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Add on/ Value added certificate courses offer by Sandip Institute of Pharmaceutical Sciences 2022-23

1. Scientific Content Writing
2. Good Laboratory Practices
3. Hands On UV-Vis, IR, HPLC & GC
4. Human Values & Professional Ethics
5. Intellectual Property Rights
6. Medical Software Learning
7. Preclinical Studies
8. Pre-formulation Studies
9. Regulatory Affairs
10. Medical Coding/ Medical Writing/ Pharmacovigilance:

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Scientific Content writing

Sr. No	Content	Hours
1	**Basics of literature survey:** Introduction to various search engine, how to use the key words for the search, use of search engine like google scholar, highwire Stanford, PubMed central, Medline, google patent, shodhganga etc	05
2	**Effective scientific writing-** Data retrieving from the research article, patent and review article, sorting of data in simple formats, Data analysis and used of data, how to structure the hypothesis, Objective and goal of research.	07
3	**Writing skills-** How to start the writing of scientific literature, difference between the review and research article writing, introduction to various types parts of thesis, the content required for the effective writing, effective way of presentation of data in charts, diagram and illustrations.	06
4	**Writing skill-** Writing should be effective, comprehensive and simplified to address the exact massage from the research, Introduction to various tools to assist your writing work like End note. Introduction to citation, types of journals and publishing house.	06

	selection of journal, impact factors, h index, following author guidelines, on line submission, proof reading of a manuscript, understanding the symbols, reviewing of a manuscript, making corrections and answering reviewers query, galley proof reading	
5	**Ethics in Publishing work:** Introduction to plagiarism, what is self-plagiarism, how to avoid plagiarism, introduction to the various tools for plagiarism checking like plagiarism checker, Urkund, Turnitin etc	06

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Good Laboratory Practices

Sr. No	Content	Hours
1	**Introduction to GLP:** Introduction to GLP, History, Scope, Principle, Fundamental points of GLP (Resources Characterization, Rules, Results, Quality assurance), WHO guidelines on GLP and GMP.	12
2	**Laboratory rules and SOP:** General Rules/Protocols for Lab Safety measures, Organization and Personnel, Facilities, Equipment, Precaution and Safety in handling of chemicals and equipment's, Laboratory tools, Glassware and instruments, Definition, preparation of Basic SOPs for instrument handling and Maintenance.	06
3	**Quality assurances and quality control:** Introduction, concept and scopes of Quality Control and Quality Assurance, Introduction of GMP and cGMP, GCP, Overview of ICH Guidelines - QSEM, with special emphasis on Q- series guidelines.	06
4	**Record Keeping and Protocol:** Levels of Laboratories, Log Book Maintenance, Keeping data records, GLP documentations, protocol for conduct of non-clinical testing, control on animal house, documentation, CPCSEA guidelines, report preparation and documentation of Laboratory work, Calibration records, Validation of methods, documentation of results, Audits & Audit reports.	06

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Hands on UV-Vis, IR, HPLC & GC

Unit	Topics	Hrs.
I	**Infrared Spectroscopy:** 1. Basic principle and detailed instrumentation of IR. 2. Types of IR: FTIR, ATR 3. Sample preparation techniques for solids & liquids. 4. Compound characterization by IR spectrum. 5. Calibration.	04
II	**Ultraviolet-Visible Spectroscopy** 1. Basic principle and detailed instrumentation of UV- Visible Spectrophotometer 2. Qualitative and quantitative application. 3. Sample analysis. 4. Analytical method development and validation. 5. Calibration.	07
III	**High Performance Liquid Chromatography** 1. Basic principle and detailed instrumentation of HPLC. 2. Sample analysis. 3. Analytical method development and validation. 4. Qualitative and quantitative application. 5. Calibration.	07
IV	**Gas Chromatography** 1. Basic principle and detailed instrumentation of GC. 2. Sample analysis by using liquid autosampler and head space sampler. 3. Analytical method development and validation. 4. Qualitative and quantitative application. 5. Calibration.	07

