PRAVARA INSTITUTE OF MEDICAL SCIENCES
(DEEMED TO BE UNIVERSITY)
Loni, Tal. Rahata, Dist. Ahmednagar 413736
NAAC Re-accrediated with 'A' Grade

SYLLABUS
Post Graduate Diploma in Animal Tissue Culture
(Centre for Biotechnology)
(Academic Council Meeting Dated 25th August, 2022)

Title: Post Graduate Diploma in Animal Tissue Culture (PGD-ATC)

CONTENT

PREAMBLE

Animal tissue culture technology is now becoming a significant model for many scientists in various fields of biology and medicine. Despite the various developments in animal cell and tissue culture from the late 1800s, until the early 1950s progress in animal tissue culture was stalled due to the non-availability of a suitable cell line. In the early 1950s, for the first time, the successful growth of cells derived from the cervical cancer of Mrs. Henrietta Lacks was demonstrated. This breakthrough using Henrietta Lacks's cells in culture successfully transformed medical and biological research, allowing numerous cellular, molecular and therapeutic discoveries, including the breakthrough of the first effective polio vaccine. This culture is now called HeLa, on which there were more than 60,000 publications by 2017, and which has been involved in numerous Nobel prize-winning innovations. Animal cell culture is a significant tool for biological research. The importance of cell culture technology in biological science was realized a long time ago. Earlier dedifferentiation-based experiments of cells due to selective overgrowth of fibroblasts resulted in the enhancement of culture techniques.

Animal cell culture involves the isolation of cells from the tissue before establishing a culture in a suitable artificial environment. Initial isolation of the cells from the tissues can be achieved by disaggregation using enzymatic or mechanical methods. The source of the isolated cells is usually an *in vivo* environment, but sometimes cells are also derived from an existing cell line or cell strain it also permits reliable and reproducible results and is thus considered a significant model system in cellular and molecular biology. Mammalian cell culture requires an optimal environment for growth. Environmental conditions are divided into nutritional requirements and physicochemical requirements. Nutritional requirements include a substrate or medium that provides support and essential nutrients such as amino acids, carbohydrates, vitamins, minerals, growth factors, hormones, and gases (O_2, CO_2). All these factors control physical and chemical factors such as pH, osmotic pressure, and temperature. In animal tissue culture, the majority of cells are anchorage-dependent and therefore require solid or semi-solid support in the form of a substrate (adherent or monolayer culture), whereas others can be cultured in the culture medium, called a suspension culture. Cell culture technologies have emerged as a tool to assess the efficacy and toxicity of new drugs, vaccines, and biopharmaceuticals, and also play a major role in assisted reproductive technology. Animal cell culture is one of the more important and diverse techniques in current research streams. Animal cells are more complex than micro-organisms. Due to their genetic complexity, it is difficult to determine

the optimum nutrient requirements of animal cells cultured under *in vitro* conditions. Animal cells require additional nutrients compared to micro-organisms, and they usually grow only when attached to specially coated surfaces. Despite these challenges, different types of animal cells, including both undifferentiated and differentiated ones, can be cultured successfully Animal cell culture is a type of biotechnological technique where animal cells are artificially grown in a favourable environment.

The growth of animal cells on artificial media is more difficult than growing microorganisms on artificial media and thus, require more nutrients and growth factors. However, advances in the culture media have made it possible to culture both undifferentiated and differentiated cells on artificial media. Animal cell cultures can be performed from different complexities of cells as complex structures like organs can also be used to initiate organ culture *in vitro*.

Depending on the purpose and application of the technique, cells, tissues, or organs can be used for the culture process. *In vitro* culture of isolated cells from different animals has helped in the discovery of different functions and mechanisms of operations of different cells. Some of the areas where animal cell culture has found most applications include cancer research, vaccine production, and gene therapy.

