Value Added Courses (VAC)

Chitkara College of Pharmacy,

Chitkara University, Punjab

List of VAC Courses:

S. No.	Value Added Course
1.	English Proficiency and Vocal Skill Course by ESL
2.	National Pharmacy Week-2023
3.	Academic and Professional Orientation Course
4.	Pharma Market and Brand Competency Course
5.	Certificate Course on Nano Drug Delivery System
6.	Tools and Techniques of Analytical Instrumentation
7.	Certificate course on Quality by Design in Pharmaceutical Product Development QbD
8.	Professional Certificate Course on Drug Regulatory Affairs
9.	Pharmacovigilance Professional
10.	Clinical Trial Management
11.	Certificate Course on Medical Writing

Value Added Courses

Course Name: ENGLISH PROFICIENCY AND VOCAB SKILL COURSE
Chitkara College of Pharmacy,
Chitkara University, Punjab

DURATION:	36 hours
CLASS:	B. Pharmacy/Pharm D/ M. Pharmacy 1st Year

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives: Upon completion of the course the student shall be able to understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation; communicate effectively (Verbal and Non Verbal); effectively manage the team as a team player; develop interview skills; develop Leadership qualities and essentials.

THE COURSE COVERAGE:

1. Introduction & Orientation
2. Leaderless Group Activities: Activities conducted for the student to introduce themselves, break the ice and encourage participation & involvement.
3. Discussion on Importance of Presentation in Today's Era
4. Dynamics of Communication: The basic process of communication, Means of communication – Word, gestures, pictures, body language, etc. Hindrances to communication – Dealing with assumptions, Barriers in Communication – Understanding and dealing with it.
5. Self-Awareness of students in terms of difficulties faced during presentations (Group discussion, role play)

Course content:

Communication Skills: Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context

Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers

Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

Elements of Communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication

Communication Styles: Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

Basic Listening Skills: Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations

Effective Written Communication: Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication

Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

Interview Skills: Purpose of an interview, Do's and Dont's of an interview

Giving Presentations: Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

Group Discussion: Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

List of teaching aids: Laptop and Projector, White Board, Worksheets

CHITKARA UNIVERSITY

VALUE ADDED COURSES

Course Name: NATIONAL PHARMACY WEEK COURSE
Chitkara College of Pharmacy,
Chitkara University, Punjab

DURATION:	40 hours
CLASS:	B. Pharma/Pharm D/ Pharm D (PB)/ M. Pharmacy (Final Year)

Scope: The major focus of NPW course is to create awareness amongst the Students regarding their Professional responsibilities, & sensitize other healthcare providers and the authorities, about the NPW theme in specific and about the pharmacy profession and role of the pharmacist in general. To develop professional skills in the areas of Drug Discovery Pharma Technology, Industrial Practices, and common pharmaceutical marketing practices. Therefore, it helps the students to create, ideate and implement novel ideas and understand their responsibilities for Qualitative Services.

Objectives: Upon completion of the course the student shall be able to develop novel idea generation capacity in new drug development, operations problem solving and ethics in drug therapy management services, as modern Medicines are like double edged swords-of great benefit if used correctly, but can cause harm if used incorrectly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards. This educational course provided by pharmacists enables the students to give patients the information they need to achieve positive health outcomes.

THE COURSE COVERAGE:

1. Competitive activities like expression on the theme
2. Quiz competition
3. Pharma games
4. Poster competition on theme
5. Product leaflet design
6. Pharma product literature review competition
7. Models portraying various aspects of pharmacy and health care issues
8. Seminar and guest lectures
9. Technical activity in Drug Discovery perspective, treatment algorithms, Industrial technology, Panel discussion on current issue in pharmaceutical sciences.

Course Content: By Sessions/Competitions/Model design/Reviews/QUIZES

1. Understand Your Professional Duties - Components of Insight in Roles in Pharmacy & Industry
2. History of pharmacy and advancements in technology
3. Quiz competition based on currents products available in markets

4. Rational use and Impact of product leaflet design by pharma product management team (PMT)
5. Case Studies and various pharmaceutical marketing plans.
6. Poster presentation on any Latest medical device technology, new drug development, any noval formulation or patents.
7. Pharmaceutical Distributors: Understanding Our Role in the Supply Chain

Books Recommended:

1. Lachman, leon and H.A. Lieberman, The theory and practices of industrial pharmacy, 3rd edition, Varghese publishing Co.
2. Gilberts S. Banker and C.T. Rhodes, Modern Pharmaceutics Marcel Decker.
3. Brody, A.L. and Marsh, K.S., Encyclopedia of packaging Technology, John Wiley and sons, New York.

