INSTITUTE OF SCIENCE, TECHNOLOGY & ADVANCED STUDIES (VISTAS)
(Deemed to be University Estd. u/s 3 of the UGC Act, 1956)
PALLAVARAM - CHENNAI
ACCREDITED BY NAAC WITH 'A' GRADE
Marching Beyond 25 Years Successfully

M.Sc. Applied Medical Biotechnology and Clinical Research

Curriculum and Syllabus
Regulations 2021

(Based on Choice Based Credit System (CBCS)
and

Learning Outcomes based Curriculum Framework (LOCF)

Effective from the Academic year
2021-2022

Department of Biotechnology
School of Life Sciences

VISION

- ✓ To develop as a department of eminence, by achieving high standards in both research and teaching, and to become a sought-after destination for highly motivated students and faculty. The Department aspires in delivering distinctive learning skills in biotechnology enabling excellence in professional competence and innovation for further betterment of society and mankind.

MISSION

- ✓ To maintain high standards of teaching by innovating pedagogy, instilling in students the ability to be lifelong learners, and continually upgrading the program curriculum with international standards of life sciences education and to meet the requirement of industry and research community.
- ✓ To adopt effective teaching methods to improve the learning process and impart knowledge of biology and technology.
- ✓ To provide a flexible curriculum that allows the students to study courses of his/her choice (through Elective courses) that will fulfill their aptitude and professional aspirations.
- ✓ To provide hands-on training and technical skills to transform students into technocrats and facilitate research and higher education in the fields of biotechnology.
- ✓ To create opportunities and a supporting infrastructure for students – through laboratory courses, projects, dissertations, and possible entrepreneurial ventures in biotechnology to achieve their aspirations. To pursue and promote cutting-edge research in selected fields of biotechnology

PROGRAMME EDUCATIONAL OBJECTIVES (PEOs)

- ✓ PEO I: The post-graduates of Biotechnology will able to attain the in-depth knowledge of the basic and application-oriented subjects of Biotechnology and allied fields.
- ✓ PEO II: The post-graduates of Biotechnology will able to gain the ability to use the concept of theories, practical skills and latest technological tools in solving any professional issues independently in a global and societal context.
- ✓ PEO III: The post-graduates of Biotechnology are equipped to design, analyze, conduct and interpret the experiments and data for the development of process/product within the realistic constraints.
- ✓ PEO IV: The Post graduates of Biotechnology will continue to learn and update knowledge to become an entrepreneur in a current competitive world of Science & technology and also contribute to society.

PROGRAMME OUTCOMES (POs)

- ✓ PO-1 Graduates will able to have knowledge on the basic of applied clinical process..
- ✓ PO-2 Handling of sophisticated instrumentations and interpretation and analysis of clinical data.
- ✓ PO-3 Developing an interdisciplinary approach and a rational thinking.
- ✓ PO-4 Designing of research projects that are cost effective, ecofriendly, potent and beneficial to human health.
- ✓ PO-5 Making the graduates to demonstrate their communication effectively and scientifically in both verbal and written form as independent researcher.
- ✓ PO-6 Providing a broad educational, and analytical knowledge necessary to make the students for appearing in competitive examinations.
- ✓ PO-7 Generating the graduates with an ability to identify, formulate and solve to deliver process/product with professional, societal and ethical responsibilities.
- ✓ PO-8 Graduates will be able to recognize need for self-learning and lifelong learning.
- ✓ PO-9 The student will be able design, solve the application-oriented problem in medical biotechnological field through project-based learning.
- ✓ PO-10 Demonstrate their ability to work effectively in team and Improvising the technical skills and implying them

PROGRAM SPECIFIC OUTCOME (PSO)

The program specific objectives of M.Sc Applied Medical Biotechnology & Clinical research are to produce professionals who later take the role of academics, entrepreneurs and researchers with the following qualities:

- ✓ PSO1. Apply fundamental knowledge of medical sciences for the human Welfare and to have successful career as professional or a researcher through lifelong learning in the field of biotechnology.
- ✓ PSO2. Demonstrate the application of medical biotechnological processes in hospitals, pharma industries that are of social and commercial importance.
- ✓ PSO3. Exhibit skills of handling pathogenic microbial processes and biochemical analysis by making use of state-of-the-art facilities and environment.