1. INTRODUCTION OF THE PROGRAMME:

Cell culture is the process by which human, animal, or insect cells are grown in a favourable artificial environment. The cells may be derived from multi cellular eukaryotes, already established cell lines, or established cell strains. In the mid-1900s, animal cell culture became a common laboratory technique, but the concept of maintaining live cell lines separated from their original tissue source was discovered in the 19th century. Animal cell culture is now one of the major tools used in the life sciences in areas of research that have a potential for economic value and commercialization. The development of basic culture media has enabled scientists to work with a wide variety of cells under controlled conditions; this has played an important role in advancing our understanding of cell growth and differentiation, identification of growth factors, and understanding of mechanisms underlying the normal functions of various cell types. New technologies have also been applied to investigate high cell density bioreactor and culture conditions. Many products of biotechnology (such as viral vaccines) are fundamentally dependent on the mass culturing of animal cell lines. Although many simpler proteins are being produced using rDNA in bacterial cultures, more complex proteins that are glycosylated (carbohydrate-modified) currently have to be made in animal cells. At

present, cell culture research is aimed at investigating the influence of culture conditions on viability, productivity, and the constancy of post-translational modifications such as glycosylation, which are important for the biological activity of recombinant proteins. Biological produced by recombinant DNA (rDNA) technology in animal cell cultures include anticancer agents, enzymes, immunobiologicals [interleukins, lymphocytes, monoclonal antibodies (mABs)], and hormones. Animal cell culture has found use in diverse areas, from basic to advanced research. It has provided a model system for various research efforts-

1. The study of basic cell biology, cell cycle mechanisms, specialized cell function, and cell-cell and cell-matrix interactions.
2. Toxicity testing to study the effects of new drugs.
3. The characterization of cancer cells, and the role of various chemicals, viruses, and radiation in cancer cells.
4. Gene therapy for replacing non-functional genes with functional gene-carrying cells..
5. Production of vaccines, mABs, and pharmaceutical drugs.
6. Production of viruses for use in vaccine production (e.g., chicken pox, polio, rabies, hepatitis B, and measles).

Today, mammalian cell culture is a prerequisite for manufacturing biological therapeutics such as hormones, antibodies, interferons, clotting factors, and vaccines.

2. SCOPE AND HIGHLIGHTS:

Currently, animal cell culture industries are expanding extensively to offer more reliable and sustainable healthcare solutions and diverse applications for current research streams. However, the establishment of a commercial animal tissue culture industry requires huge resources, and also many forms of approval, especially ethical approval, are essential to meet bioethical and safety requirements. Animal cell culture at the lab scale cannot be directly transferred to the commercial scale. To scale up or bridge the gap between animal cell labs and industry, various designs of bioreactor systems are required with special consideration for safety, bioethics, and validation part. However, the laboratory design and layout of the aseptic room and incubator should be properly planned to easily accommodate all the essential requirements and especially to prevent biological contamination.

Animal cell culture enables studies related to cell metabolism and understanding of the biochemistry of cells. It also allows observation of the effects of various compounds

like proteins and drugs on different cell types. Animal culture can be an important consideration in conservation management. As of 2020, culture and sociality were included in the aspects of the management framework of the Convention on the Conservation of Migratory Species of Wild Animals. The existence of culture in non-humans has been a contentious subject, sometimes forcing researchers to rethink "what it is to be human". The notion of culture in other animals dates back to Aristotle in classical antiquity, and more recently to Charles Darwin, but the association of other animals' actions with the actual word 'culture' originated with Japanese primatologists' discoveries of socially-transmitted food behaviors in the 1940s. Evidence for animal culture is often based on studies of feeding behaviors vocalizations, predator avoidance, mate selection, and migratory routes.

The nine applications of animal cell culture are:

[1]. Model Systems
[2]. Toxicity Testing
[3]. Cancer Research
[4]. Virology
[5]. Cell-Based Manufacturing
[6]. Genetic Counselling
[7]. Genetic Engineering
[8]. Gene Therapy and
[9]. Drug Screening and Development.

3. OBJECTIVES:

- To acquire the theoretical and practical principles of an animal cell and to familiarize the techniques involved in animal biotechnology
- To provide the necessary knowledge on animal cells for *in vitro* studies, maintenance of animal cells *in vitro*, manipulation of animal cells *in vitro*, and application of molecular techniques to *in vitro* situations.
- To understand cell handling, cell cryopreservation and revival, and contamination of cell lines with utmost care.
- To correlate theoretical aspects of cytotoxicity screening by *in-vitro* and its correlation to *in-vivo* levels.
- To understand the 2D and 3D cell culture models to study pharmacokinetic profiling studies in alternative to animal studies.

