VEER MADHO SINGH BHANDARI UTTARAKHAND TECHNICALUNIVERSITY
(Formerly Uttarakhand Technical University, Dehradun Established by Uttarakhand State Govt. wide Act no. 415 of 2005)
Suddhowala, PO-Chandanwadi, Premnagar, Dehradun, Uttarakhand (Website- www.uktech.ac.in)

SYLLABUS

For

PHARMACY

VALUE ADDED COURSES (NON CREDIT)

Effective from – Session 2022-23

GOALS OF VALUE ADDED COURSES (VACs) OR NON-CREDIT COURSES

University has started **Value Added Courses (VACs)** or **non-credit courses** to help students gain extra knowledge and practical skills beyond their main syllabus. These courses usually do not carry academic credits, but they improve students' overall development and employability.

Students can take following advantages:

1. **Skill Development**
   VACs help students learn practical skills like communication, computer applications, personality development, soft skills, entrepreneurship, digital tools, etc.
2. **Industry Readiness**
   Universities want students to become job-ready by learning current industry requirements that may not be covered in regular subjects.
3. **Holistic Development**
   These courses improve confidence, leadership, teamwork, ethics, creativity, and problem-solving abilities.
4. **Keeping Up with New Trends**
   New technologies and professional demands change quickly. VACs help students learn updated topics such as AI, data analysis, cyber security, environmental awareness, and innovation.
5. **Improving Employability**
   Additional certifications and skills make students more attractive to employers during placements and interviews.
6. **Bridging Knowledge Gaps**
   Some students may need extra support in language, technical knowledge, or professional behavior. VACs help fill these gaps.
7. **Encouraging Lifelong Learning**
   Universities promote continuous learning habits beyond regular classroom education.
8. **NAAC/NEP and Academic Quality Requirements**
   Under policies like the National Education Policy 2020 and accreditation systems such as National Assessment and Accreditation Council, universities are encouraged to provide multidisciplinary and skill-based learning opportunities.

INDEX

Syllabus

(1)

B. Pharma **Pharmaceutical Management (PVAC 101)**

Ist Sem 45 Hrs

Unit-01 Conceptual frame work

- Concept need and process in entrepreneurship development.
- Role of enterprise in national and global economy
- Types of enterprise – Merits and Demerits

Unit-2 The entrepreneur

- Entrepreneurial competency – Concepts.
- Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, achievement, factors affecting entrepreneur'' role.

Unit-03 Launching and organizing an enterprise

- Environment scanning – Information, sources, schemes of assistance, problems.
- Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis.
- Resource mobilisation - finance, technology, raw material, site and manpower.
- Costing and marketing management and quality control.

Unit-04 Growth strategies and networking

- Performance appraisal and assessment
- Profitability and control measures, demands and challenges
- Need for diversification
- Future Growth – Techniques of expansion and diversification, vision strategies

Unit-04 Preparing project proposal to start on new enterprise

Project work – Feasibility report; Planning, resource mobilization and implementation.

Book Recommended:

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C.(1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

IInd Sem: (**PVAC-201**) **1.** Industrial & Laboratory Based Training / Learning Process

Dr. Yusra Ahmad

17/08/22

Dr. Likramsingh

27/08/22

2. Submission of Project and Project Viva Voce. 10 Hrs/week
Submission of Project Report on Training Based.

(2)

B.Pharma

Pharmaceutical Quality Control (PVAC-102)

Ist Sem 45 Hrs

Unit -01 Quality Control & Quality Assurance General Concepts: Basis concepts of Quality- Developing quality culture. Definition of quality assurance concept and components of Q. A., Good Manufacturing Practices, Quality control .

Unit-02Personnel, Premises and Equipment's: Training responsibilities and hygiene of personnel. Drainage system, Sewage, Sanitation, Lighting, maintenance of building and premises; Design, size, location, construction, cleaning and maintenance of equipment's.

Unit-03Material Management: Purchasing, Raw material, packaging materials, Intermediate and Bulks products, Finished products, Rejected and recovered materials, recalled products, returned gods, Reagents and culture media, Waste materials, reference standards, Miscellaneous material.