VELS INSTITUTE OF SCIENCE, TECHNOLOGY AND ADVANCED STUDIES

M.Sc. Applied Medical Biotechnology and Clinical Research

S.No	BOARD OF STUDIES MEMBERS	
	Name	**Address**
BOARD CHAIRMAN		
1.	**Dr. B. Prakash** **Associate Professor & Head,**	Department of Biotechnology, Vels Institute of Science, Technology and Advanced Studies, Pallavaram, Chennai-600117.
BOARD MEMBER – External		
2.	**Dr. Kumar Ebenezar K** **Professor**	Faculty of Allied Health Sciences Institute, Chettinad Academy of Research & Education, Kelambakkam - 603 103, Chennai
BOARD MEMBER – Internal		
3.	**Dr. P. Shanmuga Sundaram** **Professor & Director**	School of Pharmaceutical Sciences, Vels Institute of Science, Technology and Advanced Studies, Pallavaram, Chennai-600117.
BOARD MEMBER – Internal		
4.	**Dr. M. Thenmozhi** **Associate Professor**	Department of Biotechnology, Vels Institute of Science, Technology and Advanced Studies, Pallavaram, Chennai-600117.
5	**Dr. K.Ashok kumar** **Associate Professor,**	Department of Biotechnology, Vels Institute of Science, Technology and Advanced Studies, Pallavaram, Chennai.600117.
STUDENT MEMBER – Student Representative		
6.	**Ms.D.Pavithra** Student	Vels Institute of Science, Technology and Advanced Studies, Pallavaram, Chennai-117.

VELS INSTITUTE OF SCIENCE, TECHNOLOGY & ADVANCED STUDIES (VISTAS)

CHENNAI - 600 117

CHOICE BASED CREDIT SYSTEM (CBCS)

&

LEARNING OUTCOME BASED CURRICULUM FRAMEWORK (LOCF)

PG REGULATIONS 2021

M.Sc. Aplied Medical Biotechnology & Clinical Research

Common to All Post Graduate Full-Time Programmes

(Applicable to all the candidates admitted from the academic year 2021-22 onwards)

1. DURATION OF THE PROGRAMME

1.1. Two years (Four semesters)

1.2. Each academic year shall be divided into two semesters. The odd semesters shall consist of the period from July to November of each year and the even semesters from January to May of each year.

1.3. There shall be not less than 90 working days for each semester.

2. ELIGIBILITY FOR ADMISSION

2.1. A candidate with a Bachelor's Degree in Science in the disciplinary of Biotechnology, Genetics, Biochemistry, Microbiology, Botany, Zoology, Biology, Chemistry, Physics, Home Science, Medical Lab Technology, Agriculture, B.E./B. Tech (Biotech), B.V.Sc, B.F.Sc., MBBS, BDS, B. Pharm, BPT from the University, or an examination of some other University, accepted by the Syndicate as equivalent thereto, shall be permitted to appear and qualify for the M.Sc. Applied Medical Biotechnology & Clinical Research Degree examination of this University after a course of two academic years in an affiliated college of this University.

3. MEDIUM OF INSTRUCTION

The medium of instruction for all PG programmes is English excluding Tamil, Hindi and French Language Papers

4. CREDIT REQUIRMENTS AND ELIGIBILITY FOR AWARD OF DEGREE

Candidate shall be eligible for the award of the Degree only if he/she has undergone the prescribed course of study in a College affiliated to the University for a period of not less than three academic years and passed the examinations of all the Four Semesters prescribed earning a minimum of 90 credits as per the distribution given in for Part I, II & III and also fulfilled such other conditions as have been prescribed thereof.

5. COURSE

Each course / subject is to be designed under lectures / tutorials / laboratory or field work / seminar /

practical training / Assignments / Term paper or Report writing etc., to meet effective teaching and learning needs.

6. COURSE OF STUDY AND CREDITS

The Course Components and Credit Distribution shall consist Part I, II & III: (Minimum number of Credits to be obtained) Credit Assignment Each course is assigned certain number of credits based on the following:

Contact period per week CREDITS

1 Lecture Period - 1 Credit

1Tutorial Period - 1 Credit

2 Practical Periods - 1 Credit
(Laboratory / Seminar / Project Work / etc.)

7. REQUIREMENTS FOR PROCEEDING TO SUBSEQUENT SEMESTER

7.1. Eligibility: Students shall be eligible to go to subsequent semester only if they earn sufficient attendance as prescribed therefor by the Board of Management from time to time.