4. LEARNING OUTCOMES OF P.G. DIPLOMA PROGRAMME IN ANIMAL TISSUE CULTURE:

Sr. No.	Learning Outcomes
After undergoing this programme, students will be able to:	
1.	Understand the basics of animal tissue culture techniques
2.	Understand the usefulness of the in-vitro cell culture model for various biological questions
3.	Know the preparation of media, assessment of cell growth, and cryopreservation
4.	Demonstrate the ability to establish and maintain animal cell lines in culture
5.	Demonstrate the precautions to be taken to maintain aseptic cell cultures
6.	perform basic experiments related to animal tissue culture.

5. ELIGIBILITY

A candidate for being eligible for admission to the Post Graduate Diploma in Plant Tissue Culture must have taken either:

- Bachelor of Science in Basic Sciences/Applied Sciences/Pharmacy/Ayurveda/ Medical

6. FEE STRUCTURE: As per the PIMS-DU rules.

Fee Structure for PG Diploma Programmes at Centre for Biotechnology

No	PG Diploma Programme	Intake	Tuition Fee	Eligibility & Registration Fee	Other Fee	Security Deposit	Total Fee
1	PG Diploma in Animal Tissue Culture	5	**30,000**	2500	6,500	5,000	**44,000**

7. DURATION OF THE COURSE AND COURSE COMPLETION

The duration of the post-graduate Diploma Course shall be one year and there shall be a University Examination at the end of the course. The PG Diploma in Animal Tissue Culture shall not be conferred upon a candidate unless he/she has passed all subjects, practicals, and successful completion of the project.

8. EXAMINATION FOR COURSE.

a. The performance of the student for a semester for each course shall be evaluated as under.

b. For the theory & practical courses, there shall be two components of the examination.

1. Continuous Internal Assessment (CIA) for a maximum of 30% of total marks of a course comprising of two tests (written test/home assignments/ seminars etc.)
2. Semester End Examinations (SEE) for each course for a maximum of 70% of total marks. The duration of the theory examination shall be 6 hours.

c. For the practical courses, there shall be SEE for the entire 70% marks allotted to the course as per course structure and matrix. The Practical Examinations shall be for 3 hours.

d. The marks sheet/list for Internal Assessment shall be submitted to the office of the Controller of Examination (CoE) at least one week before the commencement of SEE.

9. CONDUCTION OF EXAMINATION AND EVALUATION.

a). The Office of the CoE shall arrange to conduct the Semester End Examination for subjects.

b). The CoE shall announce the calendar of examination specifying the aspects regarding the registration of candidates, eligibility certification for the list of candidates, payment of fees prescribed, and tentative schedule of examination.

c). The CoE shall arrange to assign the registration numbers and issue 'Hall Tickets' through the college to the certified eligible students.

d). The CoE shall announce the detailed 'Time-Table' and arrange to examine as per the prescribed rules and procedures specified in Examination Manual.

e). The University Board of Appointment of Examiners (BoAE), would constitute the Board of Examiners (BoE) for each subject.

f). The Board of Studies of each subject shall submit the approved list of examiners to the office well in time based on seniority, specialization, and other details.

g). The Board of Examiners shall arrange to set 3 sets of question papers for each of the assigned courses based on the syllabi. It shall set separate sets of question papers for repeaters/improvement candidates, in case of change in the syllabi. It shall follow the model question paper approved by the Board of Studies.

h). There shall be a Central Evaluation of the theory answer scripts for subjects. The Semester End Practical or Field Work Examination for each course shall be conducted by two examiners: preferably one internal and one external examiner.

i). The Office of the Registrar (Evaluation) shall arrange for the tabulation of marks awarded and determine the results.

10. STANDARD OF PASSING

a) A candidate securing minimum marks of 50% and above in aggregate of Internal Assessment Marks and of Semester End Examination for each of the courses in a semester shall be declared to have passed in the said course.

b) There will be 50% marks for passing in continuous internal assessment.

c) The minimum for passing in the Semester End Examination of any course is 50% of the maximum marks, wherever there is an Internal Assessment component.

d) Candidates failing in any of the courses of a semester are eligible to reappear for the supplementary exanimation of said courses of the semester within 6 months.