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Human Values & Professional Ethics

Chapter	Topic	Hours
1	**Introduction to Human Values and Ethics** Definition and scope of human values and professional ethics Importance of ethical behavior in the pharmacy profession Ethical codes and guidelines for pharmacy practice	2
2	**Ethical Theories and Frameworks** • Utilitarianism • Deontology • Virtue ethics • Rights-based ethics • Ethical relativism	4
3	**Ethical Decision-Making Models** • The five-step ethical decision-making model • Applying ethical decision-making models to pharmacy scenarios • Consideration of stakeholders and their interests	4
4	**Ethical Issues in Pharmacy Practice** • Confidentiality and patient privacy • Informed consent and patient autonomy • Conflict of interest • Drug pricing and access to medication • Pharmaceutical industry influence	6
5	**Professional Values and Virtues** • Integrity and honesty • Empathy and compassion • Professional competence and continuous learning • Respect for diversity and cultural competence • Advocacy for patient welfare	4

6	**Ethical Dilemmas in Pharmacy Practice** • Case studies and group discussions on real-life ethical dilemmas • Ethical analysis and decision-making exercises • Reflection on personal values and biases	6
7	**Legal and Regulatory Frameworks** • Laws and regulations governing pharmacy practice • Professional liability and accountability • Role of regulatory bodies and professional organizations	4
8	**Ethical Considerations in Interprofessional Collaboration** • Effective communication and teamwork • Resolving ethical conflicts within healthcare teams • Respectful and ethical interactions with other healthcare professionals	2

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Intellectual Property Rights

Units	Syllabus Content	Hours
1	**Introduction To Ipr:** Meaning of property, Origin, Nature, Meaning of Intellectual Property Rights – 2 hours Introduction to TRIPS and WTO. – 2 hours Kinds of Intellectual property rights—Copy Right, Patent, Trade Mark, Trade Secret and trade dress, Design, Layout Design, Geographical Indication, Plant Varieties and Traditional Knowledge. – 5 hours	09
2	**Patent Rights and Copy Rights**— Origin, Meaning of Patent, Types, Inventions which are not patentable, Registration Procedure, Rights and Duties of Patentee, Assignment and licence, Restoration of lapsed Patents, Surrender and Revocation of Patents, Infringement, Remedies & Penalties. – 6 hours COPY RIGHT—Origin, Definition &Types of Copy Right, Registration procedure, Assignment & licence, Terms of Copy Right, Piracy, Infringement, Remedies, Copy rights with special reference to software	12
3	**Trade Marks—** Origin, Meaning & Nature of Trade Marks, Types, Registration of Trade Marks, Infringement & Remedies, Offences relating to Trade Marks, Passing Off, Penalties. – 4 hours Domain Names on cyber space. – 2 hours	6
4	**Design-** Meaning, Definition, Object, Registration of Design, Cancellation of Registration, International convention on design, functions of	6

	Design. Semiconductor Integrated circuits and layout design Act-2000.	
5	**Basic Tenents of Information Technology Act-2000 –** IT Act - Introduction E-Commerce and legal provisions E- Governance and legal provisions Digital signature and Electronic Signature. Cybercrimes	6

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Medical Software Learning

Chapter	Topic	Hours
1	• **Introduction to Medical Software (3 hours)** • Overview of pharmacy software systems and their role in pharmacy operations. • Introduction to pharmacy management systems and their benefits. • Discussion on inventory control software for pharmacies. • Ethical considerations and regulatory requirements in pharmacy software usage.	3
2	• **Pharmacy Management Systems** • Understanding the functionalities and components of pharmacy management systems. • Navigating a pharmacy management system. • Inventory management and control using pharmacy software. • Prescription processing and medication dispensing. • Reporting and analytics in pharmacy management software	6
3	• **Prescription Processing and Medication Therapy Management** • Workflow and prescription processing using pharmacy software. • Medication therapy management using pharmacy software tools. • Drug interactions, allergies, and contraindications alerts in pharmacy software. • Medication reconciliation and patient counselling.	8
4	• **Inventory Control and Ordering** • Managing pharmacy inventory using software tools.	4

