2017

Biotechnology Skill Enhancement Programme (BiSEP)

Post Graduate Diploma

in

FERMENTATION AND BIOPROCESSING

Syllabus

STRUCTURE AND SCHEME - FERMENTATION & BIOPROCESSING

Paper code	Title of the paper	Teaching hours per week	Duration of examination (hours)	Internal assessment marks	Exam. marks	Max. marks	Credits
I Semester- Theory							
BiSEP1	Upstream processing	4	3	30	70	100	4
BiSEP2	Downstream processing	4	3	30	70	100	4
BiSEP3	Facility Management and Applications of Fermentation	4	3	30	70	100	4
(Elective paper-choose any one)							
BiSEP4	1) Production/manufacturing 2) Quality Control 3) Product Development 4) Business Development	4	3	30	70	100	4
Practicals							
BiSEP5	Upstream processing and Applications of Fermentation	8	4	30	70	100	4
BiSEP6	Downstream processing	8	4	30	70	100	4
Total Marks and Credits						**600**	**24**
II Semester-Industry Internship							
Paper No.	**Title of the paper**	**Total Hours/ Semester/ Week**	**Duration of exam**	**Internal assessment marks**	**External Assessment marks**	**Max. marks**	**Credits**
BiSEP7	Industry Report or Project Report			200	200	600	24
	Presentation & Viva				200		
Total Marks and Credits						600	24
Grand Total						**1200**	**48**

Assessment by LSSSDC

Elective paper Examination-50Marks-1.5Hr duration(MCQ)

Skill Assessment –Viva-15mins durationby Examiner nominated by LSSSDC

Second semester Examination conducted by University/Institute for award of PG Diploma and assessment by LSSSDC will be undertaken together.One can plan to have LSSSDC nominated examiner to be part of Industryreport/Project report presentation

First semester-Internal Assessment -30 marks

Theory

Seminar 10 marks(2 seminars per paper)

Assignment 5 marks

Internal test 15 marks(2 internals)

Practical

Continuous assessment - 15 marks(Based on attendance, performance and record)

Internal test- 15 marks(2 internal)

First semester –End Semester Assesmnt-70marks

Theory

Part A:5*3=15(5 Questions to be answered out of 6)

Part B:5*5=25(5 Questions to be answered out of 6)

Part C:2*15=30(2 Questions to be answered out of 3)

Practical

Part A: Major Experiment:1*30=30

Part B :Minor Experiment:1*20=20

Part C:Viva/voce:20

Second semester –Internal Assessment -400 Maximum marks

Progress Report 200 marks(40marks per month for 5 months)

Industry feedback 200 marks(30 marks per month for 5 months)

Second semester-Final Assessment -200 Maximum marks

Report/Dissertation 100 marks

Presentation & Viva-voce 100marks

INDUSTRIAL INTERNSHIP EVALUATION-BiSEP

Sl.No	Parameters	Maximum marks	Marks awarded
1	Skills and knowledge acquired during internship and the ability to Display the Technical Skills required to deliver the job	20	
2	Teamwork skills -Ability to Establish Positive Relationships with the Managers and Peers	15	
3	Takes Initiative and Works with Minimal Supervision	15	
4	Stress management	5	
5	Communication & Presentation skill	5	
6	Personal Conduct and Behaviour	5	
7	Regularity (5%)	5	
	Total Marks	**70**	

Syllabus of the theory papers

BiSEP1: UPSTREAM PROCESS

Total Hours: 52

Unit- I: (8 hours)

Bioprocess development: An interdisciplinary challenge, Biotechnology & Bioprocess Engineering, steps in bioprocess development, Microbial culture, Screening and selection for fermentation processes; Preservation and improvement of industrially important microorganisms, Strain development.

Unit-II: (8 hours)

Media for industrial fermentations: Media ingredients, medium formulation, oxygen requirements, antifoams, medium optimization, Ingredients for mammalian cell culture and plant cell culture. Inoculum production for bacterial and fungal processes. Media sterilization, Batch Process (thermal death kinetics), continuous sterilization process; sterilization of fermenter and other ancillaries, filter sterilization of air and media.