11. DECLARATION OF RESULTS AND AWARD OF CLASS AND RANKS

a) The degree shall be awarded to the candidates who have passed all the courses of the program for the two semesters.

b) After the completion of tabulation of marks for each course, grade points, and credit points for each course are calculated, only in the case of successful candidates.

c) Then the SGPA of the semester and CGPA of the semesters are calculated. The specimen of the marks card is given in **Annexures 1-2.**

d) The class will be awarded to the successful candidates considering the total marks secured in the courses during the I to VI semesters.

e) The classification of successful candidates for the award of classes and CGPA, letter grade for the Programme is as follows:

Cumulative Grade Point Average (CGPA)	Total Percentage of Marks	Class to be Awarded	Letter Grade
7.5 to 10.0	> 75%	First class with Distinction	A +
6.0 and above but below 7.5	60 – 74.9%	First Class	A
5.5 and above but below 6.0	55 – 59.9 %	High Second Class	B +
5.0 and above but below 5.5	50 – 54.9 %	Second Class	B
Below 5.0	-	Fail	F

The CoE / Registrar Evaluation shall arrange to issue the marks cards for all the semesters & overall passes of all semesters indicating both marks system with the class system as well CGPA with a letter grade. Only the grades and class shall be used for only the declaration of final /overall results. On other semester examinations, it is pass or fail remarks.

12. COURSE STRUCTURE

S. No.	Course Code	Course Name	No. of Hours per Week			Credit	Distribution of marks		
			Lecture/ Tutorials	Practical	Total		Int. Exam	Univ. Exam	Total
FIRST SEMESTER									
1.	**PGD-ATC 101**	Basic Techniques in Animal Tissue Culture	4	-	4	4	30	70	100
2.	**PGD-ATC 102**	Animal Tissue Culture- Advance Technology for Modern Research	4	-	4	4	30	70	100
3.	**PGD-ATC 103**	Basic Techniques of Mammalian cell culture	4	-	4	4	30	70	100
4.	**PGD-ATC 104**	Applications of Animal Tissue culture	4		4	4	30	70	100
5.	**PGD-ATC 105**	Practical – 1 based on Paper PGD-ATC 101	-	4	4	2	30	70	100
6.	**PGD-ATC 106**	Practical – 2 based on Paper PGD-ATC 102	-	4	4	2	30	70	100
7.	**PGD-ATC 107**	Practical – 3 based on Paper PGD-ATC 103		4	4	2	30	70	100
		Total	**16**	**12**		**22**			**700**
SECOND SEMESTER									
1.	**PGD-ATC 201-ELE**	Research Methodology IPR & Laboratory Practices **(Choose anyone)**	4		4	4	30	70	100
2.	**PGD-ATC 202**	Tissue Engineering	4		4	4	30	70	100
3.	**PGD-ATC 203**	Project Dissertation & Viva Voce	-			16			250
4.	**PGD-ATC 204**	Seminar, Presentation/ Group Discussion	2			2			50
		Total				**26**			**500**

FIRST SEMESTER

Basic Techniques in Animal Tissue Culture (PGD-ATC 101)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-ATC 101	Core	Basic Techniques in Animal Tissue Culture	4		2	120	6

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Introduction	• Historical events in the development of cell culture	8
Unit II	Basic Techniques in Animal Cell Culture	• Aseptic technique • Monitoring and prevention of contamination • Preparation of primary culture • Maintainance of the cell culture • Subculturing from primary to secondary cell culture • Producing cell lines of a particular cell type • Propagating a cell line	12
Unit III	Culture media	• Basic media • Buffering capacity • Glutamine And amino acids • Serum • Antibiotics and actinomycotics • Supply and preparation of culture media	10
Unit IV	Basic Characteristics of Tissue culture	• Tissue culture • Organ culture • Explant culture • Dissociated cell culture	10
Unit V	Culturing animal cell	• Adult or embryonic tissue • Embryonic stem cells • Normal or Neoplastic tissue	10
Unit VI	Selecting Types of animal cell culture	• Organ culture or cell culture • Adherent or suspension culture • Primary culture or continuous cell line	10

Application of Animal Tissue Culture (PGD-ATC 102)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-ATC102	Core	Application of Animal Tissue Culture	4		2	120	6

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Hydrolysates in Animal cell culture	• Introduction • The advent of animal cell culture • Composition of hydrolysates • Hydrolysates can enhance biotherapeutic protein quality and yield	10
Unit II	Toxicity testing	• Toxicity testing • Concern about animal use in toxicity testing • Integrated testing strategy	10
Unit III	Virology	• Introduction • Basic Validations of animal cells used for isolation of viruses • Complications arising from the use of primary cells for virus isolation • Maintenance of virus-infected cells cultures over a few months • Engineered cell lines for virus isolation	12
Unit IV	Genetic Engineering	• Introduction • Recombinant DNA technology • Gene function and expression in mammals • Use of genomic information in animal improvement • Cloning adult mammals	13
Unit V	Advanced cell culture Techniques for Cancer Drug Discovery	• Introduction • Modeling cancer in 3D cell structure • Drug resistance and 3D Tumor model • Utilizing 3D model in Drug Discovery	15

