Department of Biotechnology Savitribai Phule Pune University

PhD (Biotechnology) Coursework

(SPPU Circular No. 98/2025; w. e. f. academic year 2025-26)

Course	Name of the Course	Credits	No. of	Responsibility
No.		(Cr)	Hours	
1	Research Methodology (RM)	04 Cr	60	Research Center & research
				Supervisor
2	Attending at least one Seminar/	01 Cr	NA	Research Center & research
	Conference/Workshop (National/			Supervisor
	International) and Presenting			
	paper/poster (SCW)			
3	'Any Two' Subject specific advanced	08 Cr	120	Research Center
	level courses from four courses (SPAL-1			
	to SPAL-4)			
4	Research and Publication ethics (RPE)	02 Cr	30	Research Center
5	Pedagogical Training/Industrial Visit	01 Cr	30	Research Center & research
	Report/Assessment Statement (PIA)			Supervisor
	Total	16 Cr	240 Hr	

Course 1 - Research Methodology (04 Cr)

Course objectives: The course aims to give background on history of science, emphasizing methodologies employed in research, using framework of these methodologies for understanding effective lab practices and scientific communication and appreciate scientific ethics. Further, the course is designed for the students to learn basic biostatistical principles and how these principles are employed to decipher the significance of findings. The course also includes the use of various ways of data presentation to educate them about the importance of articulating data in appropriate formats of presentation.

Learning outcomes: Students should be able to understand history and methodologies of scientific research, applying these to recent published papers; understand and practice scientific reading, writing and presentations; appreciate scientific ethics through case studies. Students will learn to analyze and present the data in different formats by using some computational skills.

Evaluation: Students will be evaluated through continuous assessment and terminal examination for 30 and 70 marks. Accordingly, the marks and grade points will be given.

Unit I: Research Methodology (4 lectures)

History of science and science methodologies: Empirical science; scientific method; manipulative experiments and controls; deductive and inductive reasoning; descriptive science; reductionist vs holistic biology; lab and research question; maintaining a lab notebook.

Unit II: Research Designs: (4L)

Types of Research Designs and Stages Selection and Formulation of Research Problem, Objective(s) and Hypothesis Developing Research Plan – Exploration, Description, Diagnosis, Experimentation, Determining Experimental and Sample Design.

Unit III: Scientific Communication (4L)

Importance of communicating science; Scientific writing skills, problems in scientific writing; publication and project writing; Peer review process and problems; scientific presentation skills

Unit IV: Research Ethics (4L)

Various National and International Committees/Institutional Review Boards; Ethics in publications: Citation and Acknowledgement, Plagiarism; scientific misconducts.

Unit V: Data Collection, processing and presentation (6L)

Sources of Data – Primary and Secondary, Types of Data, – Categorical, discrete, Methods of Data Collection: Survey, Interviews (in-depth or Key Informant interviews), Challenges in data collection: ethics and governance, integrity and reproducibility, underrepresentation and overrepresentation, sociocultural aspects.

Qualitative Approaches Including Grounded Theory, Ethnography, Narrative Inquiry, Phenomenology and Case-Study. Statistical Graphics – Histograms, Frequency Polygon, pie charts, Dot plots, etc.

Unit VI: Biostatistics (12 lectures)

Probability: counting, conditional probability, types of variables, dependent and independent, discrete and continuous random variables, Error propagation; Populations and samples, Sampling and its methods, random sampling, non-probability sampling, expectation, measures of central tendency, Distribution, normal and skewed distribution, variation and its measures, Standard error, Kurtosis, Student t test, F-test, paired and unpaired test, confidence interval, single-tailed, double-tailed, Wilcoxon Rank sum test, Z-distribution, Correlation and linear regression, Pearson's correlation, r value, correlation & causality, analysis of variance (ANOVA), parametric tests of statistical significance, nonparametric hypothesis tests, factorial experiment design, practical approaches in biomedical data analysis.