Unit- III: (8 hours)

Inoculum development for industrial fermentation & Microbial Kinetics:

Introduction, Criteria for transfer of inoculum, development of inocula for bacterial processes, yeast processes and mycelial processes. Inoculum development for plant fermenter, aseptic method of inoculation, achievement and maintenance of aseptic conditions.

Fermentation Material and Energy balance, Microbial growth kinetics: Microbial growth cycle, measurement of growth, Batch culture, continuous culture, fed-batch culture, applications and examples.

Unit- IV: (8 hours)

Design of bioreactors: Basic objective of fermenter design, aseptic operation & containment, body construction, agitator and sparger design, baffles, stirrer glands and bearings. Process parameters and measurement techniques: measurement of temperature, pressure and pH, DO, foam etc.; flow rate of liquid and gases; Automation (processes computerization). Validation of Fermentor

Unit- V: (10 hours)

Bioreactor configurations and types: Bubble column, airlift reactor, packed bed, fluidized bed, trickle bed, Membrane reactor, Photobioreactor, Solid state fermenter, Animal and plant cell bioreactors. Scale up and Scale down studies of bioreactors.

Heat and Mass transfer in Bioprocess, Relationship in between heat transfer, cell concentrations and stirring conditions, Measurement of KLa, Rheological properties of fermentation broths, Factors affecting broth viscosity, Mixing in Fermenters.

Unit- VI: (10 hours)

Animal cell culture: Cell culture practices, nutritional requirement of cultured cell, cell growth and propagation, prevention and eradication of contamination, Cell synchronization; Cell cloning. Measurement of cell death, Apoptosis. Cryopreservation and Cell banking- transport of animal germplasm (i.e. semen, ovum and embryos).

Scaling-up of animal cell culture. PAT (Process Analytical Technologies) for Control of large scale Cell culture. Application of animal cell culture: Stem cell cultures, embryonic stem cells and their applications, Hybridoma technology, Cell culture based vaccines

REFERENCE:

1. Comprehensive biotechnology, vol 1, 2, 3 and 4 Murray moo young, Pergamon press2004.
2. Principles of fermentation technology P.F. Stanburry& Whitaker Pergamon Press, II Ed, Butterworth Heinemann-Elsevier, 2005.
3. Bioprocess Engineering, Basic Concepts, II Ed. Michael L Shuler, FikretKargi, Prentice Hall of India pvt. Ltd. 2002.
4. Pauline M. Doran, Bioprocess Engineering Principles, Academic Press an Imprint of Elsevier.
5. Coulson & Richardson's Chemical Engineering, R.K. Sinnotl, III Ed. Vol 6 Butterworth-Heinemann-Elsevier Pub, 1999.
6. Coulson & Richardson's Chemical Engineering, J F Richardson & J H Harker, 5th Ed, Vol 2, Butterworth- Heinemann-Elsevier Pub, 2003.
7. Manual of Industrial Microbiology & biotechnology, Arnold Demain& Julian E. Davis, II Ed, ASM Press. Washington DC, 1999.
8. Current developments in Solid Substrate fermentation, Ashok Pandey, Carlos Ricardo Soccol, Christian Larroche – 2008.
9. Industrial Biotechnology by Rita Singh, S. Ghosh, Global Vision Publishing Ho, 2004
10. Industrial Biotechnology: Sustainable Growth and Economic success by WimSoetaert, Erick J. Vandamme,
11. Basic Cell Culture: A Practical Approach by J.M. Davis, 2nd ed. 2002 Oxford University press, oxford
12. Culture of Animal Cells: A Manual of Basic Technique 4th ed. By R. Ian Freshney Wiley-Liss, 2000
13. Animal Cell Culture Third Edition A Practical Approach Edited by John R. W. Masters Oxford University Press Great Clarendon Street, Oxford 0X2 6DP 2000.
14. Animal Cell Technology: From Biopharmaceuticals to Gene TherapyEdited by Leda R. Castilho Aˆ ngela Maria Moraes, Elisabeth F.P. Augusto and Michael Butler. Taylor & Francis group 2008.