	• Setting reorder points and managing stock levels. • Ordering and receiving medications through pharmacy software. • Utilizing barcodes and scanning technologies for inventory control.	
5	**Billing and Claims Processing** • Pharmacy billing processes and claims management. • Third-party billing and reimbursement using pharmacy software. • Managing insurance information and prior authorizations. • Handling rejected claims and resubmission processes.	5
6	• **Data Security and Privacy** • Ensuring data security and privacy in pharmacy software usage. • HIPAA compliance and patient data protection. • Best practices for data backup and disaster recovery. • Training pharmacy staff on data security and privacy.	4

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Preclinical Studies

Chapter	Topics	Credit hours
1	**Introduction to preclinical studies and types of Preclinical studies** • Importance of preclinical studies • In-Vitro • In vivo	4
2	**Importance of preclinical studies for drug discovery**	4
3	**Ethical bodies for animal studies** • CPCSEA and approval	4
4	**Introduction to Different types of Laboratory animals and importance** • Rats • Mice • Guinea Pigs • Rabbits	2
5	**In vitro studies** • Introduction to various in vitro studies like anti-oxidant, anti-inflammatory etc., • Cell culture techniques • In vitro assay procedures	6
6	**Toxicity studies and their use in pre clinical services** • OECD guidelines • Acute oral toxicity • Sub acute toxicity • Sub chronic toxicity • Chronic toxicity • Carcinogenicity etc.	6
7	**Euthanasia techniques of animals after study as per CPCSEA**	2
8	**Preparation of study protocols according to standard guidelines**	2

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Pre-formulation Studies

Unit	Content	Allotted Hours
Unit I	**The Scope of Pre-formulation Studies** Introduction, Pre-formulation Testing Criteria, Regulatory Requirements, Testing Systems, Solid-State Characterization Transport Across Biological Membranes	5
Unit II	**Dissociation, Partitioning, and Solubility** Introduction, The Ionization Principle, Quantitative Structure –Activity Relationships, Partitioning, Measurement Strategies	5
Unit III	**Release, Dissolution, and Permeation** Introduction, Release, Assay Systems, The Biopharmaceutics Drug Classification Systems	5
Unit IV	**Solid-State Properties** Introduction, Crystal Morphology, Polymorphism, High-Throughput Crystal Screening, Solvates, Hydrates, Amorphous Forms, Hygroscopicity, Solubility, Study Methods	5
Unit V	**Dosage Form Considerations in Preformulation** Introduction, Solid Dosage Form Considerations, Solution Formulations, Emulsion Formulations, Freeze-Dried Formulations, Suspensions, Topical, Pulmonary Delivery, General Compatibility	5

Unit VI	**Chemical Drug Substance Characterization** Introduction, Scheme of Characterization, Impurities, Good Manufacturing Practice	5
Unit VII	**Characterization of Biopharmaceutical Drugs** Introduction, Preformulation Studies, Packaging and Materials, Physio-Chemical Characterization Tests, Design of Preformulation Studies	5

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Regulatory Affairs

Units	Syllabus	Hours
1	• **Introduction to Regulatory Affairs** • Definition and scope of regulatory affairs • Role of regulatory affairs in the pharmaceutical industry • Global regulatory guidelines and key regulatory authorities .	2 Hours
2	□**Regulatory Guidelines and Standards** • Overview of international regulatory guidelines and standards • Good Laboratory Practices (GLP) • Good Clinical Practices (GCP) • Good Manufacturing Practices (GMP) • Good Pharmacovigilance Practices (GVP)	2 Hours
3	□**Drug Development Process** • Preclinical testing and data requirements • Phases of clinical trials and regulatory considerations • Investigational New Drug (IND) application • New Drug Application (NDA) and Biologic License Application (BLA)	4 Hours
4	□**Regulatory Submissions and Interactions** • Electronic Common Technical Document (eCTD) format • Preparation and submission of regulatory dossiers • Regulatory meetings and communications with regulatory authorities	4 hours