7.2. Attendance: All Students must earn 75% and above of attendance for appearing for the University Examination. (Theory/Practical)

7.3. Condonation of shortage of attendance: If a Student fails to earn the minimum attendance (Percentage stipulated), the HODs shall condone the shortage of attendance up to a maximum limit of 10% (i.e. between 65% and above and less than 75%) after collecting the prescribed fee towards the condonation of shortage of attendance. Such fees collected and should be remitted to the University.

7.4. Non-eligibility for condonation of shortage of attendance: Students who have secured less than 65 % but more than 50 % of attendance are NOT ELIGIBLE for condonation of shortage of attendance and such Students will not be permitted to appear for the regular examination, but will be allowed to proceed to the next year/next semester of the program

7.5. Detained students for want of attendance: Students who have earned less than 50% of attendance shall be permitted to proceed to the next semester and to complete the Program of study. Such Students shall have to repeat the semester, which they have missed by rejoining after completion of final semester of the course, by paying the fee for the break of study as prescribed by the University from time to time.

7.6. Condonation of shortage of attendance for married women students: In respect of married

women students undergoing PG programs, the minimum attendance for condonation (Theory/Practical) shall be relaxed and prescribed as 55% instead of 65% if they conceive during their academic career. Medical certificate from the Doctor together with the attendance details shall be forwarded to the university to consider the condonation of attendance mentioning the category.

7.7. Zero Percent (0%) Attendance: The Students, who have earned 0% of attendance, have to repeat the program (by rejoining) without proceeding to succeeding semester and they have to obtain prior permission from the University immediately to rejoin the program.

7.8. Transfer of Students and Credits: The strength of the credits system is that it permits inter Institutional transfer of students. By providing mobility, it enables individual students to develop their capabilities fully by permitting them to move from one Institution to another in accordance with their aptitude and abilities.

7.8.1. Transfer of Students is permitted from one Institution to another Institution for the same program with same nomenclature. Provided, there is a vacancy in the respective program of Study in the Institution where the transfer is requested. Provided the Student should have passed all the courses in the Institution from where the transfer is requested.

7.8.2. The marks obtained in the courses will be converted and grades will be assigned as per the University norms.

7.8.3. The transfer students are not eligible for classification.

7.8.4. The transfer students are not eligible for Ranking, Prizes and Medals.

7.8.5. Students who want to go to foreign Universities up to two semesters or Project Work with the prior approval of the Departmental / College Committee are allowed to get transfer of credits and marks which will be converted into Grades as per the University norms and are eligible to get CGPA and Classification; they are not eligible for Ranking, Prizes and Medals.

8. EXAMINATION AND EVALUATION

8.1. **EXAMINATION:**

i) There shall be examinations at the end of each semester, for odd semesters in the month of October / November, for even semesters in April / May. A candidate who does not pass the examination in any course(s) shall be permitted to appear in such failed courses in the subsequent examinations to be held in October / November or April / May.

ii) A candidate should get registered for the first semester examination. If registration is not possible

owing to shortage of attendance beyond condonation limit / regulations prescribed OR belated joining OR on medical grounds, the candidates are permitted to move to the next semester. Such candidates shall re-do the missed semester after completion of the programme.

iii) The results of all the examinations will be published through University Website. In the case of passed out candidates, their arrear results, will be published through University Website.

8.2 **To Register for all subjects**: Students shall be permitted to proceed from the First Semester up to Final Semester irrespective of their failure in any of the Semester Examination, except for the shortage of attendance programs. For this purpose, Students shall register for all the arrear subjects of earlier semesters along with the current (subsequent) Semester Subjects.

8.3. Marks for Continuous Internal Assessment (CIA) Examinations and End Semester Examinations (ESE) for PART I, II, III

8.3.1 There shall be no passing minimum for Continuous Internal Assessment (CIA) Examinations.

8.3.2 For End Semester examination, passing minimum shall be 40% (Forty Percentage) ofthe maximum marks prescribed for the Course/Practical/Project and Viva-Voce.