Animal Tissue Culture -Advance Technology for Modern Research (PGD-ATC 103)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-ATC103	Core	Animal Tissue Culture-Advance Technology for Modern Research	4		2	120	6

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Advances in Cell Culture	• 3D cell culture • 3D cell culture and cancer • 2D versus 3D cell culture	15
Unit II	Mammalian cell culture technology	• Preparing an aseptic environment • Preparation of cell growth medium • Creating a correct cell culture environment • Checking cells • Subculturing • Subculturing of suspension cell line	15
Unit III	Recent achievements and perspectives in the production of biopharmaceuticals	• Introduction • A monoclonal antibody as a drug • Fusion protein drug • Drug approval and recognition	15
Unit IV	Special issue on Recent advances in Animal cell culture	• Bioprinting • Medical application of 3D bioprinting • Future prospective	15

Basic Techniques of Mammalian Cell Culture (PGD-ATC 104)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-ATC104	Core	Basic Techniques of Mammalian cell culture	4		2	120	6

Sr. No.	Topic	Detail of syllabus	Hrs.
Unit I	Trypsinization and subculturing cells from a monolayer	• Trypsinization principle • Trypsinization protocol • Subculturing procedure • Monolayer cell culture	
Unit II	Passaging cells in suspension culture	• Introduction • Materials • Protocol of passaging suspension cells	
Unit III	Freezing Human cells grown in monolayer culture	• Introduction • Preparation • Cryoprotectants • Equilibration • Storage • Recovery • Cryopreservation protocol	
Unit IV	Thawing and recovering of human cells	• Cell thawing principle • Cell thawing protocol • Cell recovery, cell recovery after thawing • Cryopreservation and thawing of cells	
Unit V	Cell Counting & Viability	• Cell counting (hemocytometer) • Trypan blue staining	

Practicals

Paper – PGD-ATC 105: Practical 1 Based on paper PGD- ATC 101

1. ATC laboratory design and equipment used in ATC –
2. Structure and design of ATC Laboratory
3. Equipment used:
4. Biosafety Cabinet, CO_2 incubator, inverted microscope, autoclave, Filter sterilization assembly, Centrifuge, Refrigerator, pH meter, etc.
5. Introduction to the aseptic condition –
6. Maintaining aseptic condition
7. Glassware washing, packing, sterilization
8. Filter sterilization assembly, forceps, glass pipettes, Petri plates, beaker & conical flask
9. Buffer preparation
10. Media preparation and sterilization
11. ELISA

Paper – PGD-ATC 106: Practical 2 Based on paper PGD- ATC 102

1. Maintenance of cell line – observation of cell line and feeding of media, subculturing – viable cell count, split ratio
2. Toxicity testing (MTT)
3. Cell cycle analysis (flow Cytometry)

Paper – PGD-ATC 107: Practical 3 Based on paper PGD- ATC 104

1. Thawing of VERO Cell Culture
2. Passaging
3. Cell Quantification and percent viability
4. Cryopreservation
5. Initiation of primary cell culture - Initiation of primary cell culture from chick embryo by trypsinization

SECOND SEMESTER

Research Methodology (PGD-ATC 201 ELV)

Course Code	Category	Course Name	L	P	Total Hours	Credits (T+P)
PGD-ATC 201 ELV	Elective	Research Methodology	4	-	60	4