Value Added Courses

Course Name: ACADEMIC AND PROFESSIONAL ORIENTATION COURSE (APOC)
Chitkara College of Pharmacy,
Chitkara University, Punjab

DURATION:	36 hours
CLASS:	B. Pharma/Pharm D/ Pharm D (PB)/ M. Pharmacy (First Year)

Scope: The major focus of APOC is to know about the Pharma Science & Industry working background. Pharmacists/Pharma Scientists/Technologists/Regulatory Officers/Pharma Practitioners play a critical role in the health care process by ensuring that their patientsare offered qualitative Pharmaceutical products and the best services, and impact of the pharmacist in the patient care process in multifold. This course explains the role a pharmacist can have in patient care, research and development, academia as well as industrial setups and connects the Pharma academic curriculum and how it will be carried out in next 4 or 2 yrs of education. It stimulates the students to incorporate many professional/life and interpersonal skills during education, to explores their potential by involving the various settings in which pharmacists work; and examines what training is necessary for success in the pharmacy field.

Objectives: Upon completion of this course, students will be able to:

- ✓ Discuss the role of the pharmacist and duties
- ✓ Describe pharmacy career opportunities and settings where pharmacists/Researchers/Technologists/Analysts/Clinical Officers work
- ✓ List several drug-related health Drug Discovery/Development/care issues important to the profession of pharmacy
- ✓ Describe the pharmacy educational process from admissions to advanced training
- ✓ Discuss pharmacists' entrepreneurial role.

THE COURSE COVERAGE:

The institutes undertake orientation program to provide information to students regarding different examinations, pharmacy subjects that are included during their four-year curriculum, and various scholarships offered to them, but fails in explaining the various avenues available for them after the successful completion of the course. Moreover, the students are not made aware of how significant their role in the healthcare system in this global era is and fails to impart the sense of pride, honor, dignity and respect of becoming professional Pharmacist.

Course Content

Introduction to Pharma Industry
Introduction to curriculum
Industry talk
Clinical Expert talk
Professional skill session
Balancing work life-Yoga and meditation

Creative sports

Technical Sessions:

Patient Care and the Role of the Pharmacist
Drug Costs, Drug Pricing, and Prescription Insurance
Pharmacy Practice Settings
Pharmacist Training and Licensure
Post-Graduate Opportunities

Books Recommended:

1. Lachman, leon and H.A. Lieberman, The theory and practices of industrial pharmacy, 3rd edition, Varghese publishing Co.
2. Stuart Anderson, Making Medicines: A Brief History of Pharmacy and Pharmaceuticals, 1st edition, Pharmaceutical Press, 2005.

Value Added Courses

Course Name: PHARMA BRAND AND MARKET COMPETENCY COURSE
Chitkara College of Pharmacy,
Chitkara University, Punjab

DURATION:	30 hours
CLASS:	B. Pharma/Pharm D/ Pharm D (PB)/ M. Pharmacy (Final Year)

Scope: The course will provide practical training on common pharmaceutical marketing practices. Therefore, it helps the students to identify the marketing tools and technique which commonly used in pharmaceutical industry.

Objectives: Upon completion of the course the student shall be able to understand the simulation to real life working in pharma management. Understanding Decision Making and Strategy Creation in the field of pharma marketing. Above all, this course provides access to online Data bank of pharma marketing case studies and real-life marketing plans.