	• Post-submission requirements and updates	
5	**□Pharmacovigilance and Post-Marketing Surveillance** • Adverse drug event reporting and monitoring • Post-marketing safety studies • Risk management plans • Labeling and package inserts	4 Hour
6	**□Regulatory Compliance and Inspections** • Regulatory inspections and audits • Corrective and preventive actions (CAPA) • Quality management systems • Compliance with regulatory requirements	4 hours
7	**□Global Regulatory Harmonization** • International Conference on Harmonisation (ICH) guidelines • Mutual Recognition Agreements (MRAs) • Harmonization initiatives and their impact on regulatory affairs	2 hours
8.	**□ Regulatory Affairs in Specialized Areas** • Regulatory considerations for generics and biosimilars • Medical devices and diagnostics regulations • Nutraceuticals and dietary supplements regulations • Regulatory affairs in emerging technologies (e.g., gene therapies, cell-based products)	4 hours
9.	**□ Current Trends and Future Developments** • Regulatory challenges and emerging issues • Digital health technologies and regulatory implications • Regulatory affairs careers and professional development opportunities	4 hours

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Medical Coding/ Medical Writing/ Pharmacovigilance

Units	Syllabus	Hours
1	**Medical Coding:** **(CPT, ICD 9-CM, ICD -10 CM, DSM, CDT, APC, and HCPCS)** CPT – Current Procedural Terminology ICD – International Classification of Diseases DSM- Diagnostic and Statistical manual CDT – Code on Dental Procedures and Nomenclature. APC- Ambulatory Payment Categories HCPCS- Healthcare Common Procedure Coding System .	5 Hours
2	Health Insurance Policies Health insurance Portability and Accountability Act Evaluating medical services, procedures, and guidelines Documenting medical records Medical Ethics Anaesthesia	5 Hours
3	**Medical Writing:** 1- Introduction in Healthcare Communication and Medical Writing: • Understanding the term 'Medical Writing' • Types of medical writing • Qualities required in a medical writer • Target audience • Employers and clients 2- The Writing Process • The four steps in the writing process • Prewriting strategies • Drafting	5 Hours

	• Revising • Refining 3- Online and Offline Writing Skills for Media • Reader behaviors • Differences between web and print media • Effective web writing techniques	
4	□**Regulatory Submissions and Interactions** • Electronic Common Technical Document (eCTD) format • Preparation and submission of regulatory dossiers • Regulatory meetings and communications with regulatory authorities • Post-submission requirements and updates	5 hours
5	□ Basic Rules of Writing • Basic structure of a write-up • Writing the basic components • Grammar basics • General rules of writing	5 Hour
6	Consumer writing • General rules for consumer writing • Types of consumer writing • Consumer news • Consumer reviews • Blogs • Newsletters • Fact sheets • Care guides	5 hours
7	**Pharmacovigilance:** 1. Introduction to Pharmacovigilance • History and development of Pharmacovigilance • Importance of safety monitoring of Medicine • WHO international drug monitoring programme	5 hours

	• Pharmacovigilance Program of India(PvPI) 2. Basic terminologies used in pharmacovigilance • Terminologies of adverse medication related events • Regulatory terminologies 3. Drug dictionaries and coding in pharmacovigilance • WHO adverse reaction terminologies • Med DRA and Standardised MedDRA queries • WHO drug dictionary • Eudravigilance medicinal product dictionary	
8.	4. Information resources in pharmacovigilance • Basic drug information resources • Specialized resources for ADRs 5. Establishing pharmacovigilance programme • Establishing in a hospital • Establishment & operation of drug safety department in industry • Contract Research Organisations(CROs) • Establishing a national programme 6. Pharmacovigilance methods • Passive surveillance–Spontaneous reports and case series • Stimulated reporting • Active surveillance-Sentinel sites, drug event monitoring and registries • Comparative observational studies–Cross sectional study, case control study and cohort study • Targeted clinical investigations	5 hours