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 Laboratory Animal Management
(Centre for Biotechnology)
(Academic Council Meeting Dated 25th August, 2022)

Title: Post Graduate Diploma in Laboratory Animal Management (PGD-LAM)

CONTENT

PREAMBLE

The objective of this Post Graduate Diploma in Laboratory Animal Management (PGD-LAM) course is to generate skilled human resources ready for employment in the industry and academia. This is a unique opportunity for skill development and training in the area of laboratory animal care, animal ethics, housing requirements, handling, breeding and breeding techniques and care and management of laboratory animals. The course will cover the basics of how to manage the animal facility, routine care and management practices of laboratory animals, quality procedures and techniques. The trained and skilled candidates will have good job prospects in the area of biomedical research, preclinical research and development in public and private research institutes, pharma industries and academia. The candidates will have an opportunity for practical exposure to various animal or test systems, animal housing requirements, laboratory animal handling, breeding practices, and routine care & management of laboratory animals.

1. INTRODUCTION OF THE PROGRAMME:

The programme aims at promoting professional development and capacity building in the area of animal and preclinical research. Pre-clinical or Non-clinical research is a multidisciplinary subject that is evolving rapidly with the core components of animal welfare science, ethics, laws, housing, handling, breeding, animal facility maintenance, and drug administration by various routes. In general, we are concerned about the welfare of all animals that are managed in some way by humans, and we have particular responsibilities for their care. In the past, the greatest concern about animal study has been given to 'farm animal welfare. Over time, welfare issues pertaining to working, performing, companion, zoo and lab animals have also received attention. Keeping all this in view, the PGDLAM programme covers basic procedures related to laboratory animal housing, proper handling and breeding techniques, care and management, animal ethics, welfare, laws, and routine maintenance of animal facility operations as per accepted national and international standards.

2. SCOPE AND HIGHLIGHTS:

This Program will train you in the areas such as:

- National and international requirements of laboratory animal housing, care and management practices.
- Develop and improve skills related to animal handling, drug administration and blood sampling.
- Applications or role of animals in research, testing, drug development and teaching - learning.
- Exposure to various theoretical and practical aspects related to preclinical research or animal experimentations.
- Animal ethics, laws and policies related to animal welfare, principles of 3R's (Replacement, Reduction & Refinement) as alternatives to animal testing.

3. OBJECTIVES:

- To acquire or study various laboratory skills related to housing care and maintenance and animal handling.
- To study or be aware of animal welfare, ethics principles and laws while conducting scientific and teaching activities using animals.
- To provide comprehensive hands-on training for learning the basics with an insight to laboratory techniques.

4. LEARNING OUTCOMES OF P.G. DIPLOMA PROGRAMME IN LABORATORY ANIMAL MANAGEMENT

S. No.	Learning Outcomes
1.	Develop knowledge of Laboratory animal biology including; basics of genetics, nutrition, housing requirements, and accepted national and international guidelines required for an animal facility.
2.	Application of scientific principles to animal housing, handling, care, breeding, feeding, watering, growth and development, and health management.
3.	Role of animals in biomedical or non-Clinical research.
4.	Understanding basic concepts relating to the animal experimental design and analysis of research parameters.
5.	Awareness on principles of animal welfare, care and ethics in animal research. To study various alternative /*in vitro* methods to animal testing.

5. ELIGIBILITY

A candidate for being eligible for admission to the Post Graduate Diploma in Laboratory Animal Management must have taken either:

- Bachelor of Science in Basic & Applied Sciences/ Pharmacy

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

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 Laboratory Animal Management	5	30,000	2500	6,500	5,000	44,000

7. DURATION OF THE COURSE AND COURSE COMPLETION

The duration of the diploma course shall be one year and there shall be a University Examination at the end of each semester. The PGDLAM shall not be conferred upon a candidate unless he/she has passed in all subjects, practicals, and successful completion of the project.

8. EXAMINATION FOR COURSE.

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

a) 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 3 hours.

b) For the practical courses, there shall be Semester End Examinations for the entire 70% marks allotted to the course as per course structure and matrix. The Practical Examinations shall be for 6 hours.

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

9. CONDUCTION OF EXAMINATION AND EVALUATION.

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

b). The Controller of Examination 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 Controller of Examination shall arrange to assign the registration numbers and issue 'Hall Tickets' through the college to the certified eligible students.