THE COURSE COVERAGE:

1. Market research and Pharmaceutical development
2. Product portfolio decisions
3. Marketing approvals
4. Product placement and niche positioning
5. Product pricing and regulatory affairs
6. Brand development. Product management decisions
7. Pharmaceutical Indirect selling/Technical selling
8. Distribution & logistics: Introduction

Course Content:

1. Understand Your Brand's Market - Components of Insight Building
2. SWOT Analysis
3. Segment Directional Policy Matrix Approach
4. Market Access, Medical Affairs & Commercial
5. Building an Effective and Efficient Tactical Plan, Using Impact/Cost analysis and Customer Centric Objective & Key Result
6. Tactical Plan Design: Using Impact/Cost analysis and Customer Centric Objective & Key Result
7. Pharma Product Management Team (PMT)
8. Product managers & its role and responsibilities in pharma companies and understanding of key responsibilities and job functions.
9. Case Studies and various pharmaceutical marketing plans.
10. Marketing Approval: licenses, registrations and authorizations for new products
11. Pharmaceutical Distributors: Understanding Our Role in the Supply Chain

Books Recommended:

1. Mohan S, Jai D.” Drug Store and Business Management “, 1st edition, 1995, S.V Kar & Co, Jalandhar .

2. Singh S, Singh P.” Drug Store and Business Management”, 1st edition, 1995, S. Dinesh & Co. Circular Road Jalandhar.

3. Koontz & O’Donnel Principles of Management Tata Mc Graw Hill, Delhi.

VALUE ADDED COURSE

Course Name: CERTIFIED COURSE ON NANO DRUG DELIVERY SYSTEM

Chitkara College of Pharmacy, Chitkara University, Punjab

DURATION : 30 hours

CLASS : B. Pharmacy/Pharm D/ M. Pharmacy 1st Year

Course Content:

1. **Noval Drug Delivery Systems (NDDS) (2hrs)**
    a. Conventional Drug delivery systems
    b. Advantages and disadvantages of Novel Drug delivery systems
    c. NDDS Classification
2. **Nanoparticulates and Their Applications in Drug Delivery (8 hrs)**
    a. Short Introduction and Basic principles on Nanotechnology
    b. Lipidic nanosystems (Lipidic drug carriers, Liposome, Solid lipid nanoparticles etc.)
    c. Polymeric nanosystems (Polymerosomes, Dendrimers etc.)
    d. Mixed nanosystems (Hybridic nanosystems, Chimeric nanosystems)
    e. Miscellaneous nanosystems (Metallic and surfactant based nanosystems)
3. **Nanotechnology-based Advanced Therapeutics (8 hrs)**
    a. Photothermal therapy
    b. Ultrasound-mediated therapy
    c. Acoustic cavitation therapy
    d. DNA delivery for gene therapy
    e. Vaccines delivery
    f. Theranostics
4. **Nanosystems Optimization and Characteristics (4 hrs)**
    a. Qbd Based Optimisation aspects for NDDS
    b. Biophysical principles of nanosystems
    c. Stability of nanosystems
5. **Nano-Similar and Regulatory aspects (4 hrs)**
6. **Ethical Issues and Future Perspectives (4 hrs)**
    a. Unintended interactions (Cellular interaction and Organ uptake)
    b. Toxicology and human health
    c. Environmental concerns

VALUE ADDED COURSE

Course Name: TOOLS AND TECHNIQUES OF ANALYTICAL INSTRUMENTATION

Chitkara College of Pharmacy, Chitkara University, Punjab

DURATION : 30 hours

CLASS : B. Pharmacy/Pharm D/ M. Pharmacy 1st Year

Objective:

Analysis is an integral part of drug discovery and development process. The identified potential new chemical/molecular entity (NCE/NME) goes through an elaborate path of pre-clinical development (including safety, efficacy and quality aspects; pharmaceutical development) and clinical development.

Each stage of this path includes analysis of drug molecule that is being developed, using several analytical techniques.

The analysis of bulk drugs/intermediates (active pharmaceutical ingredient, API), drug product formulations, impurities and degradation products, biological samples containing drugs and their metabolites, plays an important role in pharmaceutical development research. Further the regulators worldwide demand increasingly high quality and safety standards of drugs and pharmaceuticals from the pharmaceutical industry. For meeting these standards, reliable analytical techniques and methods are constantly required and being developed by analytical scientists. Thus, pharmaceutical analyses play a vital role in advancing the concepts and theories of analytical science as well as provide an important information on practical aspects of drug design and development, quality control/quality assurance of drug manufacturing. Traditional analytical methods are commonly applied to chemical analysis of drugs and pharmaceuticals. However, in the recent past modern pharmaceutical analysis has been evolved significantly and led to development of combination (hyphenation) techniques, chemometrics, high throughput technologies, miniaturization and nanotechnology. Recently futuristic analytical techniques namely process analytical tools (PAT) are being developed.