15. Pharmaceutical Biotechnology Concepts and Applications Gary Walsh John Wiley & Sons Ltd, The Atrium, Southern Gate, Chichester, West Sussex PO19 8SQ, England 2007
16. Cell and Tissue Culture: Laboratory procedures in Biotechnology Edited by Alan Doyle and J. Bryan Griffiths Wiley & Sons Ltd, The Atrium, Southern Gate, Chichester, West Sussex PO19 8SQ, England 1998.

BiSEP2: DOWNSTREAM PROCESSING

Total Hours: 52

Unit- I: (6 hours)

Basic concepts of Bio-separation Technology: Separation characteristics of proteins and enzymes – size, stability, properties; purification methodologies, Characteristics of bio products; Flocculation and conditioning of broth, overview of reaction processes involved in separation

Unit- II: (8 hours)

Methods for extraction of proteins -Cell disruption methods for intracellular products Osmotic shock, Homogenization, various types of homogenizes, Sonication, Enzyme digestion. Centrifugation: basic principles, design characteristics; ultracentrifuges; principles and applications.

Unit- III: (8 hours)

Filtration (batch and continuous filtration). Membrane based separation processes, Micro-filtration; Reverse osmosis, Nanofiltration, Ultrafiltration and Affinity ultrafiltration, Membrane modules. Liquid-liquid extraction, Supercritical fluid extraction, precipitation**,** distillation, drying of product.

Unit- IV: (10 hours)

Product Resolution/Fractionation - Chromatography: Gel filtration chromatography, Ion-exchange chromatography (IEC), Chromatofocusing. Affinity chromatography: Immunoaffinity purification, Immunoaffinity matrices, ligand affinity, hydrophobic interaction chromatography (HIC), HPLC, RP – HPLC.

Unit- V: (8 Hours)

Electrophoresis – Theory and factors affecting. Polyacrylamide and Agarose gel electrophoresis; Capillary electrophoresis; 2 D- Electrophoresis; isoeletric focusing; Pulsed field gel electrophoresis. Western blotting, staining techniques.

Unit- VI: (12 Hours)

Analysis of the final product - Protein-based contaminants, Removal of altered forms of the protein of interest from the product stream, Product potency, Determination of protein concentration (all the major protein assays – principles). Amino acid analysis, Peptide mapping, N-terminal sequencing, Analysis of secondary and tertiary structure. Detection of protein-based

product impurities: rapid methods for detection of specific organisms and toxins (immunological/molecular methods).

REFERENCES:

1. Basic Principles of Membrane technology, 2nd edition, Marcel Mulder. Springer, 2007.
2. Biocatalytic Membrane reactors, Enrico Drioli&LidiettaGicorna. Taylor Francis Group, 2004.
3. Biochemical Engineering Fundamentals, 2nd Edition, James E. Bailey, David F. Ollis. McGraw Hill International Editions, 1986.
4. Biophysical chemistry - Principles and techniques, A. Upadhyay, K. Upadhyay, N. Nath. Himalaya Publishing house, 2005
5. Bioprocess Engineering, Basic Concepts, 2ndEdition, Michael L. Schuler, FikretKargi. Prentice Hall of India Pvt. Ltd., 2002.
6. Bioseparations Principles and Techniques, B. Sivasankar. Prentice hall of India Pvt. Ltd., 2007.
7. Fermentation - A Practical Approach, B. Mc Neil and L. M Harvey, Oxford University Press, 1990.
8. Fermentation Microbiology and Biotechnology, Bryce C.F and EI Mansi. Taylor and Francis, London, 2002.
9. Handbook of Bioseparations, Volume 2, Edited by SatinderAhuja. Academic Press, 2000.
10. Introduction to Biochemical Engineering, 2nd Edition, D.G Rao. Tata McGraw Hill International Editions, 1986.
11. Manual of Industrial Microbiology & biotechnology, 2nd Edition, Arnold Demain& Julian E. Davis, ASM Press, Washington DC, 1999.
12. Membrane Technology and applications, 2nd Edition, Richard W Baker. John Wiley & Sons Ltd, 2004.
13. Prescott and Dunn's Industrial Microbiology, 4th Edition, Edited by Gerald Reed, CBS Publishers and Distributors, New Delhi, 1999.
14. Principles and techniques of practical biochemistry, 6th Edition, Keith Wilson and John M Walker, Cambridge University press, Cambridge. 1995.
15. Principles of Fermentation technology, 2nd Edition, Stranburry P.F and Whittaker, Pergamon press, 2004
16. Techniques used in Bio product analysis, Butterworth Heinemann Ltd, 1992.