Unit-04 Manufacturing operations and control: Revised schedule M, sanitation of manufacturing premises, Mix –ups and cross contamination, processing of intermediates and Bulk product, Packaging operations, I.P.Q.C., Release of finished products process deviations, Drug product inspection, expiration dating, Document and formats.

Unit-05 Documents and Records, Quality control of Biological products and Sterile Pharmaceutical Products International Biological standards, safety testing of pharmaceutical Quality control of antibiotics. GMP aspects related to sterile products-General guidelines, personnel, building and premises, equipment, sanitation, processing, sterilization, Quality control and validation.

Recommended Books:

1. Pharmaceutical Quality Assurance, MA Potdar, Nirali Prakashan, Pune
2. Validation of Pharmaceutical process, F. J. Carleton and J. Agalloco, Marcel Dekker Inc.
3. Pharmaceutical Process Validation, Second Ed., Ira R. Ferry & Robert Nash., Marcel Dekker Inc.
4. Quality Planning & Analysis by J. M. Juran and F. M. Gryna, Tata Mcgraw Hill, India.
5. Improving Quality through Planned experimentation by Moen, Tata Mcgraw Hill.
6. Good Manufacturing Practices for Pharmaceutical; A Plan for total Quality Control, 4 th Ed, Sidney willing.
7. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
8. Pharmaceutical Process Validation; By F. R., Berory and Robert A. Nash
9. Impurities Evaluation of Pharmaceutical; Satinder Ahiya Marcel Decker.
10. Quality Control of Packaging material in the Pharmaceutical Industry: Kenneth Harburn, Marcel Dekker.
11. Juran's Quality Control Handbook J.M. Jupron.4th Ed. Good design practices for GMP Pharmaceutical facilities. Andrew A Signature, Marcel Dekker.
12. cGMP for Pharmaceuticals. Pharma. Med. Press, I st edition by Manohar H. Potdar

IInd Sem: **(PVAC-201)** **1.** Industrial & Laboratory Based Training / Learning Process

3. Submission of Project and Project Viva Voce. 10 Hrs/week

B. Pharma **Drug Regulatory Affairs (PVAC-103)** (9)

Ist Sem 45 Hrs

Unit-01Drug Regulatory Affairs: Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.

Unit-02 GMP of Pharmaceuticals: Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, container and closures, production and process, packaging and labeling, laboratory and control of records and reports.

Unit-03 Intellectual property: Concepts and fundamentals of Intellectual property protection (IPP) and Intellectual property Rights (IPR), Economic importance, important mechanism for protection of Intellectual property. Patents, Industrial and layout designs, Drug related controversies –case studies, traditional knowledge, life forms and crops, current global strategies and solutions.

Unit-04 Quality Control: Basic concepts of Quality control, Total Quality Management, Philosophy of GMP, cGMP, GLP, ISO. Introduction of ICH guidelines

Unit-05 Quality Assurance: Concept of quality assurance, Sources of variation, General Validation Process.

Recommended books:

1. Pharmaceutical product development 2006, edited by N.K. Jain, CBS publishers and distributors. New Delhi, and references there in.
2. Good manufacturing practices for pharmaceuticals: A plan for total quality control from manufacturer to customer, Vth edition, revised and expanded by Sidney H. Willig, Marcel and Dekker.
3. http://www.patentinoffice.nic.in
4. http://www.patentmatics.com
5. http://www.iprlawindia.org
6. http://www.indianpatent.org.in
7. http://www.wipo.int
8. Intellectual Property: Patents, trademarks, and Copyright (Nutshell Series) by Arthur R. Miller and Michael H. Davis.
9. Protection of Industrial Property Rights, P. Das and Gokul Das.
10. Law and Drugs, law publ. SN Katju.
11. Original laws published by Govt. of India.
12. Laws of drugs in India, Hussain.
13. New Drug Approval Process, R.A. Guarino, Vol 100, Marcel Dekker, NY.

14. Fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org.
15. M. Potdar, Pharmaceutical Facilities: Design, Layouts & Validation 2nd edn, Pharmamed Press

IInd Sem: **(PVAC-203)** **1.** Industrial & Laboratory Based Training / Learning Process
2. Submission of Project and Project Viva Voce. 10 Hrs/week

SYLLABUS FOR ADD ON COURSES

Semester	3rd		
Program	Pharmacy		
Course Code	**AD 301**	Credit	**NC**
Subject	**BASIC COMPUTER SKILLS**	Duration	**36 Hours**

Objectives of the Course:

The course is designed to aim at imparting a basic level appreciation programme for the Common man. After completing the course the incumbent is able to the use the computer for basic purposes of preparing his personnel/business letters, viewing information on Internet (the Web), sending mails, using internet banking services etc.

Module-I (Total Hours-8)

Understanding Word Processing: Word Processing Basics; Opening and Closing of documents; Text creation and Manipulation; Formatting of text; Table handling; Spell check, language setting and thesaurus; Printing of word document.

Module-II (Total Hours-6)

Using Spread Sheet: Basics of Spreadsheet; Manipulation of cells; Formulas and Functions; Editing of Spread Sheet, printing of Spread Sheet.

Module-III (Total Hours-8)

Making Small Presentation: Basics of presentation software; Creating Presentation; Preparation and Presentation of Slides; Slide Show; Taking printouts of presentation / handouts.

Module-IV (Total Hours-8)

Communications and collaboration: Basics of electronic mail; Getting an email account; Sending and receiving emails; Accessing sent emails; Using Emails; Document collaboration; Instant Messaging; Netiquettes.

Course Outcomes (COs):

AD 301-CO1: Demonstrate a basic understanding of computer
AD301-CO2: Utilize web technologies.
AD 301-CO3: Demonstrate basic understanding of network principles
AD 301-CO4: Apply the skills that are the focus of this program to business scenarios.

References:

1. Computer Fundamentals, 1st Edition, 2017, RS Salaria, Khanna Publishing House
2. Fundamentals of Computers, 6th Edition, V. Rajaraman, NeeharikaAdabala, PHI Learning Private Ltd.
3. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002

Semester	4th

Program	Pharmacy		
Course Code	**AD 401**	Credit	**NC**
Subject	**HUMAN VALUES AND PROFESSIONAL ETHICS**	Duration	**36 Hours**

Objectives of the Course:

Promotion of Ethics and **Human Values** are as under :
To create awareness, conviction & commitment to **values** for improving the quality of life through education, and for advancing social and **human** well being.

Module-I (Total Hours-6)

Introduction –Need, Basic Guidelines and Content

Understanding the need, basic guidelines, content and process for value Education
Self Exploration – What is it? – its content and process: 'Natural Acceptance' and Experiential Validation – as the mechanism for self explanation
Continuous Happiness and Prosperity – A look at basic Human Aspirations

Module-II (Total Hours-6)

Process for Value Education

Right Understanding, Relationship and Physical Facilities – basic requirements for fulfillment of aspirations of every human being with their correct priority
Understanding Happiness and prosperity correctly – A critical appraisal of the current scenario
Method to fulfill the above human aspirations; understanding and living in harmony at various levels

Module-III (Total Hours-8)

Understanding Harmony in the Human Being
Understanding human being as a co-existence of the sentient 'I' and the material 'Body'
Understanding the needs of Self ('I') and 'Body' – Sukh and Suvidha
Understanding the Body as an instrument of 'I' (I being the doer, seer and enjoyer)

Module-IV (Total Hours-8)

Harmony in Myself
Understanding the characteristics and activities of 'I' and harmony in 'I'
Understanding the harmony of I with the Body: Sanyam and Swasthya: correct appraisal of Physical needs, meaning of Prosperity in detail
Programs to ensure Sanyam and Swasthya – practice exercises and Case Studies will be taken up in Practice Sessions

Module-V (Total Hours-8)

Understanding Harmony in the Family and Society – harmony in Human - Human Relationship
Understanding harmony in the family – the basic unit of human interaction
Understanding values in human relationship; meaning of Nyaya and Program for its fulfillment to ensure Ubhay-tripti Trust (Vishwas) and Respect (Samman) as the foundational values of relationship.