Unit VII: Introduction to intellectual property (4L)

Types of IP: patents, trademarks, copyright & related rights, industrial design, traditional knowledge, geographical indications, protection of new GMOs; International framework for the protection of IP; IP as a factor in R&D; IPs of relevance to biotechnology and few case studies; introduction to history of GATT, WTO, WIPO and TRIPS; plant variety protection and farmers rights act; concept of 'prior art': invention in context of "prior art"; patent databases - countrywise patent searches (USPTO, EPO, India); analysis and report formation.

Unit VIII: Patenting (6L)

Basics of patents: types of patents; Indian Patent Act 1970; recent amendments; WIPO Treaties; Budapest Treaty; Patent Cooperation Treaty (PCT) and implications; procedure for filing a PCT application; role of a Country Patent Office; filing of a patent application; precautions before patenting-disclosure/non-disclosure - patent application- forms and guidelines including those of National Bio-diversity Authority (NBA) and other regulatory bodies, fee structure, time frames; types of patent applications: provisional and complete specifications; PCT and conventional patent applications; international patenting-requirement, procedures and costs; financial assistance for patenting-introduction to existing schemes; publication of patents-gazette of India, status in Europe and US; patent infringement- meaning, scope, litigation, case studies and examples; commercialization of patented innovations; licensing – outright sale, licensing, royalty; patenting by research students and scientists-university/organizational rules in India and abroad, collaborative research - backward and forward IP; benefit/credit sharing among parties/community, commercial (financial) and non-commercial incentives.

Unit IX: Biosafety and Biosecurity (4L)

Introduction; historical background; introduction to biological safety cabinets; primary containment for biohazards; biosafety levels; GRAS organisms, biosafety levels of specific microorganisms; recommended biosafety levels for infectious agents and infected animals; definition of GMOs & LMOs; principles of safety assessment of transgenic plants – sequential steps in risk assessment; concepts of familiarity and substantial equivalence; risk – environmental risk assessment and food and feed safety assessment; problem formulation – protection goals, compilation of relevant information, risk characterization and development of analysis plan; risk assessment of transgenic crops vs cisgenic plants or products derived from RNAi, genome editing tools.

Unit X: National and international regulations (6L)

International regulations: Cartagena protocol, OECD consensus documents and Codex Alimentarius; Indian regulations: EPA act and rules, guidance documents, regulatory framework – RCGM, GEAC, IBSC and other regulatory bodies; Draft bill of Biotechnology Regulatory authority of India - containments – biosafety levels and category of rDNA experiments; field trails – biosafety research trials – standard operating procedures - guidelines of state governments; GM labeling – Food Safety and Standards Authority of India (FSSAI).

Unit XI: Bioethics (6L)

Introduction, ethical conflicts in biological sciences - interference with nature, bioethics in health care - patient confidentiality, informed consent, euthanasia, artificial reproductive technologies, prenatal diagnosis, genetic screening, gene therapy, transplantation. Bioethics in research – cloning and stem cell research, Human and animal experimentation, animal rights/welfare, Agricultural biotechnology - Genetically engineered food, environmental risk, labeling and public opinion. Sharing benefits and protecting future generations - Protection of environment and biodiversity – biopiracy.

Recommended Textbooks and References:

- 1) Stroud, K. A., & Booth, D. J. (2009). Foundation Mathematics. New York, NY: Palgrave Macmillan.
- 2) Aitken, M., Broadhursts, B., & Haldky, S. (2009) Mathematics for Biological Scientists. Garland Science.

- 3) Billingsley, P. (1986). Probability and Measure. New York: Wiley.
- 4) Rosner, B. (2000). Fundamentals of Biostatistics. Boston, MA: Duxbury Press.
- 5) Daniel, W. W. (1987). Biostatistics, a Foundation for Analysis in the Health Sciences. New York: Wiley.
- 6) Valiela, I. (2001). Doing Science: Design, Analysis, and Communication of Scientific Research. Oxford: Oxford University Press.
- 7) On Being a Scientist: a Guide to Responsible Conduct in Research. (2009). Washington, D.C.: National Academies Press.
- 8) Gopen, G. D., & Smith, J. A. The Science of Scientific Writing. American Scientist, 78 (Nov-Dec 1990), 550-558.
- 9) Mohan, K., & Singh, N. P. (2010). Speaking English Effectively. Delhi: Macmillan India.