BiSEP3: FACILITY MANAGEMENT AND APPLICATIONS OF FERMENTATION

Total Hours: 52

Unit- I: **(8 hours)**

Cleanroom - What is a Cleanroom? The Need for Cleanrooms, Types of Cleanrooms,
Basis of Cleanroom Standards, Federal Standard 209E/IS0 standards- ISO14000-1, Pharmaceutical Cleanroom Classification, Sources of clean room documents and standards - The International Confederation of contamination Control Societies (ICCCS). Recommended Practices and Guides of the Institute of Environmental Sciences and Technology (IEST), International Clean room Forum.

Unit -II: **(10 hours)**

The Design of Turbulently Ventilated and Ancillary Cleanrooms- Air supply, High efficiency air filters, Air movement within a turbulently ventilated Cleanroom, Room pressurization and air movement control between rooms, Construction materials and finishes. Ancillary Clean Rooms – Clothing change area, Material transfer area, Containment Rooms.
Design of Unidirectional Cleanrooms and Clean Air Devices. Cleanroom Testing and monitoring Airborne Particle Counters, Continuous Monitoring Apparatus for Airborne Particles, Microbial Sampling of the Air. Cleanroom Clothing,Operating a Cleanroom, Cleanroom Disciplines, Methods to Monitor Hazards and Control Methods.

Unit- III: **(8 hours)**

Microbial primary and secondary metabolites: Aminoacids (glutamic acid, lysine) by modified strains, Vitamins (A and C) and Recombinant protein production insulin. Organic acids (citric acid). Production of Antibiotics (penicillin).

Unit- IV: **(8 hours)**

Microbial Enzymes: Microbial production and purification of lipase. Immobilization of enzymes. Microbial exopolysaccharides (EPS): classification and applications of cyclodextrin, alginate, chitosan.

Unit- V: **(8 hours)**

Plant Cell Suspension Culture and Secondary Metabolities: Establishing cell cultures, Types of suspension culture. Production of secondary Metabolites – Immobilized cell culture system, Hairy root cultures. Role of elicitors and precursor feeding on stimulation of chemical production, Biotransformation and methods of biotransformation, transformation of steroids.

Unit- VI: (10 hours)

Microbial food: miso, tofu, cheese-cheddar, sauerkraut. Probiotics, Microbial Biomass- Baker's yeast, SCP. Mushroom cultivation. **Microbial beverages**: Production of wine and beer. **Microalgal culture and its industrial application:** omega 3- fatty acids, β-carotene, biodiesel production.

REFERENCE:

1. Cleanroom Technology: Fundamentals of Design, Testing and OperationWilliam Whyte, Second edition, John Wiley & Sons, UK, 2010
1. Clean room Technology - W.Whyte
2. Clean room Design-Technology and Engineeering-W.whyte
3. Introduction to Contamination Control and Cleanroom Technology: Author: Matts Ramstorp.
4. Cleanrooms: facilities and practices: Michael Kozicki, Stuart A. Hoenig, Patrick J. Robinson
5. Clean Room Design:Minimizing Contamination Through Proper Design::BengtLjungqvist, BeritReinmüller
6. Encyclopedia of Cleanrooms, Bio-Cleanrooms, and Aseptic Areas Dr. Philip R. Austin, P.E.
7. Comprehensive Biotechnology, vol 1,2,3 & 4 Murray moo young, Pergamon Press, 2004
8. Industrial microbiology, Cassida, Wiley Eastern Ltd, 1993
9. Industrial biotechnology, Cruger&Cruger 2nd Ed, Sutherland MA Sinauer Associates 1990
10. Manual of Industrial Microbiology & biotechnology, Arnold Demain& Julian E. Davis, II Ed, ASM Press. Washington DC, 1999.
11. Microbial biotechnology, Fundamental of Applied Microbiology Alexander, G, WH Freeman and com. 1993
12. Industrial Microbiology, Ed 4. Prescott & Dunn, 2004, McGraw Hill Book Pub.
13. Microbial Technology : Fermentation Technology , 2nd Edition, Vol. II Peppler, H.J. and D. Perlman, (2004), Academic Press / Elsevier.
14. FermentationMicrobiologyandBiotechnology2ndEditionEl-Mansi,E.M.T.(2007)., CRC/Taylor&Francis.