8.3.3 In the aggregate (CIA and ESE) the passing minimum shall be of 40%.

8.3.4. He/She shall be declared to have passed the whole examination, if he/she passes in all the courses wherever prescribed in the curriculum by earning 140 CREDITS in Part I, II, III.

9. Question Paper Pattern for End Semester Examination

APPENDIX – A- PATTERN OF QUESTION PAPER

PART – A (50 words) Answer 10 questions without choice	10 × 3 = 30 marks
PART – B (200 words) Answer 5 questions out of 8 questions	5 × 8 = 40 marks
PART – C (500 words) Answer 2 questions out of 5 questions	2 × 15 = 30 marks
	Total = 100 marks

QUESTION PAPER FOR PRACTICALS

The External examiner will prepare a question paper on the spot from the syllabus prescribed and supplied by the Controller's Office.

10. SUPPLEMENTARY EXAMINATION: Supplementary Examinations are conducted for the students who appeared in the final semester examinations. Eligible criteria for appearing in the Supplementary Examinations are as follows:

10.1 Eligibility: A Student who is having a maximum of two arrear papers is eligible to appear for the Supplementary Examination.

10.2 Non-eligibility for those completed the program: Students who have completed their Program duration but having arrears are not eligible to appear for Supplementary Examinations.

11. RETOTALLING, REVALUATION AND PHOTOCOPY OF THE ANSWER SCRIPTS:

11.1 Re-totaling: All PG Students who appeared for their Semester Examinations are eligible for applying for re-totaling of their answer scripts.

11.2 Revaluation: All current batch Students who have appeared for their Semester Examinations are eligible for Revaluation of their answer scripts. Passed out candidates are not eligible for Revaluation.

11.3 Photocopy of the answer scripts: Students who have applied for revaluation can download their answer

scripts from the University Website after fifteen days from the date of publication of the results.

12. The examination and evaluation for MOOCs will be as per the requirements of the regulatory bodies and will be specified at the beginning of the Semester and notified by the university NPTEL-SWAYAM Coordinator (SPOC).

13. CLASSIFICATION OF SUCCESSFUL STUDENTS

13.1. PART I TAMIL / OTHER LANGUAGES; PART II ENGLISH AND PART III CORE SUBJECTS, ALLIED, ELECTIVES COURSES AND PROJECT: Successful Students passing the Examinations for the Part I, Part II and Part III courses and securing the marks

a) CGPA 9.00 to 10.00 shall be declared to have passed the examination in **First class with Outstanding**.

b) CGPA 7.50 to 8.99 shall be declared to have passed the examination in **First class with distinction**.

c) CGPA 6.00 to 7.49 shall be declared to have passed the examination in **First Class**.

d) CGPA 5.00 to 5.99 in the aggregate shall be declared to have passed the examination in the **SECOND** Class.

e) CGPA 4.00 to 4.99 shall be declared to have passed the examination in the **THIRD** Class.

14. MARKS AND GRADES: The following table shows the marks, grade points, letter grades and classification to indicate the performance of the Student:

14.1. Computation of Grade Point Average (GPA) in a Semester, Cumulative Grade Point Average (CGPA) and Classification

GPA for a Semester: = ∑iCiGi ÷ ∑iCi That is, GPA is the sum of the multiplication of grade points by the credits of the courses divided by the sum of the credits of the courses in a semester.

Where, Ci= Credits earned for course i in any semester,

Gi = Grade Points obtained for course i in any semester

n = Semester in which such courses were credited.

CGPA for the entire programme: = ∑n∑iCniGni ÷∑n∑iCni That is, CGPA is the sum of the multiplication of grade points by the credits of the entire programme divided by the sum of the credits of the courses of the entire programme.

Grade Conversion Table – PG			
Range of Marks	**Grade Points**	**Letter Grade**	**Description**
90 – 100	10	O	Outstanding
82 – 89	9	A+	Excellent
75 – 81	8	A	Very Good
67 – 74	7	B+	Good
60 – 66	6	B	Above Average
50 – 59	5	C	Average
40 – 49	4	D	Minimum for pass
0 – 39	0	RA	Reappear
		AAA	Absent

14.2. Letter Grade and Class CGPA

Overall Performance - PG		
CGPA	**GRADE**	**CLASS**
4.00 - 4.99	D	Third Class
5.00 - 5.99	C	Second Class
6.00 - 6.69	B	First Class
6.70 - 7.49	B+	
7.50 - 8.19	A	First Class with Distinction*
8.20 - 8.99	A+	
9.00 - 10.00	O	First Class - Outstanding*

The Students who have passed in the first appearance and within the prescribed semester of the PG Programme (Major, Allied and Elective courses only) are eligible.