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

e). The University Board of Appointment of Examiners (BoAE), would constitute 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 programme 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 fails 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-LAM 101**	Care and Management of Laboratory Animals	4	-	4	4	30	70	100
2.	**PGD-LAM 102**	Nutritional Requirements for Animals	4	-	4	4	30	70	100
3.	**PGD-LAM 103**	Principles of Animal Ethics and Associated Laws	4	-	4	4	30	70	100
4.	**PGD-LAM 104**	Animal Handling Techniques & Animal models	4		4	4	30	70	100
5.	**PGD-LAM 105**	Practical – 1 based on Paper PGD-LAM 101	-	4	4	2	30	70	100
6.	**PGD-LAM 106**	Practical – 2 based on Paper PGD-LAM 102	-	4	4	2	30	70	100
7.	**PGD-LAM 107**	Practical – 3 based on Paper PGD-LAM 104		4	4	2	30	70	100
		Total	**16**	**12**		**22**			**700**
SECOND SEMESTER									
1.	**PGD-LAM 201 ELV**	Research Methodology / IPR & Laboratory Practices **(Choose anyone)**	4	-	4	4	30	70	100
2.	**PGD-LAM 202**	New Trends in Animal Experimental Biology	4	-	4	4	30	70	100
3.	**PGD-LAM 203**	Project Dissertation & Viva Voce	-	-		16	-	-	250
4.	**PGD-LAM 204**	Seminar, Presentation/ Group Discussion	2	-		2	-	-	50
		Total	**10**		**08**	**26**			**500**

FIRST SEMESTER

Animal Care and Management of Laboratory Animals (PGD-LAM 101)

Course Code	Category	Course Name	L	P	Total Hours	Credits (T+P)
PGD-LAM 101	**Core**	**Animals Care and Management of Laboratory Animals**	**4**	**2**	**120**	**6**

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Introduction	• Animal house/facility – design and maintenance, Infrastructure, environmental conditions and other requirements as per CPCSEA Guidelines for various laboratory animal research (rodents, large animals, fish, avian species). • Formation, functionalities, documentation, review and approval of animal protocols by the Institute Animal Ethics Committee (IAEC) • Role of "Committee for the Purpose of Control and Supervision of Experiments on Animals" (CPCSEA) in animal research. • Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) requirements	15
Unit II	Animal Biology and Breeding	• Introduction: Definition of animal breeding, History of animal breeding, Value of genetic improvement. • Variation: Phenotypic variation, Genetic variation, Concept of heritability. • Systems of mating: Inbreeding and Cross-breeding • Animal breeding programs: Nucleus breeding program, Genotype-X environment interaction, emerging technologies • Test system, various species and strains of lab animals and their application in research	15
Unit III	Environmental Factors	• Climatic control: Temperature, Humidity, Ventilation, Light and dark cycle, Other Environmental factors: Noise, odour, Bedding Population Density and space • Occupational safety and personal hygiene in the animal facility.	15

Sr. No.	Topic	Details of Syllabus	Hrs.
		• Contaminant analysis of feed, water, bedding material • Proximate analysis of feed, water, proper cleaning, hygiene and sanitation in the animal facility • Movement of personnel, and material in and out of the facility	
Unit IV	Laboratory Animal Care	• The well-being of Laboratory Animals • Sanitation and Sterilization of Animal Accessories • Reception. • Quarantine • Methods of Animal Handling • Maintenance. • Identification and Documentation of Records • Feed and Water • Contaminant analysis • Training of personnel involved in the animal facility: animal care personnel, scientific staff • Health monitoring of animals	15

Nutritional Requirements for Animals (PGD-LAM 102)

Course Code	Category	Course Name	L	P	Total Hours	Credits (T+P)
PGD-LAM 102	**Core**	**Nutritional Requirements for Animals**	**4**	**2**	**120**	**6**

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Animal nutrition – energy & protein	• Basic terminology, chemistry and classification of carbohydrates, fats and proteins. • Fat and Protein in different species of animals.	5
Unit II	Digestion and metabolism of Carbohydrates	• Digestion and Absorption of carbohydrates, Bioenergetics, biological oxidation, glycolysis, Citric acid cycle, pentose phosphate pathway and glycogenesis, gluconeogenesis, respiratory chain and oxidative phosphorylation and ATP generation. • Recent advances in glycogenic precursors on acetate utilization. • Disorders of carbohydrate metabolism.	12
Unit III	Digestion and metabolism of Protein	• Catabolism of amino acids, transamination and determination, urea cycle. Conversion of amino acids into other bioactive compounds. Biosynthesis of nutritionally non-essential amino acids. Metabolism of purines and pyrimidines. • Non-Protein Nitrogen (NPN) metabolism, urea fermentation potential & metabolizable protein. • Amino acids imbalance, antagonism and toxicity. • Disorders of nucleic acid & amino acid metabolism.	13
Unit IV	Digestion and metabolism of Fat	• Biosynthesis and oxidation of fatty acids. Volatile fatty acids as a source of energy in ruminants. Fatty acid oxidation, Ketogenesis and cause of ketosis in	10

