basic but crucial email etiquettes.
6. Critically introspect own personality.
7. Acquire knowledge of communication at managerial level.
8. Apply the learnt skills of usage of modern tools for effective communication.

CONTENT	Total Hours
UNIT 1 : Role of Communication in business, Importance of communication skills in business .	8
UNIT 2 : Speeches, Group Discussions, Enhanced Role plays, Presentation Skills, Conduct	10
UNIT 3 : Preparation for Personal Interviews	12
UNIT 4 : Email Etiquettes	6
UNIT 5 : Personality Development – Practices and Exercises	8
UNIT 6 : Managerial communication	10
UNIT 7 : Modern tools for effective communication : Web-ex/VOIP/Dash box	6
Reference Books: <ul style="list-style-type: none"> ● Das &Rao : Communication skills ● Effective communication – Urmila Rai/S.M.Rai – Himalaya Publishing House 	

PASSING PERFORMANCE GRADING :

The Performance Grading of the learner shall be on ten point scale be adopted uniformly.

Letter Grades and Grade Point

Semester GPA/ Program CGPA Semester / Program	% of Marks	Alpha-Sign/Letter Grade Result	Grading Point
9.00 – 10.00	90.0 - 100	O (Outstanding)	10
8.00 - < 9.00	80.0 < 90.0	A+ (Excellent)	9
7.00 - < 8.00	70.0 < 80.0	A (Very Good)	8
6.00 - < 7.00	60.0 < 70.0	B+ (Good)	7
5.50 - < 6.00	55.0 < 60.0	B (Average)	6
5.00 - < 5.50	50.0 < 55.0	C (Pass)	5
Below 5.00	Below 50	F (Fail)	0
AB (Absent)		Absent	

NOTE : VC : Vocational Courses, SEC : Skill Enhancement Courses, AEC : Ability Enhancement Courses, VEC : Value Education Courses, VSC : Vocational Skill Course, IKS : Indian Knowledge System, OJT: On The Job Training, FP: Field Projects.

The performance grading shall be based on the aggregate performance of Internal Assessment and Semester End Examination.

The Semester Grade Point Average (SGPA) will be calculated in the following manner: $SGPA = \frac{\sum CG}{\sum C}$ for a semester, where C is Credit Point and G is Grade Point for the Course/ Subject.

The Cumulative Grade Point Average (CGPA) will be calculated in the following manner: $CGPA = \frac{\sum CG}{\sum C}$ for all semesters taken together.

PASSING STANDARD:

Passing 50% in each subject /Course separate Progressive Evaluation (PE)/Internal Evaluation and Semester-End/Final Evaluation (FE) examination.

- A. Carry forward of marks in case of learner who fails in the Internal Assessments and/ or Semester-end examination in one or more subjects (whichever component the learner has failed although passing is on total marks).
- B. A learner who PASSES in the Internal Examination but FAILS in the Semester-end Examination of the Course shall reappear for the Semester-End Examination of that Course. However, his/her marks of internal examinations shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.
- C. A learner who PASSES in the Semester-end Examination but FAILS in the Internal Assessment of the course shall reappear for the Internal Examination of that Course. However, his/her marks of Semester-End Examination shall be carried over and he/she shall be entitled for grade obtained by him/her on passing.

ALLOWED TO KEEP TERMS (ATKT)

- A. A learner shall be allowed to keep term for Semester II irrespective of the number of heads/courses of failure in the Semester I.
- B. A learner shall be allowed to keep term for Semester III wherever applicable if he/she passes each of Semester I and Semester II.

OR

- C. A learner shall be allowed to keep term for Semester III wherever applicable irrespective of the number of heads/courses of failure in the Semester I & Semester II.
- D. A learner shall be allowed to keep term for Semester IV wherever applicable if he/she passes each of Semester I, Semester II and Semester III.