In pharmacopoeial monographs assay methods for drugs including spectroscopy, chromatography, titrimetry, capillary electrophoresis and other electroanalytical methods are mentioned. The more advanced hyphenated analytical methods such as GC-MS, LC-MS, LC-MS-NMR, CE-MS etc. are finding applications in drug analysis.

Course Content - SCIENTIFIC TOPICS to be deliberated

- Fundamental principles and applications of spectroscopic techniques, UV, IR, NMR, X-Ray Diffraction, Spectrofluorometry and Mass Spectrometry including MALDI, in analysis of drugs and pharmaceuticals and biopharmaceuticals
- Modern Analytical Techniques such as HPTLC, HPLC, UPLC, hyphenated techniques such as LC-MS, Capillary electrophoresis (CE) and CE-MS and their applications in analysis of drugs and biopharmaceuticals
- Analytical Method Validation
- GPC and other spectroscopic tools for analysis of biopharmaceuticals
- Standardization and quality control of herbal drugs and formulation
- Stability testing and Impurity profiling of APIs and formulations: Challenges and Issues
- Good Laboratory Practices (Quality Control) and Significance of QA and QC in Pharma Industry
- Pharmacopoeial testing of drugs
- Analysis of Nanoparticles and Nano-formulations
- Solid state Pharmaceuticals
- Hands-on training sessions on above mentioned spectroscopic, chromatographic and hyphenated analytical techniques
- Non-Destruction Analytical Techniques/Process Analytical Tools (PAT)
- Visits to 2-3 pharmaceutical industries

CHITKARA UNIVERSITY

VALUE ADDED COURSE

Course Name: QbD in Pharmaceutical Product Development

Chitkara College of Pharmacy, Chitkara University, Punjab

DURATION : 30 hours

CLASS : B. Pharmacy/Pharm D/ M. Pharmacy 1st Year

COURSE CONTENT

1. **Computers in Pharmaceutical Research**
    a. Evolution of Role of computers in pharma world
    b. Advantages of use of computers
    c. Introduction to Quality by Design (QbD) Principles
2. **Computer aided Formulation Development**
    a. Introduction to Formulation Development
    b. Overview of QbD concepts in formulation development: Industrial Perspective
    c. Understanding the terminology employed
3. **Risk Assessment in Formulation Development**
    a. Application of risk assessment in QbD for formulation processes
    b. Approaches like FMEA, REM
    c. ICH Regulatory guidelines
4. **Computer-Aided Formulation Development Tools**
    a. Overview of software tools for formulation design and optimization
    b. Hands-on training in using computational tools for data analysis and modelling
5. **Design of Experiments (DoE) in QbD**
    a. Basics of experimental design and its application in QbD studies
    b. Screening and Optimization designs
    c. Practical exercises in designing and analyzing formulation experiments
6. **Data Analysis for Formulation Optimization**
    a. Half normal plots, Pareto charts, 3-D response surface plots, 2-D contour plots
    b. Introduction to multivariate data analysis techniques
    c. Understanding significance of design space, numerical desirability, overlay plot
    d. Methods for determining and optimizing design space using computer-aided tools
7. **Process Validation and Robustness Testing**
    a. Principles of process validation in formulation development
    b. Robustness testing using computational methods for process optimization
8. **Analytical Quality by Design**
    a. Introduction to use of QbD in analysis

b. Terminology employed
c. Applications and Case studies on AQbD

9. **Case Studies and Applications**
   a. Analysis of real-world case studies applying QbD principles
   b. Discussion on challenges and best practices in implementing QbD for formulation development

Suggested Readings:

1. Pharmaceutical Quality by Design: A Practical Approach by Walkiria S. Schlindwein (Editor), Mark Gibson (Editor) ISBN: 978-1-118-89520-7
2. Pharmaceutical Quality by Design Principles and Application by Sarwar Beg and Md Saquib Hasnain ISBN: 978-0-12-815799-2
3. Design of Experiments for Pharmaceutical Product Development Volume I : Basics and Fundamental Principles by Sarwar Beg ISBN978-981-33-4719-9
4. https://database.ich.org/sites/default/files/Q8_R2_Guideline.pdf
5. https://database.ich.org/sites/default/files/Q9_Guideline.pdf
6. https://database.ich.org/sites/default/files/ICH_Q14_Document_Step2_Guideline_2022_0324.pdf