Sr. No.	Topic	Details of Syllabus	Hrs.
		ruminants. Biosynthesis of sterols and phospholipids. • Disorders of lipid metabolism.	
Unit V	Animal nutrition – minerals, vitamins and Feed additives	• Essential minerals, the General role of minerals, the requirement of minerals, Factors affecting requirements and Probable essential minerals. • Macro elements and microelements, their distribution, metabolism, physiological functions, deficiencies & excesses, requirements and sources. • Toxic minerals- Definition, history, classification, chemistry, functions, deficiencies and excesses, requirements • Sources of water-soluble and fat-soluble vitamins. • Composition of diet, Diet for maintenance, growth for various species of animals	20

Animal Ethics and Associated Laws/Regulations (PGD-LAM 103)

Course Code	Category	Course Name	L	P	Total Hours	Credits (T+P)
PGD-LAM 103	**Core**	**Animal Ethics and Associated Laws and Issues**	**4**	**2**	**120**	**6**

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Introduction and Foundations	• What is "Animal"? • Ethical Foundations of Animal Law • Animals as Property and Beyond • CPCSEA Guidelines for various laboratory animal research (rodents, large animals, fish, avian species). • Formation, functions, documentation, review and approval of animal protocols by IAEC • Role of IAEC and CPCSEA in animal research. • AAALAC requirements	17
Unit II	Laws, policies of animals welfare	• Historical Background • Animal Welfare Acts (Animal Cruelty): State and Federal • Sciences and Animal Suffering • Prevention of Cruelty to Animals (PCA) act, Animal Welfare Board of India • Assessment of pain and distress, classification (Clinical signs observation/scoring and grim ace scale scoring) • Ethics of humane experimentation and 3-Rs (Replacement, Reduction & Refinement) • Procedural and Substantive Barriers (Barriers to Prosecution; What Animals are Excluded?) • Affirmative Cruelty • Neglect • Applications to various contexts • Links between Animal Cruelty & Crimes against	17

Sr. No.	Topic	Details of Syllabus	Hrs.
		Humans	
Unit III	Alternatives to animal testing	• Conventional testing and alternative testing (*In vitro / In silico* models) • Early alternatives methods: Cell culture, Structure activity correlationships • Current alternatives methods: Cell, organ culture, automated cell culture, integrated testing and modelling • Future alternatives: Organ -on Chips, human on-chips, mechanistic based studies • Use of lower vertebrates' species for testing	20
Unit IV	Constitutional law	• Standing (Individuals and Organizations) • Due Process • First Amendment.	06

Animal Handling and Animal Models (PGD-LAM 104)

Course Code	Category	Course Name	L	P	Total Hours	Credits (T+P)
PGD-LAM 104	**Core**	**Animal Models**	**4**	**2**	**120**	**6**

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Handling and Animal Welfare	• Animal handling methods • Pain & Distress - Assessment and Categorization • Animal ethics and animal usage - 3R's • Affection for the Animals • Proper Attitude • Allocation of Sufficient Time: Power of Patience • Use of Voice, Touch, and Body Language • Always on Guard: Safety First • Distraction versus Pain for Restraint • Respect for Handlers • Adaptation to Special Circumstances • Appropriate Attire, Grooming, and Personal Habits • Anesthesia, Analgesia and Euthanasia in lab animals • Clinical signs observation of lab animals • Supply of Environmental enrichment to animals and its importance	15
Unit II	Methods of Handling and Restraint	• Pre-handling Considerations • Pre-restraint Considerations • Effects on Animals • Surroundings and Conditions • Personnel	10
Unit III	Risks of Disease to Handlers and Other Animals	• Animal bites, exposure to allergens and zoonoses • Zoonoses: Transmission of Disease from Animals to Humans • Transmission of Disease among Animals by their Handlers	10