BiSEP4: Syllabus of the Elective theory papers

(Choose any one from the following)

BiSEP4a: PRODUCTION/ MANUFACTURING BIOLOGIST

Total Hours: 52

Unit- I:

Supervision of bio pharmaceutical production process: Supervise bio pharmaceutical production activities: Bio pharmaceutical production schedule and guidelines to production operators to handle production activities, Directions for junior biologists/ production operators - proper ingredients, temperatures, pressure and mixing times, etc.

Unit – II:

Documentation and Reporting: Documentation - Documentation of activities in the production process, Record of production output for each shift operation in the Batch Process.

Reporting – Following of approved guidelines of respective Drug Administration Body (MHRA, USFDA, CDSCO, etc.), Standard Operating Procedures and other statutory requirements, Reporting of breakdowns, Maintenance of GMP standards at shop floor and conditions suitable for production of quality products.

Unit – III:

Manage staff and inventory: Staff - Procedures to be followed in Managing staff details at production site. Role of production staff during audit

Inventory - Stock of raw materials and chemicals for production activities, Requirement and source materials as per daily production schedule, labeling, raw material conditions, batch no., shelf life and quantities, etc.

Unit – IV:

Maintain a healthy, safe and secure working environment in the life sciences facility: Self monitor and safety principles and standards, behavioural safety of workmen to current Good Manufacturing Practicies (cGMP). Shop floor standards. Reporting of health issues, safety and security policies and procedures.

Managing emergency procedures: illness, accidents, fires, evacuation of worker/s during emergency.

Unit – V:

Coordination with Shift Supervisor: Work instructions from reporting supervisor, Reporting to supervisor - process-flow improvements and production defects received from previous process, potential hazards or expected process disruptions, maintenance and repair schedule proactively, handover of completed work.

Unit – VI:

Coordination within the team and with cross functional teams: Team player: Working with colleagues and sharing of work, work flow related difficulties. Interact with colleagues from cross functional teams: Feedback from Quality Control and Quality Assurance, Completion of work on time, support to Quality

Assurance team during audits, coordination during breakdowns and for preventive and corrective maintenance, Coordination with Stores.

BiSEP4b: PRODUCT DEVELOPMENT - BIOLOGIST

Total Hours: 52

Unit- I: 12 hours

Essentials of product development: Company protocols for research, privacy policies, institutional and professional code of ethics and standards of practice, IPR guidelines, Knowledge of basic laboratory procedures, GLP and GMP, relevant EOPs, SOPs, process flows in manufacturing, product life cycle and product properties, competitor products. Stability studies – generate stability data & prepare stability reports for innovation products

Unit-II: 10 hours

Reporting and documentation: Reporting – different standard reference materials used like drugs, products, side effects, adverse reactions, process details, statistical analysis of test data. Documentation – methods and procedures of writing and maintaining lab, research records, research performance reports, schemes and guidelines, power point presentations, tables, charts, word documents, development of research objectives and proposal writing for funding and contractual purposes, publications and technical writing, Regulatory compliance of the final documents

Unit-III: 8 hours

Planning and communication: Research planning – resource, time, timeline & budget considerations, technical feasibility analysis on the NPD ideas by analyzing current development plans, plan day to day activities. Research communications - preparation of progress reports/ research outcomes for steering groups/ bodies, principal investigator, communication with upstream and downstream teams