Course 2 - Seminar /Conference/Workshop (01 Cr)

Course objectives: It is highly desired that the candidate shall present his/her research work in the Seminar/Conference/Workshop etc. (National/International)

Learning outcomes: Scientific communication and interactions, collaborations, etc.

Evaluation: Research Center and Research Supervisor will evaluate the student for their performance and offer the grade point.

Course 3 – Subject-specific Advanced Level Courses (SPAL)

<u>SPAL 1</u> - Theoretical Foundations in research project (04 Cr)

Course objectives: This course aims to equip students with the fundamental theoretical knowledge and practical skills needed to design and conduct rigorous research projects. Emphasis will be placed on understanding research methodologies, designing experiments, and analyzing data.

Learning outcomes: Students will gain in-depth understanding about the literature into the subject-specific to their research. Research objectives and its know-how will be improved in the research.

Evaluation:

Internal: Literature review (evaluated by Supervisor); for 30 marks

External: Theoretical examination based on the questionnaire provided by Supervisor/mentor. For 70 marks

Course Overview:

Unit I: Identification of knowledge gap through literature survey and problem identification.

Unit II: Blueprint of research plan citing national and international research.

Unit III: Hypothesis building and research strategies employed to circumvent the research problems.

Unit IV: Novelty and translational opportunities in the proposed research plan.

SPAL 2 - Experimental designs in Research Project (T) (04 Cr)

Course Objectives: This course focuses on fostering innovation within research projects, emphasizing creative problem-solving, identifying research opportunities, and developing ground-breaking methodologies. Students will learn to design and implement innovative research projects that push the boundaries of current knowledge.

Learning outcomes: Students will gain in-depth understanding about the literature into the subject-specific to their research. Research objectives and its know-how will be improved in the research.

Evaluation:

Internal: Innovative case study, project proposal, prototype development, etc. (evaluated by Supervisor); For 30 marks

External: Theoretical examination based on the questionnaire provided by Supervisor/mentor. For 70 marks

Course Overview:

Introduction to Innovation in Research; Understanding Innovation Ecosystems; Identifying Research Gaps and Opportunities; Techniques for Creative Thinking and Brainstorming; Conducting State-of-the-Art Reviews; Case Studies of Innovative Research; Developing Innovative Research Questions; Formulating Hypotheses for Novel Research; Methodological Approaches for Innovation; Design Thinking in Research; Leveraging Technology and Tools for Innovative Research; Introduction to Emerging Technologies; Prototyping and Experimentation; Pilot Testing Innovative Ideas; Assessing Impact and Scalability; Finalizing and Presenting Research Proposals; Peer Review and Feedback Sessions

SPAL 3 - Advanced Techniques in Biotechnology Research (T) (04 Cr)

Course objectives: In last decade or so, numerous new laboratory techniques are developed. These techniques hold essential importance in the cutting-edge biotechnology research.

Learning outcomes: Students will learn recent advancements in tools and techniques employed in wet-lab research in biotechnology.

Evaluation:

Internal: Assignment/poster presentation (Evaluation by Supervisor); For 30 marks External: Theoretical examination based on the questionnaire provided by Supervisor/mentor. For 70 marks

Course Overview:

- Recent developments in gene editing and genetic engineering
- Recent developments in Microscopy
- Recent developments in Omics
- Advances in NGS/RNA sequencing/Microarray/Single cell-based sequencing
- Recent advances in big data analysis (through R)
- Introduction to emerging techniques like Synthetic biology, Chip-seq, optogenetics, functional genomics, Cryo Electron Microscopy, Microfluidics, 3D bioprinting, precision medicine, Biomanufacturing, Bio-fuel, Bioengineering among others

SPAL 4 - Current Topics in Biotechnology (T) (04 Cr)

Course objectives: Last couple of decades has witnessed enormous growth in newer innovations in biotechnology. The diagnostic and therapeutic approaches, plant varieties and microbial use in human life is being revolutionized. It is pertinent in today's education for the students to abreast with these novel innovative ideas in biotechnology.

Learning outcomes: Students will be well-verse with recent advances in diverse field of biotechnology and its practical applications.