Sr. No.	Topic	Details of Syllabus	Hrs.
		• Anthroponosis: Transmission of Disease from Handlers to Animals • Treatment and safety precautions during animal bite, allergy and zoonotic diseases. • Use of Personnel Protective Equipment and its importance in animal facility	
Unit IV	Methods of Animal Handling	• Training for various animal handling methods • Reinforcements • Shaping and Chaining • Counter conditioning • Habituation and Desensitization • Aversive Training Methods	10
Unit V	Animal Models	• Introduction • Concept of animal models • Classification of animal models • Classification of disease models: Induced disease models, spontaneous animal disease models, transgenic disease models, application of animals in studying human diseases such as cancer, immunology, inflammation, metabolic disorders etc.,	15

Paper – PGD LAM 105: Practical 1 Based on paper PGD LAM 101

1. Handling of Laboratory animals.
2. Blood collection in laboratory animals.
3. Routes of Drug Administration in laboratory animals

Paper – PGD LAM 106: Practical 2 Based on paper PGD LAM 102

1. Evaluation of Cereal Grains
2. Proximate Analysis
3. Energy analysis
4. Fiber analysis
5. Nitrogenous Constituents of Feeds
6. Measures of Digestibility
7. Mineral analysis
8. Indigestible Markers
9. Dietary nutrients and contaminants evaluation

Paper – PGD LAM 107 Practical 3 Based on paper PGD LAM 104

1. Care and maintenance of laboratory animals.
2. Breeding of laboratory animals.
3. Dose administration in laboratory animals.
4. Toxicological evaluation (acute, sub-chronic, and chronic).
5. Pharmacological evaluation (different animal models)

Note: For the animal experimentation, the animals which will be used are already utilized for the animal experimentations or the demonstrations will be given to the students during other major experimentations which are conducted during the course at our Central Animal Facility.

SECOND SEMESTER

Research Methodology (PGD-LAM 201 ELV)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-LAM 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

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit IV	Interpretation and Report Writing	• Meaning and Technique of Interpretation • Precautions in interpretation • Significance of report writing • Different steps in writing a report • 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) • 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	20

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-LAM 201 ELV)

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

Sr. No.	Topic	Detail 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

Sr. No.	Topic	Detail of syllabus	Hrs.
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 GI and trademarks -	05
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 for 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 equipments • 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.

New Trends in Animal Experimental Biology (PGD-LAM 202)

Course Code	Category	Course Name	L	T	P	Total Hours	Credits (T+P)
PGD-LAM 202	Core	New Trends in Animal Experimental Biology	4			60	4

Sr. No.	Topic	Details of Syllabus	Hrs.
Unit I	Cloning	• Introduction • Cloning of Animals • Applications and their Uses • Preparation of the cloned animals and Maintenance	20
Unit II	Genetically Engineering	• Introduction • Genetically Engineered Animals • Preparation of Genetically Engineered Animals • Application and their Uses	20
Unit III	Development and Maintenance	• Development of Transgenic Animals • Knockout Animals	20

PGD- LAM 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.

Recommended Books/References/Websites for Core Subjects

1 Compendium of a Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). Department of Animal Husbandry and Dairying, Ministry of Fisheries, Animal Husbandry and Dairying, Government of India, 2018, THE PREVENTION OF CRUELTY TO ANIMALS ACT, 1960 and all other documents available for download at https://cpcsea.nic.in/Auth/index.aspx, https://cpcsea.nic.in/Content/54_1_ACTSANDRULES.aspx and https://cpcsea.nic.in/Content/55_1_GUIDELINES.aspx

2 Handbook of Laboratory Animal Science, Volume II, Animal models, second edition, Edited by Jann Hau and Gerald L. Van Hoosier, Jr. CRC Press.

3 Guide for the Care and Use of Laboratory Animals, National Research Council, Eighth Edition, National Academic Press.

4 Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) guidelines. Website: https://www.aaalac.org/

5 Recognition and Alleviation of Pain and Distress in Laboratory Animals (1992), National Academics Press, 160 pages, available at http://nap.naptionalacademies.org/1542.

6 Animal Models in Toxicology, Edited by Shayne C. Gad, Shayne C. Gad, 3rd edition.

7 Guide to the Care and Use of Experimental Animals, Volume 1, 2nd Edition Canadian Council on Animal Care. https://ccac.ca/en/standards/guidelines/.