Unit-IV: 6 hours

Problem solving and decision making: Research initiatives – use new areas of research, techniques and methods, extend research/ product portfolio, creative analysis & interpretation of research data. Decision making – collaborative, appropriate, optimum & best possible solution, Trouble- shoot & Resolve problems to avoid delays

Unit-V: 8 hours

Safety and Security at workplace: Different types of occupational health hazards, knowledge of chemical substances, characteristics & safety measures, use of safety gears, masks, gloves & accessories, evacuation procedures for workers & visitors. Health, safety & security issues – types (illness, fire accidents), company policies and procedures, When and how to report, summon medical assistance & emergency services

Unit-VI: 8 hours

Interpersonal Skills: Understand work output requirements, company rules, guidelines & policies related to the process flow, identifying and reporting issues requiring intervention, delivery of quality work on time & report any anticipated reasons for the delay, effective interpersonal communication, conflict-resolution techniques, importance of collaborative working, multi-tasking, training the team members, knowledge of project management

BiSEP4c: QUALITY CONTROL/QUALITY ASSURANCE BIOLOGIST

Total Hours: 52

Unit-I: 16 hours

Essentials of quality control: Preparations - buffer, solvents, solutions and microbial media for running bio-analytical quality tests, assays to carry out quality control procedures on biopharmaceutical products.

Concepts of pharmacopeia like BP, USP, EP and other applicable guidelines such as WHO, ICH and EMEA, etc., statistical tools and software like combistats, safe handling of infectious materials like cultures, strains and seed strains, procedures for handling infectious spillage control, GLP/GMP, biochemical analysis of proteins, bio analytical and microbiological methods, working of instruments/apparatus/equipment, biological assays, application of various analytical techniques such as HPLC, capillary electrophoresis including icIEF, FTIR, Circular Dichroism, UV and Fluorescence spectroscopy, ELISAs, enzyme assays and other applicable methods for the testing of biopharmaceuticals, application of microbiological techniques such as air monitoring, water testing, surface monitoring, microbial monitoring, biosafety levels and biosafety hazards

Unit-II: 10 hours

Quality Assurance: Quality checks - quality assurance samples, master sample, internal controls, statistical analysis of test data, techniques and concepts of statistical quality control and statistical process control, non-conformities. Operational aspects – calibration, accuracy checks of quality control equipments like stability chambers and BOD incubators, HPLC, gas chromatography, photoflourometer, etc., application softwares used in quality analysis

Unit-III: 6 hours

Safety and Security at workplace: Different types of occupational health hazards, knowledge of chemical substances, characteristics & safety measures, use of safety gears, masks, gloves & accessories, evacuation procedures for workers & visitors. Health, safety & security issues – types (illness, fire accidents), company policies and procedures, When and how to report, summon medical assistance & emergency services

Unit-IV: 6 hours

Interpersonal Skills: Understand work output requirements, company rules, guidelines & policies related to the process flow, identifying and reporting issues requiring intervention, delivery of quality work on time & report any anticipated reasons for the delay, importance of team work, resolution of conflicts, multi-tasking, training the team members, knowledge of project management

Unit-V: 6 hours

Clean work station: Cleaning the work area and equipments, materials and equipments required for cleaning, adequate ventilation for the work area, personal protective equipments, dealing with accidental damage, procuring and storing housekeeping equipment and supplies, disposal of wastes, maintain schedules and records for housekeeping

Unit-IV: 8 hours

Reporting and documentation in quality: Reporting – company procedures**,** escalation matrix for reporting identified issues - defects, problem, incidents, quality issues and test results, feedback to production manager and R&D staff. Documentation – procedures and good documentation practices, offline and online mode, accuracy, details, controlled document files and test records, regulatory and compliance requirements**,** inspection - procedures, protocols and checklists, inspection reports.