CHITKARA UNIVERSITY

VALUE ADDED COURSE

Course Name: Professional Certificate Course on Drug Regulatory Affairs

Chitkara College of Pharmacy, Chitkara University, Punjab

DURATION : 30 hours

CLASS : M. Pharmacy

Course Objectives

- To provide foundational knowledge of global regulatory frameworks for drug development and approval.
- To equip students with skills for regulatory submissions, compliance, and quality management.
- To prepare students for careers in regulatory affairs in the pharmaceutical industry.

Introduction to Drug Regulatory Affairs (4 Hours)

Overview of regulatory affairs and its importance, Regulatory agencies (USFDA, EMA, CDSCO, WHO) and their roles, Basics of drug approval pathways (NDA, ANDA, MAA).

Regulatory Guidelines and Compliance (6 Hours)

ICH guidelines (Q, E, and M series), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP), Global regulatory differences and harmonization efforts.

Dossier Preparation (6 Hours)

Common Technical Document (CTD) and electronic CTD (eCTD) structure, Drug Master Files (DMFs) and clinical trial applications (CTAs), Practical exercises in dossier preparation.

Intellectual Property and Post-Approval Compliance (6 Hours)

Basics of intellectual property rights (IPR) and patents, Post-approval regulatory requirements: Variations, renewals, and amendments, Risk Management Plans (RMPs) and Periodic Safety Update Reports (PSURs).

Industry Trends and Career Development (4 Hours)

Emerging trends: AI and digital tools in regulatory affairs, Career opportunities in regulatory affairs, Guest lectures and industry interaction.

Suggested Readings and Resources

- ICH Guidelines (ICH-Q, ICH-E, ICH-M series).
- "Regulatory Affairs in the Pharmaceutical Industry" by Javed Ali et al.
- "FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics" by Douglas J. Pisano and David S. Mantus.
- Relevant guidelines from regulatory bodies such as USFDA, EMA, and CDSCO.

CHITKARA UNIVERSITY

VALUE ADDED COURSE

Course Name: Pharmacovigilance Professionals

Chitkara College of Pharmacy, Chitkara University, Punjab

DURATION : 30 hours

CLASS : Pharm D/ M. Pharmacy

Course Objectives:

- To Train M.Pharm and Pharm D. students in the field of Pharmacovigilance.
- Bridging the gap between academia and industry.
- Industry oriented learning.

Course Content - TOPICS to be deliberated

- **General introduction and basics of pharmacovigilance**: Introduction to Pharmacovigilance, History of Pharmacovigilance, Objectives of Pharmacovigilance, AE,ADR and Side Effects, Dechallenge /Rechallenge concept.
- **Event Seriousness and Causality assessment:** To prioritize cases as per seriousness and to assess case causality, methods of causality assessment, Minimum criteria for case validity.
- **Labelling**: Labelling and core labelling documents.
- **Case Narrative**: How to write a narrative in cohesive and chronological manner.
- **Case processing overview:** How to process a case.
- **Case submission timelines for regulatory authority**: Case submission timelines for different regulatory authorities on the basis of seriousness, validity, Important regulatory Authorities.
- Sources of ICSR, SUSAR and its importance, Special situation scenarios, Special situation scenarios, Basics of MedDRA and WHODD.
- How source document looks like.
- How Safety database looks like.

Suggested Readings:

1. Cobert's Manual of Drug Safety and Pharmacovigilance by Barton Cobert, William W Gregory, Jean- Loup Thomas.
2. Complete guide to Pharmacovigilance and interview preparation by Ankil K Pawar, Dr. Tejas S Pochpute.
3. A textbook of Pharmacovigilance by Dr. Ashish Garg and Dr. Sweta Garg.

CHITKARA UNIVERSITY

VALUE ADDED COURSE

Course Name: Clinical Trial Management

Chitkara College of Pharmacy, Chitkara University, Punjab

DURATION : 30 hours

CLASS : Pharm D/ M. Pharmacy

About the course

This course will provide an opportunity to start and develop student's career in Clinical research. This course offers a scientific examination of the effects, dangers, and advantages of medications or pharmaceutical products.