8 Alternatives to Animal Testing Proceedings of Asian Congress 2016 edited by Hajime Kojima · Troy Seidle Horst Spielmann E, Springer Open.

9 Alternatives to Animal Testing: New Ways in the Biomedical Sciences, Trends and Progress, Second Edition, Editor(s):Dr. Christoph A Reinhardt, First published:24 February 1994.

10 Handbook of Experimental Pharmacology, ISBN 978-3-030-33655-4 ISBN 978-3-030-33656-1 (eBook), Available at https://doi.org/10.1007/978-3-030-33656-1 , Good Laboratory Practice in Non-Clinical Pharmacology and Biomedicine, Volume 257, Anton Bespalov, Martin C. Michel, Thomas Steckler, SpringerOpen

11 Alternative to animal studies, National Center for 3Rs -Reduction, Refinement, Replacement, https://www.nc3rs.org.uk/

12 National Good Laboratory Practices Compliance Monitoring Authority (NGCMA), DST, Govt, of India. Visit website for all documents related to OECD GLP https://dst.gov.in/ngcma.

13 Training Manual for The Trainer, Good Laboratory Practice, Who Second Edition. Available Online.

14 Good Laboratory Practice (GLP), available online at https://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm,

https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm

15 Schedule Y_DRUGS AND COSMETICS (IIND AMENDMENT) RULES, 2005

MINISTRY OF HEALTH AND FAMILY WELFARE, (Department of Health)

NOTIFICATION, New Delhi, the 20th January, 2005.

16 FDA-Redbook 2000: IV.B.1. General Guidelines for Designing and Conducting Toxicity Studies, APRIL 2007. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/redbook-2000-ivb1-general-guidelines-designing-and-conducting-toxicity-studies

17 OECD Test Guidelines for Chemicals, https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm

18 A Good Practice Guide to the Administration of Substances and Removal of Blood, Including Routes and Volumes, JOURNAL OF APPLIED TOXICOLOGY J. Appl. Toxicol. 21, 15–23 (2001).

19 Natural Pathogens of Laboratory Mice, Rats, and Rabbits and Their Effects on Research, DAVID G. BAKER, CLINICAL MICROBIOLOGY REVIEWS, Apr. 1998, p. 231–266.

20 Gordon CJ. Temperature Regulation in Laboratory Animals. New York: Cambridge University Press; 1993

21 Gordon CJ. Temperature and Toxicology: An integrative, comparative and environmental approach. Boca Raton, FL: CRC Press; 2005.

22 Green EL. Genetics and Probability in Animal Breeding Experiments. New York: Oxford University Press; 1981.

23 Hedrich HJ. Genetic Monitoring of Inbred Strains of Rats. New York: Gustav Fischer Verlag; 1990.

24 NRC. Nutrient Requirements of Rabbits. 2nd rev ed. Washington: National Academy Press; 1977.

25 NRC. Laboratory Animal Records. Washington: National Academy Press; 1979.

26 Suckow MA, Doerning BJ. Assessment of veterinary care. The IACUC Handbook. 2nd ed. Silverman J, Suckow MA, Murthy S, editors. Boca Raton, FL: CRC Press; 2007.

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 Laboratory Animal Management
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-LAM 101	**Care and Management of Laboratory Animals**	4	30		70	35		100	50			
	PGD-LAM 102	**Nutritional Requirements for Animals**	4	30		70	35		100	50			
	PGD-LAM 103	**Principles of Animal Ethics and Associated Laws**	4	30		70	35		100	50			
	PGD-LAM 104	**Animal Handling Techniques & Animal models**	4	30		70	35		100	50			
	PGD-LAM 105	**Practical – 1 based on Paper PGD-LAM 101**	2	30		70	35		100	50			
	PGD-LAM 106	**Practical – 2 based on Paper PGD-LAM 102**	2	30		70	35		100	50			
	PGD-LAM 107	**Practical – 3 based on Paper PGD-LAM 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 Laboratory Animal Management
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-LAM 201-ELE	Research Methodology	4	30		70	35		100	50			
	PGD-LAM 201-ELE	IPR & Laboratory Practices **(Choose anyone)**				70	35						
	PGD-LAM 202	New Trends in Animal Experimental Biology	4	30		70	35		100	50			
	PGD-LAM 203	Project Dissertation & Viva Voce	16	30					250	50			
	PGD-LAM 204	Seminar, Presentation/ Group Discussion	2	30					50	50			
Grand Total			**26**						**500**				

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

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