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Introduction of Research	• Characteristics of Research • Steps involved in Research • Research in Pure and Applied Sciences - Inter-Disciplinary Research. • Factors that hinder Research • Significance of Research • Research and scientific methods • Research Process– Criteria of Good Research • Problems encountered by Researchers • Literature review.	12
Unit II	Identification of Research Problem	• Selecting the Research problem • The necessity of defining the problem • Goals and Criteria for identifying problems for research.	08
Unit III	Research Design	• Need for Research design • Formulation of Research design • Features of a research design • Important concepts related to Research design. • Different research designs • Computer and internet in research designs.	10
Unit IV	Interpretation and Report Writing	• Meaning and Technique of Interpretation • Precautions in interpretation • Significance of report writing • Different steps in writing a report • The layout of a Research report. • Types of reports • Mechanics of writing a research report • Precautions for writing a research report	10
Unit V	Statistical Techniques and Tools	• Introduction to statistics, Functions & Limitations • Sample size estimation • Measures of central tendency • Calculation of percentage and frequency • Arithmetic mean – Median – Mode • Standard deviation & Standard Error • Co-efficient of variation (Discrete serious and continuous serious)	20

Sr. No.	Topic	Details of Syllabus	Hrs.
		• Correlation & Regression • Sampling distribution • Concept of point and interval estimation • Level of significance • Degree of freedom • Analysis of variance (ANOVA & ANOVA followed by different tests) • One-way and two-way classified data • 'F'-test, 'Z ' test & Chi-square Test • Basic knowledge of SPSS, GraphPad Prism, R and EPI-Info	

Recommended Books/References

1. A Hand Book of Methodology of Research, Rajammall, P. Devadoss and K. Kulandaivel, RMM Vidyalaya press, 1976.
2. Research Methodology Methods & Techniques, C.R. Kothari – New Age international Publishers, Reprint 2008.
3. Research Methdology, R. Panneerselvam, PHI Learning Pvt. Limited, Delhi.
4. Thesis and Assignment Writing, J. Anderson, Wiley Eastern Ltd., 1997.
5. Research Methodology, Mukul Gupta, Deepa Gupta – PHI Learning Private Ltd., New Delhi, 2011.
6. Fundamentals of Mathematical statistics, S.C. Gupta and V.K. Kapoor, Sultan Chand& Sons, New Delhi,1999.
7. Statistical Methods, G.W. Snedecor and W.G. Cochrans, Lowa State University Press, 1967.
8. Methods in Biostatistics by B. K. Mahajan
9. Fundamentals of Biostatistics by Khan &Khanum
10. Fundamentals of Biostatistics by U.B.Rastog
11. Basic & Clinical Biostatistics, Beth Dawson and Robert G. Trapp. Lange Medical Books/McGraw-Hill Medical Publishing Division

IPR & Laboratory Practices (PGD-ATC 201 ELV)

Course Code	Category	Course Name	L	P	Total Hours	Credits (T+P)
PGD-ATC 201 ELV	Elective	IPR & Laboratory Practices	4	-	60	4

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Overview of Intellectual Property	• Introduction and the need for intellectual property right (IPR) - Kinds of Intellectual Property Rights: Patent, Copyright, Trade Mark, Design, Geographical Indication, Plant Varieties and Layout Design • Genetic Resources and Traditional Knowledge • Trade Secret • IPR in India: Genesis and development • IPR in abroad - Major International Instruments concerning Intellectual Property Rights: Paris Convention, 1883, the Berne Convention, 1886, the Universal Copyright Convention, 1952, the WIPO Convention, 1967,the Patent Co-operation Treaty, 1970, the TRIPS Agreement, 1994	09
Unit II	Patent	• Patents - Elements of Patentability: Novelty, Non-Obviousness (Inventive Steps), • Industrial Application - Non - Patentable Subject Matter - Registration Procedure, Rights and Duties of Patentee, Assignment and license, • Restoration of lapsed Patents, Surrender and Revocation of Patents, Infringement, Remedies & Penalties – • Patent office and Appellate Board	08
Unit III	Trademarks	• Concept of Trademarks • Different kinds of marks (brand names, logos, signatures, symbols, well-known marks, certification marks and service marks) • Non Registrable Trademarks • Registration of Trademarks • Rights of holder and assignment and licensing of marks • Infringement, Remedies & Penalties • Trademarks registry and appellate board	08
Unit IV	Other forms of IP	• Design: meaning and concept of the novel and original - Procedure for registration, the effect of registration and term of protection • Geographical Indication (GI) Geographical indication: meaning, and the difference between	05