Evaluation:

Internal: Assignment/poster presentation (Evaluation by Supervisor); For 30 marks External: Theoretical examination based on the questionnaire provided by Supervisor/mentor. For 70 marks

Course Overview:

Microbial Biotechnology: Microbial cell as Industrial Workhorse, Process Optimisation Strategies, On-farm microbial bioreactors for residue valorisation, Sustainable Green Technology for hydrogen production, Biofuel production from agricultural and dry municipal wastes, Biomining critical metals from e-waste, Smart microbial biosensors for oil-spill Early Warning, Biosensor for rapid pathogen detection at Point-of-Care, Magnetotactic-bacterial magnetosomes for recyclable metal "nano-hooks", Single-Use Bioreactors – Technology Innovation and Market Trends, Microbial Cell Engineering – CRISPR, ZFN, Talen, etc, CRISPR-encoded antimicrobials against AMR. Any other advancements in microbial biotechnology.

Animal Biotechnology: Knowledge of CRISPR-Cas9 genome editing technology and its applications, CAR T-cell therapy: development and challenges, Stem cell technology and its use in regenerative medicine, Microphysiological systems as an alternative to animal research, AI/ML in Drug Discovery, Synthetic genome technology (Synthetic Yeast), Single Cell Genomics, CRISPR Cas prime editing tool and its advantage. Any other advancements in animal biotechnology.

Plant Biotechnology: Plant tissue culture, Synthetic biology in Agriculture, *In planta* biomanufacturing - plants as biofactories, Metabolic pathway engineering for specialized metabolite biosynthesis, Plant engineering for abiotic and biotic stress tolerance- climate smart agriculture, Plant microbiome engineering, transformation and speed breeding technologies, Plant cell-based Biopharmaceutical production (e.g. Taliglucerease alpha, pegunigalsidase alfa, etc.). Any other advancements in plant biotechnology.

Recommended Textbooks and References:

- 1. Prospect of Animal Biotechnology and Future Developments, (Edn 2025) Edited By Arti Gupta, Ali Asghar Rastegari. Taylor and Francis Publishing
- 2. Animal Biotechnology. (Author P. K. Gupta) Rastogi Publications
- 3. Microbial Biotechnology: Principles and Applications (Edited by Lee Yuan Kun) World Scientific Publishing
- 4. Plant Biotechnology: Principles and Applications. Springer; (Edn 2017), by Malik Zainul Abdin, Usha Kiran, Kamaluddin, Athar Ali

Course 4 – Research and Publication Ethics -2 (02 Cr)

Department of Biotechnology will run the UGC-approved 02 credits course as per the UGC letter no. D.O.F. 1-1/2018 (Journal/CARE) and SPPU circular No. 65/2020 dated 3rd Mar. 2020.

Course objectives: To make student aware of the publication process and ethical publishing. The course will also sensitize the students about the publication ethics and scientific misconducts during publication process.

Learning outcomes: Students will understand the publication process and different forms of publishing the research papers. Moreover, students will learn the ethics in publishing. **Evaluation**: Students will be evaluated through continuous assessment and terminal examination for 15 and 35 marks, as internal and external evaluation respectively. Accordingly, the marks and grade points will be given.

Course Overview:

Modules	Unit Title	Teaching Hours		
Theory				
RPE1	Philosophy and Ethics 4	4		
RPE 2	Scientific Conduct 4	4		
RPE 3	Publication Ethics 7	7		
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Practice				
RPE 4	Open Access Publishing	4		
RPE 5	Publication Misconduct	4		
RPE 6	Database and Research Metrics	7		

Course 5 – Pedagogical Training/Industrial Visit Report/Assessment Statement (04 Cr)

Course objectives: The students to learn the process of translation of the education towards socioeconomic progress of the country.

Learning outcomes: Students will receive on-site exposure to the industries and laboratories serving in the biotechnological processes.

Evaluation: Students will submit the research report and it will be evaluated by research supervisor (7 marks) and by the centre (18 marks). Accordingly, the marks and grade points will be given.

Course Overview:

Visit to the Industry or any relevant laboratory engaged in biotechnological applications. Report writing and submission to the Supervisor and the Centre for evaluation.

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