Course Outcomes (COs):

AD401-CO1: Understand the need , basic guidelines, content and process for value Education
AD401-CO2: Identify Happiness and prosperity correctly, Method to fulfill the above human aspirations.
AD 401-CO3: Assess the human being as a co-existence of the sentient 'I' and the material Body'.
AD-401-CO4: Evaluate the characteristics and activities of 'I' and harmony in 'I'.

Reference:

1. Professional Ethics and Human Values-2013, Govindarajan M, PHI Learning Private Ltd.
2. A Foundation Course in Human Values and Professional Ethics-2010, Gaur R.R., Sangal R., Rupa Publication , India

Semester	5th		
Program	Pharmacy		
Course Code	AD501	Credit	**NC**
Subject	**Hands on training on Analytical Instruments**	Duration	**36 Hours**

Objectives of the Course:

At the end of the course, students should be able to apply their knowledge of the theoretical underpinnings and practical applications of contemporary instruments used in chemical analysis to the analysis of actual samples.

Course contents/Curriculum (Total Hours-6 for each Instrument)

1. Overview of Instrumental Analysis and Measurements

Introduction, theory, principle, instrumentation concepts, applications, and calibration and validation of instruments (any six out of the following);

a. UV-Visible spectrophotometer
b. Nephelometer
c. Flame Photometer
d. Conductometer
e. Potentiometer
f. Polarimeter
g. Refractometer
h. High Performance Liquid Chromatography
i. pH meter
j. Brookfield viscometer
k. Dissolution apparatus

Course Outcomes (COs):

AD501 **CO1:** Describe the various types of instrumental techniques used in chemistry.
AD501 **CO2:** Understand the theoretical basis of instruments.
AD501 **CO3:** Identify the components and uses of various parts of instruments.
AD501 **CO4:** Understand the calibration of various analytical instruments.
AD501 **CO5:** To evaluate and statistically analyse the data gathered using various instrumental techniques.
AD501**CO6:** Interpret the results of the chemical analysis.

References:

1.Instrumental Methods of Chemical Analysis by B.K Sharma
2.Organic spectroscopy by William Kemp
3.Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
4. Spectrophotometric identification of Organic Compounds by Silverstein
5. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
6. Martiń's Physical Pharmacy and Pharmaceutical Sciences
7. Fundamentals of analytical chemistry by Skoog, Douglas A.; West, Donald M.
8. Modern analytical chemistry by Harvey D.

Semester	6th		
Program	Pharmacy		
Course Code	**AD601**	**Credit**	**NC**
Course Name	**LEADERSHIP SKILLS**	**Duration**	**36 Hours**

Objectives of the Course:

1. Students to develop essential skills to influence and motivate others
2. Inculcate emotional and social intelligence and integrative thinking for effective leadership
3. Create and maintain an effective and motivated team to work for the society
4. Nurture a creative and entrepreneurial mindset

Module I (Total Hours-06)

Understanding Leadership: Defining Leadership; Global Leadership Attributes; Practicing Leadership.

Module II (Total Hours-06)

Recognizing Your Traits: Historical Leaders; What Traits Do These Leaders Display? Leadership Studies: What Traits Do Effective Leaders Exhibit.

Module III (Total Hours-06)

Engaging People's Strength: Explore how strengths can make one a better leader. Understand the concept of strength; Describe the historical background of strengths based leadership. Examine how to identify strengths; Review measures used to assess strengths; Examine strengths based leadership in practice.

Module IV (Total Hours-06)

Philosophy and Styles: Leadership Explained Theory X and Theory Y; Leadership Styles Explained; Leadership Styles in Practice

Module V (Total Hours-06)

Attending to Tasks and Relationships: Task and Relationship Styles Explained; Task and Relationship Styles in Practice.

Module VI (Total Hours-06)

Developing Leadership Skill: Understanding administrative skills and their use in practice. Understanding interpersonal skills and their use in practice. Understanding conceptual skills and their use in practice.

Course Outcomes (COs):

AD601 CO1: Build a strong foundation to grow managerial career.

AD601 CO2:Acquire core Leadership Competencies

AD601 CO3: Develop essential skills to influence and motivate others.

AD601 CO4: Ability to create and maintain an effective and motivated team to work for society.