Course Objectives:

- To create clinical research professionals who can work in various industries.
- To Train M.Pharm and Pharm D. in the field of Clinical Research.
- Improved placement prospective.

Course Content

- History & evolution of GCP: What is GCP, history and evolution of GCP.
- Ethical and unethical disasters of history: Disasters in the history including ethical and non-ethical.
- ICH-GCH principles: Discussion on principles of ICH-GCH.
- Clinical data management: Management of clinical data, how to manage clinical data in a effective manner.
- Clinical operations: Activities supporting clinical trial process from start- up to completion process.
- Sponsor roles and responsibility: Roles and responsibilities of sponsor such as- monitoring, quality assurance, compliance.
- Investigator roles: Roles of investigator in clinical trials.
- Ethics Committee and Functions: Ethics committee, documentation required for ethical approval, procedure for ethical registration.

Suggested Readings:

Clinical research career guide by Sarbjit Sidhu.

Textbook of Clinical Research by Dr. Vikas Dhikav.

Clinical Research- What is it and how it works by Lori Nesbitt.

CHITKARA UNIVERSITY

VALUE ADDED COURSE

Course Name: Certificate Course in Medical Writing

Chitkara College of Pharmacy, Chitkara University, Punjab

DURATION : 30 hours

CLASS : Pharm D/ M. Pharmacy

Course Objectives

- To introduce the principles and practices of medical writing.
- To develop skills for preparing accurate and ethical medical documents.
- To familiarize students with regulatory, clinical, and scientific writing standards.
- To equip students for careers in the pharmaceutical and healthcare industries.

Introduction to Medical Writing (4 Hours)

Definition, scope, and importance of medical writing, Types of medical writing, Regulatory writing, Skills and qualifications for medical writers, Overview of the medical writing industry and career opportunities.

Principles of Scientific Writing (6 Hours)

Writing basics: Clarity, conciseness, and coherence, Structuring scientific content, IMRAD format (Introduction, Methods, Results, and Discussion), Use of language and grammar in medical writing, Literature search and referencing techniques, PubMed, Scopus, and other databases, Citation styles (Vancouver, APA, etc.), Avoiding plagiarism and ensuring ethical writing practices.

Writing Regulatory Documents (6 Hours)

Introduction to regulatory frameworks (ICH-GCP, FDA, EMA), Key regulatory documents, Investigator's Brochure (IB), Clinical Study Protocol (CSP), Clinical Study Report (CSR), Informed Consent Forms (ICF), Writing safety narratives and adverse event reports, Ethical considerations in regulatory writing.

Scientific Manuscripts and Publications (6 Hours)

Structure of a scientific manuscript, Title, abstract, introduction, methods, results, and discussion., Preparing high-quality tables, graphs, and figures, Writing and submitting review articles, case reports, and systematic reviews.

Clinical Trial Writing (4 Hours)

Overview of clinical trials and documentation requirements, Writing clinical trial protocols and amendments, Preparing case report forms (CRFs) and patient narratives, Summarizing clinical trial results for publications and reports.

Medical Writing for Non-Scientific Audiences (4 Hours)

Writing patient education materials, Brochures, leaflets, and FAQs, Drafting marketing and promotional content, Introduction to medical journalism and content creation, Practical assignments: Writing and reviewing non-scientific medical content.

Suggested Readings:

- "Medical Writing: A Guide for Clinicians, Educators, and Researchers" by Robert B. Taylor
- "Essentials of Writing Biomedical Research Papers" by Mimi Zeiger
- "How to Write and Publish a Scientific Paper" by Barbara Gastel and Robert A. Day
- "Writing Science: How to Write Papers That Get Cited and Proposals That Get Funded" by Joshua Schimel
- ICH Guidelines E6 (R2): Good Clinical Practice
- "Regulatory Writing: An Overview" by Carol A. Wolff
- "Scientific Writing and Communication: Papers, Proposals, and Presentations" by Angelika H. Hofmann
- "The Chicago Manual of Style"
- "Fundamentals of Clinical Trials" by Lawrence M. Friedman et al.
- "Practical Guide to Clinical Data Management" by Susanne Prokscha
- "AMA Manual of Style: A Guide for Authors and Editors"
- "Writing for the Healthcare Audience" by Nancy Tkaczuk