OR

- E. A learner shall be allowed to keep term for Semester IV wherever applicable irrespective of number of heads/courses of failure in the Semester I, Semester II, and Semester III

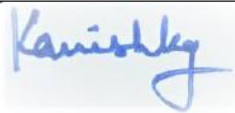



University of Mumbai's





Garware Institute of Career Education and Development

Board of Studies – Committee members

Post Graduate Diploma in Pharma Management (PGDPM)

Date & Time : 30th June 2023 at 3.30pm

Sr.	Name	Signature
1	Dr. Keyurkumar M. Nayak, Director, UM-GICED	
2	Mrs. Kanishka Goraksha Course Coordinator Garware Institute of Career Education & Development, University of Mumbai, Vidyanagari, Kalina, Santacruz(E), Mumbai - 400 098	
3	Mr. Neeraj Kumar Managing Director Hippocrat Biotech Pvt Ltd #4, D wing, New Rawal Nagar CHSG, Mira Road East, Thane 401107	
4	Mr. Ganesh Gharat Manager Intas Pharmaceuticals Limited (Biopharma Division) Plot no. 423/P/A, Sarkhej- Bavla Highway, Tal:Sanand, Ahmedabad 382213	
5	Mr.Rohit Thanage Senior Area Sales Manager Boehringer Ingelheim India ltd 202 and a part of unit 201 Godrej 2 Pirojsha Nagar Vikroli East Mumbai 400079	
6	Mr.Hitendra Bhatia Senior Manager - Regulatory Affairs Genpact India Private Limited (RTP Sakinaka, Andheri East, Mumbai - 400072, Maharashtra, India)	<div>Hitendra Bhatia</div> <div>Digitally signed by Hitendra Bhatia Date: 2023.07.02 19:03:02 +05'30'</div>

7	<p>Prof. Sonali Manwatkar</p> <p>Assistant Professor</p> <p>Vishwakarma University, School of Pharmacy, Survey No. 2,3,4 Laxmi Nagar, Kondhwa Budruk, Pune - 411048, Maharashtra, India.</p>	
8	<p>Prof Jolly Parikh</p> <p>Professor and I/c Principal</p> <p>A R College of Pharmacy & G H Patel institute of Pharmacy, PO box 19, Vallabhvidyanagar 388120 Anand, Gujarat.</p>	
9	<p>Ms.Madhura Rane</p> <p>Assistant Manager- Regulatory Affairs</p> <p>Glenmark Pharmaceuticals, Andheri, Mumbai</p>	
10	<p>Ms. Nikita Chandure</p> <p>Clinical Data Manager</p> <p>Novartis</p> <p>Inspire BKC,G block 6&7 floor main road, Bandra Kurla Complex, Bandra East, Mumbai.</p>	

Keyurkumar M. Nayak

Dr. Keyurkumar M. Nayak,
Director,
UM-GICED



Prof.(Dr.) Anil Kumar Singh
Dean,
Faculty of Interdisciplinary Studies

Justification for (P.G Diploma in Pharma Management)

1.	Necessity for starting the course	The University of Mumbai's Garware Institute of Career Education & Development plans to introduce One year full time P.G Diploma in Pharma Management. The Pharma Management course aims to develop students, by rigorous training and academics for positions in Product Management Department, Pharma Sales Department, Quality assurance and Quality Control Department, Regulatory Affairs Department, Medical services Department in Pharmaceutical Companies, CRO.
2.	Whether the UGC has recommended the course:	Yes, UGC has recommended the course as per gazette no. DL(N)-04/0007/2003-05 dated 11th July 2014. UGC encourages the incorporation of skill oriented and value-added courses to develop skilled manpower.
3.	Whether all the courses have commenced from the academic year 2023-2024	Yes, it would be commencing from the Academic year 2023-24 as per NEP 2020. However, the course was launched in the year 2006.
4.	The courses started by the University are self-financed, whether adequate number of eligible permanent faculties are available?	Yes, this course is self-financed. The expert visiting faculty from industries come to teach this course.
5.	To give details regarding the duration of the Course and is it possible to compress the course?	The duration of the course is One year (Two Semester). It cannot be further compressed.
6.	The intake capacity of each course and no. of admissions given in the current academic year:	The intake capacity of this course is 60 students. The admission procedure is still ongoing.
7.	Opportunities of Employability/ Employment available after undertaking these courses:	Opportunities for positions in Product Management Department, Pharma Sales Department, Quality assurance and Quality Control Department, Regulatory Affairs Department, Medical services Department in Pharmaceutical Companies, CRO. .



Dr. Keyurkumar M. Nayak,
Director,
UM-GICED



Prof.(Dr.) Anil Kumar Singh
Dean,
Faculty of Interdisciplinary Studies