Reference:

1. Leadership And Team Building (2010), Uday Kumar Haldar, Oxford University Press
2. Leadership and Management Development, Dalton Kevin, Pearson.

Review and Reconfirmation all the syllabus, examination scheme, rules and regulations framed by the BOS (Pharmacy) for B.Pharm, M.Pharm, Pharm –D and Pharm-D (PB) on 13.12.2022.

B. Pharma 7th sem

Annexure-01

(10)

Course Title: Scientific Writing and AI Tools

Duration: 30 hours
Level: Undergraduate
Mode: Offline

Course Objectives

1. **To familiarize students with the standard structure and components of research papers and academic writing.**
2. **To develop the ability to write scientifically with clarity, coherence, and precision.**
3. **To train students in using AI-powered tools for grammar checking, summarization, referencing, and literature review.**
4. **To enhance research productivity by integrating AI tools in the academic workflow.**
5. **To introduce ethical practices in research writing and scientific publishing.**

Course Outcomes

By the end of this course, students will be able to:

CO1: Write well-structured and grammatically correct scientific documents, including research papers, abstracts, and reports.

CO2: Apply the correct format and style in writing different components of a research paper (e.g., abstract, introduction, methodology).

CO3: Use AI tools effectively for grammar enhancement, paraphrasing, citation management, and content generation.

CO4: Integrate AI tools into the research workflow to improve efficiency in literature review, writing, and publishing.

CO5: Demonstrate awareness of ethical standards in research writing, including plagiarism prevention and proper attribution.

12/9/25

(11)

Syllabus

Module 1: Foundations of Scientific Writing (6 hours)

- Importance and types of scientific writing(Reviews, Original research, Books, monographs)
- Structure of a scientific paper (IMRaD format)
- Writing styles: formal, concise, and objective writing
- Common grammar and style issues in scientific writing

Module 2: Writing Components of Scientific Articles (8 hours)

- Title, Authors information, Abstract, and Keywords
- Introduction and Literature Review
- Materials and Methods
- Results and Discussion
- Future perspectives
- Conclusion and References
- Graphical Abstracts and Figures

Module 3: Publishing Process and Ethics (4 hours)

- Choosing the right journal (Impact Factor, indexing, SCI, SCOPUS, Google Scholar,)
- Peer review process
- Plagiarism software (Turnitin, orkund, etc)
- Ethical guidelines in research and publishing (COPE, ICMJE)

Module 4: Introduction to AI Tools for Writing (10 hours)

- AI tools for grammar and style checking: Grammarly, Hemingway, ProWritingAid
- Tools for paraphrasing and rephrasing: Quillbot, Wordtune
- AI-based summarizers and translators
- Referencing tools: Zotero, Mendeley, EndNote
- Literature search with AI: Semantic Scholar, Research Rabbit, Elicit

Module 5: Advanced AI Tools in Research Workflow (8 hours)

- Using ChatGPT, Scite, and Elicit for literature review

9/9/25

- AI for generating hypotheses and research questions
- Language models for generating abstracts and research summaries
- Using AI in data visualization and presentation
- Risks and limitations of AI in scientific writing
- Legal aspects

Assessment

- **Assignments**
- **Mini-project (write a mock paper)**
- **Final Test / Presentation**

Suggested Readings & Resources

- Day, R. A., & Gastel, B. (2012). *How to Write and Publish a Scientific Paper*
- Glasman-Deal, H. (2010). *Science Research Writing for Non-Native Speakers of English*
- Online tools: Grammarly, ChatGPT, Mendeley, Quillbot, Scite.ai

12/9/25

(M.Pharma value Added Course) Annexure – III
Non credit

(B)

Course Title: Safety Management in Pharmaceutical Industry

Course Description:

This value-added course in Safety Management in the Pharmaceutical Industry is designed for Master of Pharmacy students to gain essential knowledge and skills to ensure a safe and compliant working environment in pharmaceutical manufacturing, research, and distribution settings. The course will cover various aspects of safety, risk assessment, and regulatory compliance specific to the pharmaceutical industry.