Sr. No.	Topic	Details of Syllabus	Hrs.
		GI and trademarks -	
Unit V	Introduction Good Documentation Practices -GLP and Quality Assurance	• History of Good Laboratory Practices • Good Laboratory Practices- Introduction, OECD, FDA and WHO Guidelines on GLP & GMP • Quality assurance in Good Laboratory Practices • Good record keeping: Forms update: Form-C, Form-D, Part-A, Part -B, Firm -E etc.,	08
Unit VI	Quality standards and Quality Assurances	• Quality Standards- Advantages and Disadvantages • Quality Assurance- Their functions and advantages • Quality assurance and quality management in the industry • Customer requirement of quality • Government and trade standards of quality Federal Food and Drug Law FDA Action BSTI Laws, BSTI action and activities Other food laws (Legalization) • Trade and Company Standards Control by National, International, Social Organizations (example: FAO, GAFTA, WHO, UNICEF, CAB), Society (example: NSB, Professional societies)	12
Unit VII	Biosafety	• General lab equipment • Introduction & development of Biosafety • Practices & Principles • Definitions & Biosafety levels, 1, 2, 3, 4,; Biological safety cabinets • Shipment of biological specimens • Decontaminations • Biosafety manuals; Medical surveillance, Emergency response. • Biological waste management	10

Recommended Books/References/Website:

1. T. M. Murray & M. J. Mehlman, Encyclopedia of ethical, legal and policy issues in biotechnology, John Wiley & sons 2000.
2. Ethical Issues in Biotechnology by Richard Sherlock & John D. Morrey, Rowman& Littlefield Publishers.
3. Nithyananda, K V. (2019). Intellectual Property Rights: Protection and Management. India, IN: Cengage Learning India Private Limited.
4. Neeraj, P., &Khusdeep, D. (2014). Intellectual Property Rights. India, IN: PHI learning Private Limited.
5. Ahuja, V K. (2017). Law relating to Intellectual Property Rights. India, IN: Lexis Nexis.
6. Subramanian, N., &Sundararaman, M. (2018). Intellectual Property Rights – An Overview. Retrieved from http://www.bdu.ac.in/cells/ipr/docs/ipr-eng-ebook.pdf
7. World Intellectual Property Organisation. (2004). WIPO Intellectual property Handbook. Retrieved from https://www.wipo.int/edocs/pubdocs/en/intproperty/489/wipo_pub_489.pdf.
8. Cell for IPR Promotion and Management (http://cipam.gov.in/)
9. World Intellectual Property Organisation (https://www.wipo.int/about-ip/en/)
10. Office of the Controller General of Patents, Designs & Trademarks (http://www.ipindia.nic.in/)
11. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, Volume I & II, Mumbai.
12. Good Laboratory Practice Regulations, Sandy Weinberg Vol. 69, Marcel Dekker Series.
13. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, WHO Publications.
14. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series.

Tissue Engineering (PGD-ATC 202)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-ATC104	Core	Tissue Engineering	4			60	4

Sr. No.	Topic	Detail of syllabus	Hrs.
Unit I	Introduction	• Classic tissue engineering • Tissue engineering is multidisciplinary by necessity • Process of tissue engineering • Types of cells	8
Unit II	Cell Biology-The Basis of Growth and Differentiation	• Mammalian cell types • Differentiation • Mechanism • Epigenetic control – the importance of epigenetic control • Mechanism of epigenetic regulation	15
Unit III	Animal cell culture media	• Introduction • The media used in animal cell and tissue culture – Natural medium and synthetic medium • Culture procedure • Preparation of starting material	12
Unit IV	Morphogenesis	• Introduction • Overview of mechanics in animal morphogenesis • Mechanical patterning in animal morphogenesis	15
Unit V	Tissue culture	• Introduction • Types of cell culture • Safety considerations in animal tissue culture	10

Recommended Books/References/Website for Core Subjects:

1. Jackson AT., Bioprocess Engineering in Biotechnology, Prentice Hall, Engelwood Cliffs, 1991.
2. Shuler ML and Kargi F., Bioprocess Engineering: Basic concepts, 2nd Edition, Prentice Hall, Engelwood Cliffs, 2002.
3. Mansi EMTEL, Bryle CFA. Fermentation Microbiology and Biotechnology, (2nd Ed). Taylor & Francis Ltd, UK, 2007.
4. Colin Ratledge and Bjorn Kristiansen, Basic Biotechnology (2nd Ed.).Cambridge University Press. 2002.
5. Prescott, Sc and Dunn, C. Industrial Microbiology, McGraw Hill, New York. 1984
6. Michael, L. Shulers and Fikret Kargi. Bioprocess Engineering: Basic concepts (2nd Ed.) Prientice Hall Publishers. 2001
7. Paulins, M. D. Bioprocess Engineering Principles. John Wiley Publishers.2003
8. R Ian Freshney (2010) Culture of Animal Cells (6th Ed), Wiley-Blackwell
9. John Davis (2011) Animal Cell Culture Essential Methods, Wiley & Sons
10. Satyanarayana U (2008) Biotechnology, Books and Allied Ltd.
11. Molecular Biotechnology: 4th edition. (2010), Glick B.R., Pasternak J.J., Patten C. L., ASM press, USA
12. Ernst-L Winnacker, From Genes to Clones: Introduction to Gene Technology. WILEY-VCH Verlag GmbH, Weinheim, Germany Reprinted by Panima Publishing Corporation, New Delhi. 2003
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PGD- ATC 203: Project

The purpose of introducing project work is to enable the students to apply the knowledge, skills, and attributes, acquired during the entire course, to the solution of specific problems related to practical work. The students will have to go through all the steps of problem-solving such as defining the problem, analysis of the problem, collecting required information and resources, formulating alternatives, selecting the best solution, and practicing it.

The project work aims at, besides developing problem-solving abilities in the students, the development of confidence and expertise in a particular field. The student may get the required skills to analyze the problem, use instruments, and use techniques and orientation of learning experiences towards their applications in the world of work. Students shall identify the problem with the help of their project guide.

Annexure-1

PRAVARA INSTITUTE OF MEDICAL SCIENCES

(DEEMED TO BE UNIVERSITY)

Centre for Biotechnology

Loni 413736, Ahmednagar District, Maharashtra State, India

Post Graduate Diploma Program in Animal Tissue Culture
The Pattern of Marks Statement

Semester: I
Month & Year: _____ Name of the Student:_____ Reg. No: _____

	Course Number & Code	Title of Course	Credits	Internal Assessment Marks		Semester End Exam.			Total Marks			GP	CP
				Max.	Secured	Max.	Min. for Pass	Marks Secured	Max.	Min. for Pass	Secured		
	PGD-ATC 101	Basic Techniques in Animal Tissue Culture	4	30		70	35		100	50			
	PGD-ATC 102	Animal Tissue Culture- Advance Technology for Modern Research	4	30		70	35		100	50			
	PGD-ATC 103	Basic Techniques of Mammalian cell culture	4	30		70	35		100	50			
	PGD-ATC 104	Applications of Animal Tissue culture	4	30		70	35		100	50			
	PGD-ATC 105	Practical – 1 based on Paper PGD-ATC 101	2	30		70	35		100	50			
	PGD-ATC 106	Practical – 2 based on Paper PGD-ATC 102	2	30		70	35		100	50			
	PGD-ATC 107	Practical – 3 based on Paper PGD-ATC 104	2	30		70	35		100	50			
Grand Total			**22**						**700**				

Annexure-2

PRAVARA INSTITUTE OF MEDICAL SCIENCES

(DEEMED TO BE UNIVERSITY)

Centre for Biotechnology

Loni 413736, Ahmednagar District, Maharashtra State, India

Post Graduate Diploma Program in Animal Tissue Culture
The Pattern of Marks Statement

Semester: II
Month & Year: _____ Name of the Student:_____ Reg. No: _____

	Course Number & Code	Title of course	Credits	Internal Assessment Marks		Semester End Exam.			Total Marks			GP	CP
				Max.	Secured	Max.	Min. for pass	Marks secured	Max.	Min. for pass	Secured		
	PGD-ATC 201-ELE	Research Methodology	4	30		70	35		100	50			
	PGD-ATC 201-ELE	IPR & Laboratory Practices **(Choose anyone)**				70	35						
	PGD-ATC 202	Tissue Engineering	4	30		70	35		100	50			
	PGD-ATC 203	Project Dissertation & Viva Voce	16	30					250	50			
	PGD-ATC 204	Seminar, Presentation/ Group Discussion	2	30					50	50			
Grand Total			**26**						**500**				

PRAVARA INSTITUTE OF MEDICAL SCIENCES * Loni - 413736 Tal - Rahata Dist. Ahmednagar (M.S. India) * (Deemed to be University)

Registrar
Pravara Institute of Medical Sciences
(Deemed to be University)
Loni - 413736,Tal. Rahata
Dist. Ahmednagar (M.S. India)