BiSEP4d: BUSINESS DEVELOPMENT - BIOLOGIST

Total Hours: 52

Unit-I: 12 hours

Essentials of business development: Basics of Business Planning (Market mapping, Sales forecasting, Prioritization), Sales planning, MSL Mapping, Customer profiling, Call planning, In clinic effectiveness, KOL/KBL relationship management, Product messaging, identify the gaps in the current pipeline for new products and keep a watch on the competitor products. Distribution management, process flows in manufacturing, supply chain, research & development and quality functions at a broad level, escalation matrix for reporting identified issues, expiry and sales returns

Unit-II: 12 hours

Qualify leads and sell accreditation: Qualification of leads - new lead sources for sales, in-licensing/ out-licensing opportunities - city and telephone directories, trade and professional association membership lists, and other public records, telephone calls and visit prospective accredited businesses, sales presentation within established business guidelines and approved business sales script, liaison with companies for in-licensing/ out-licensing opportunities, creation of awareness among doctors/Key Opinion Leaders (KOL) / Key Business

Unit-III: 10 hours

Analysis of secondary sales data: Analysis - computer packages like MS Office /application software/ERP like SAP, Oracle, etc standard operating procedures and actions required for non-conformance products, methods and techniques involved in evaluating information received from market, key players, MIS systems, gaps in product line, statistical analysis of test data, adverse drug reactions of the products of the organisation

Unit-IV: 6 hours

Interpersonal Skills: Reporting structure in the company, company's policies on: preferred communication medium, reporting and escalation policy, quality delivery standards, and personnel management. Effective interpersonal communication, conflict-resolution techniques, importance of collaborative working

Unit-V: 6 hours

Market research and analysis: Benchmark company data with competitor presence/ market trends - sources for gathering information and understanding rising trends in market, data extraction, and interpretation analysis techniques from systems, market research techniques

Unit-VI: 6 hours

Business plans: Planning business strategies - short and long-term, existing product portfolio and current market presence, marketing and communication strategy, new opportunities into new markets, feedback from customers for developing and refining marketing, advertising and communication plans

BiSEP4e: MEDICAL WRITING

Total Hours: 52

Unit-I: **08 hours**

Introduction & Scope- Origin of technical documentation: ICH guidelines, Basic report writing review Clarity: basic principles of clarity Communication cycle**. CTD Triangle: Information on the CTDe of medical writing:** The medical literature and Clinical Writing; Scope of clinical writing, Examples of Medical Writing, Required skills, Decision making ; planning and organization; critical thinking, Analytical thinking; ; Primary employers; Spectrum of jobs/engagement of clinical writers.

Unit-II: **15 hours**

Scientific publishing - Scientific Article: Principal parts and content, The medical literature and the scientific publication process, Title, abstract, keywords, introduction, Objectives. Material, methods, results, discussion. Technical Issues in Medical Writing**:** Tables: Advantages; characteristics of a good table, Figures: Types of Figures, Copyright,Permissions Citations: Referencing; citation-parts; Publication practices and authorship; Scientific Integrity, Misconduct in research; Ethics of authorship, Plagiarism and other forms of misconduct in research, In-text citation styles (APA, MLA), Mendelay and other open access software to formalize citations.

Unit-III: **13 hours**

Data acquisition, Basic report writing review Clarity: Managing and Sharing Data, Data ownership, Ethical and Data Acquisition Issues. Data Management Concerns, Privacy and Confidentiality.

Regulatory writing: Definition of terms: laws, regulation, guidelines, Role of Regulatory Affairs in the Drug Development, The Investigational New Drug (IND) Application as the Platform for Drug Development, Regulatory Environment in India. Regulatory bodies-National and international. Selected regulations and guidance for drug studies (FDA).

Unit-IV: **10 hours**

Medico-Marketing Writing/Reporting and documentation - Standard Operating Procedures-SOP **-** Developing Effective Standard Operating Procedures, How to Write Standard Operating Procedures,Writing for Biotech Industry/Pharmaceutical Industry, Pharmaceutical Marketing, Writing An Effective Case Study For A Medical Device,Advertising drugs; Legal considerations. Writing- Vetting of advertisements , Truthful presentation, Essentials for public advertising, Professional advertisement essentials. Minimum requirements.

Unit-V: **06 hours**

Common technical document (CTD)-India **Safety Writing-**Safety (MSDS)- industry perspective SAFETY NARRATIVES - Clinical Trials . Other issues: consistency, tracking, delivery Medico-Marketing Writing , Origin of technical documentation, ICH guidelines.