Course Outcomes:

1. Understand the Regulatory Framework and Standards for Safety in Pharmaceutical Industry

Upon completion of the course, students will be able to:

Explain the key regulations and guidelines governing safety practices in the pharmaceutical industry, such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Distribution Practices (GDP).

Describe the role of regulatory bodies (e.g., FDA, EMA) in ensuring safety compliance and the consequences of non-compliance.

Analyze how adherence to safety standards contributes to product quality, patient safety, and overall risk management in pharmaceutical operations.

2. Identify and Assess Safety Hazards in Pharmaceutical Operations

Upon completion of the course, students will be able to:

Identify potential safety hazards and risks in various pharmaceutical manufacturing, testing, and distribution stages.

Conduct comprehensive safety assessments, including hazard identification, risk analysis, and risk evaluation.

Apply appropriate risk mitigation strategies and control measures to minimize or eliminate safety hazards in pharmaceutical facilities.

3. Implement Effective Safety Management Systems and Practices

Upon completion of the course, students will be able to:

Design and implement safety management systems that align with industry best practices and regulatory requirements.

Develop safety protocols, procedures, and standard operating procedures (SOPs) for different aspects of pharmaceutical operations.

Establish protocols for incident reporting, investigation, and corrective action to enhance safety performance and prevent recurrence of safety incidents.

4. Promote Safety Culture and Employee Engagement in the Pharmaceutical Workplace

Upon completion of the course, students will be able to:

29/7/2023
Dr. Sanjay Singh

Lalit Bisht 29/07/23

29/07

Understand the importance of fostering a safety-first culture within the pharmaceutical industry.

Identify strategies for promoting safety awareness and engagement among employees at all levels of the organization.

Demonstrate effective communication and training methods to educate employees about safety protocols and practices.

Recognize the significance of safety leadership and the role of management in driving continuous improvement in safety performance.

Syllabus:

Unit 1: Introduction to Safety Management in Pharmaceutical Industry **12 Hours**

1. Introduction to Pharmaceutical Safety:

- Overview of pharmaceutical industry operations and safety concerns
- Importance of safety management in pharmaceutical manufacturing, R&D, and distribution

2. Regulatory Framework:

- Understanding national and international safety regulations and guidelines (e.g., FDA, EMA, WHO)
- Compliance requirements and consequences for non-compliance

3. Hazard Identification and Risk Assessment:

- Principles of hazard identification and risk assessment in pharmaceutical settings
- Risk analysis techniques and safety control measures
- Case studies on previous safety incidents in the pharmaceutical industry

Unit 2: Safety Practices in Pharmaceutical Manufacturing **12 Hours**

1. Good Manufacturing Practices (GMP):

- Overview of GMP and its role in ensuring safety and quality in pharmaceutical manufacturing
- GMP guidelines for facilities, equipment, personnel, and processes
- GMP audits and inspections

2. Occupational Health and Safety (OHS) in Pharma Industry:

- Identifying workplace hazards and risk management in pharmaceutical manufacturing
- Personal protective equipment (PPE) requirements and usage
- Ergonomics and employee well-being

3. Process Safety Management:

- Understanding process safety hazards and preventive measures

- Process safety planning, emergency response, and incident investigation
- Implementing process safety management systems

Unit 3: Pharmaceutical Supply Chain Safety **12 Hours**

1. Warehouse and Distribution Safety:
   - Best practices for safe storage and handling of pharmaceutical products
   - Transportation safety and cold chain management
   - Quality assurance in the supply chain
2. Drug Safety and Pharmacovigilance:
   - Introduction to pharmacovigilance and its role in monitoring drug safety
   - Adverse drug reaction reporting and signal detection
   - Risk-benefit assessment and risk communication
3. Environmental Health and Safety (EHS) in Pharma Industry:
   - Identifying environmental hazards associated with pharmaceutical manufacturing
   - Sustainable practices and waste management in the pharmaceutical industry
   - Compliance with environmental regulations

Assessment and Evaluation:

- Quizzes and Assignments: Regular assessments to gauge understanding of concepts.
- Case Studies: Analyzing real-life safety incidents in the pharmaceutical industry.
- Group Projects: Collaborative projects on risk assessment and safety improvement.
- Final Examination: Comprehensive exam covering all course topics.

29/7/2023 29/07/23 29/07

M. Pharma 2nd Sem

Annexure-03

(16)

VAC in Entrepreneurship Pharmaceutical Industries 5.0

Course Objectives:

1. To understand the pharmaceutical industry landscape, from R\&D to manufacturing to market.
2. To equip students with skills needed to launch, manage, and scale a pharmaceutical venture.
3. To understand regulatory, financial, marketing, ethical, and operational aspects of pharmaceutical entrepreneurship.
4. To develop business thinking applied to drug development, nutraceuticals, herbal medicines, etc.

Course Outcome:

CO-1 Students will be able to map the industry ecosystem and spot opportunity gaps. CO-2 Students will be able to understand technical development process; identify cost/time burdens; recognize what is feasible for start-ups

CO-3 students will be able to learn what approvals are needed, how to comply with and how to protect innovations.

CO-4 Students will be able to prepare a business plan, estimate costs/revenues and assess risk.

CO-5 Students will understand how to position a product, access customers, comply with marketing laws.

Duration: The course will be spread in 4–6 weeks divided into 30 hours duration with following breakup:

Theory + Workshop + Project and Industrial visit.

Syllabus Outline

Module 1: Introduction to Pharmaceutical Entrepreneurship 5 Hr

• Overview of pharmaceutical, biotech, herbal, and nutraceutical industries

• Key players: startups, SMEs, big pharma.

• Trends, opportunities & challenges (India & global)

• Case studies of successful pharma entrepreneurship

Module 2: R&D, Drug Discovery & Development 5Hr

• Drug discovery stages: target selection, screening, lead optimization, preclinical and clinical studies.

• Preformulation and formulation basics

• Stability, bioavailability, drug delivery systems.

Module 3: Regulatory Affairs, Quality, & Compliance 5Hr

• Regulatory landscape in India (CDSCO, AYUSH, etc.) and global norms (FDA, EMA)

• GMP, GLP, GCP standards

Intellectual Property Rights (IPR), patents, data protection

• Ethical issues, safety, pharmacovigilance.

Module 4: Industrial layout & support systems 5Hr

• Pharmaceutical Industry (contract manufacturing, franchises, proprietary brands, services)

• Financial fundamentals: costing, budgeting, capital raising, investor pitching

• Feasibility studies and SWOT Analysis.

• Funding sources: loans, venture capital, government schemes, angel investors, Devbhoomi Udymita yojona

Module 5: Marketing, Branding & Market Access 5Hr.

• Pharma marketing: regulatory restrictions, ethical marketing, brand vs generic

• Pricing strategies, market segmentation, distribution channels

• Digital marketing in pharma, social media ethics, tele-pharmacy

• Market access & reimbursement

Module 6: Operations, Supply Chain & Manufacturing 5Hr

• Basics of pharmaceutical manufacturing: solid, liquid, semi-solid dose forms

• Equipment, plant layout, scale up, pilot vs full scale production

• Supply chain, procurement, inventory, cold chain

• Quality control, packaging, labelling, Automation & logistics |

Assessment / Evaluation

Assignments / Quizzes on key topics (e.g. regulatory, R\&D, quality)

Industrial Field Visit & report, its Presentation

References

https://www.sciencedirect.com/science/article/pii/S294975312400050X

https://www.sciencedirect.com/science/article/pii/S2213846324002098

Pharm.D 4th year

Annexure-02

18

Pharmacoeconomics and Public Health Outcomes Research – Continued Survey

Course Objective:

→ Patient assessment

→ Therapeutic planning

→ Medication therapy management

→ Patient counselling

→ Ethical practice

Course Outcomes: The Student will be able to understand and practice:

→ Disease state management

→ Clinical calculation & compounding

→ Effective communication

→ Interprofessional collaboration

→ Professionalism

Themes of the survey: Any one of them.

a → Malnutrition

b → Anemia

c → Women's Health

d → Mental Health

e → Pharmacoeconomics

f → Health Technology Assessment

g→ Case Studies & Research Paper Review

h → Budget Impact Analysis

i→ Health Outcomes Research Design