Unit-VI: **06 hours**

Interpersonal Skills: Understand work output requirements, company rules, guidelines & policies related to the process flow, identifying and reporting issues requiring intervention, delivery of quality work on time & report any anticipated reasons for the delay, importance of team work, resolution of conflicts, multi-tasking, training the team members, knowledge of project management

BiSEP4f: SCIENTIST- CLINICAL RESEARCH AND DEVELOPMENT

Total Hours: 52

Unit-I: **12 hours**

Basics of Clinical Pharmacology: Pharmacokinetics and Pharmacodynamics and its clinical applications. Rational Prescribing. Adverse Drug Effects, Toxicology and Drug Interactions.PK-PD study, significance in clinical research.BA-BE study, significance in clinical research. Route of drug administrations, advantage & disadvantages. First Human Dose, Drug Designing and Formulation. Examining organs, tissues, fluids or cells. Physical examination, laboratory testing and through diagnostic imaging techniques including radiography and ultrasound.

Unit-II: **10 hours**

Clinical Development: Definitions & Terminologies, History in Clinical Research, Regulations and Ethics in Clinical Research.IND, NDA& ANDA processes, requirements & guidelines. Clinical trial Preparation, Clinical Research Monitoring, Patient recruitment and retention, Adverse Event and Serious Adverse Event Reporting, Agreement and Clinical Trial Budget, Error Fraud and Misconduct QA/QC,Compliance Audit and Inspection, Project and Vendor Management, Finance Management of Clinical Trials.

Unit-III: **12 hours**

Clinical Evaluation/Reporting and documentation: Scope, Definations, General principles of clinical evaluation, Source of data/document used in clinical evaluation (stage1), Appraisal of clinical data (Stage2), Analysis of clinical data (stage3).The Clinical Evaluation Report and the role of the notified body in assessment of clinical evaluation data- Examination of design dossier, Evaluation as part of the quality system procedure and Notified body specific procedure and expertise. **Data Science -** Study Setup and CRF Designing for a clinical trial, Creating Reports and Transferring data. Clinical data analysis and reporting using software, Understanding and reviewing statistical analysis plan. Creating Analysis Datasets.

Unit-IV: **10 hours**

Safety and Security at workplace: Different types of occupational health hazards, knowledge of chemical substances, characteristics & safety measures, use of safety gears, masks, gloves & accessories, evacuation procedures for workers & visitors. Health, safety & security issues – types (illness, fire accidents), company policies and procedures, When and how to report, summon medical assistance & emergency services

Unit-V: **8 hours**

Interpersonal Skills: Understand work output requirements, company rules, guidelines & policies related to the process flow, identifying and reporting issues requiring intervention, delivery of quality work on time & report any anticipated reasons for the delay, importance of team work, resolution of conflicts, multi-tasking, training the team members, knowledge of project management

Syllabus of the practical papers

BiSEP5: Lab- I: UPSTREAM PROCESSING AND APPLICATIONS OF FERMENTATION

- Isolation of industrially important microorganisms
- Production of Industrially important Enzyme by submerged fermentation (Lab scale)
- Shake flask to lab scale fermenter studies
- Production of Industrially important Enzyme by solid state fermentation
- Production of Organic acids
- Production of Antibiotics
- Wine preparation
- Production of alcohol by microbes.
- Beer production, sampling and total and viable yeast cells
- Study of Microbial Growth Kinetics
- Production of biofuel by microorganism

BiSEP6: Lab-II: DOWNSTREAM PROCESSING

- Cell disruption by ultrasonication**.**
- Soxhlet extraction of plant metabolites and usage of flash evaporator.
- Partial purification of industrial important enzymes by ammonium sulphate precipitation.
- Partial purification of industrial important enzymes by dialysis and reverse osmosis.
- Chromatography of Industrial Important Enzymes.
- SDS-Polyacrylamide gel electrophoresis (SDS-PAGE)- Molecular weight
- Cell Separation by Centrifugation
- Purification and estimation of Organic Acid
- Purification of antibiotics and antibiotic assay
- Estimation of alcohol