15. RANKING

- Students who pass all the examinations prescribed for the Program in the FIRST APPEARANCE ITSELF ALONE are eligible for Ranking / Distinction.
- In the case of Students who pass all the examinations prescribed for the Program with a break in the First Appearance are only eligible for Classification.
- Students qualifying during the extended period shall not be eligible for RANKING.

16. MAXIMUM PERIOD FOR COMPLETION OF THE PROGRAMS TO QUALIFY FOR A DEGREE

16.1. A Student who for whatever reasons is not able to complete the programs within the normal period (N) or the Minimum duration prescribed for the programme, may be allowed two years period beyond the normal period to clear the backlog to be qualified for the degree. (Time Span = N + 2 years for the completion of programme)

16.2. In exceptional cases like major accidents and child birth an extension of one year considered beyond maximum span of time (Time Span=N + 2 + 1 years for the completion of programme).

17. REVISION OF REGULATIONS, CURRICULUM AND SYLLABI

The University may from time-to-time revise, amend or change the Regulations, Curriculum, Syllabus and Scheme of examinations through the Academic Council with the approval of the Board of Management.

Vels Institute of Science and Technology and Advanced studies (VISTAS)

M.Sc Applied Medical Biotechnology & Clinical Research

Overall credit distribution / Course Components with credits
(Minimum Credits to be earned: 90)

M.Sc, Applied Medial Biotechnology & Clinical Research Course (Common Template)

M.Sc. Course Components

Component	**I Sem**	**II Sem**	**III Sem**	**IV Sem**	**Total Credits**
Program Core & Languages	14	16	14	14	60
Discipline Specific Elective (DSE) & Generic Elective (GEC)	8	4	8	4	22
Skill enhancement Course (SEC)	2	2+2	2	-	8
Total Credits	**24**	**24**	**24**	**18**	**90**

Learning Outcome based Curriculum Framework

Preamble

Completion of graduation course in biosciences basically delivers a platform for basic understanding of the subject. Inventions, innovations and technology have revolutionized and enriched the biological sciences. The demand for skilled manpower requires thorough knowledge of the subject. It also demands for incorporating latest knowledge and advanced technologies to fulfill the changing needs of society. The public private sector prefers the experienced manpower. Considering this, M.Sc. in any biological science course is designed to provide thorough and updated knowledge of the subject which makes easy entry of the students into the public private sector. Uniqueness of the course is of having 6 months mandatory research projects. During the period students are getting an opportunity to work in nationally and internationally acclaimed research institutes and industries. This generates skilled human resources as per the demands of the society. The course has other research elements including scientific writing, writing research projects, preparing publications, preparing research posters for the conferences and the entire process also generates innovative minds to work in the capacity of scientists.

1. Introduction:

In the increasingly globalized society, it is important that the younger generation especially the students are equipped with knowledge, skills, mindsets and behaviors which may enable them to perform their duties in a manner so that they become important contributors to the development of the society. This will also help them to fully utilize their educational training for learning a decent living so that the overall standard of their families and surroundings improve leading to development of welfare human societies. To achieve this goal, it is imperative that their educational training is improved such that it incorporates the use of newer technologies, use of newer assessment tools for mid-course corrections to make sure that they become competitive individuals to shoulder newer social responsibilities and are capable of undertaking novel innovations in their areas of expertise. In the face of the developing knowledge society, they are well aware about the resources of self-development using on-line resources of learning which is going to be a major component of learning in the future. The learning should also be a continuous process so that the students are able to re-skill themselves so as to make themselves relevant to the changing needs of the society. In the face of this need, the educational curricula, teaching learning processes, training, assessment methods all need to be improved or even re-invented.

2. Learning Outcomes based approach to Curriculum Planning: (LOCF)

Learning Outcome based approach to curriculum planning (LOCF) is almost a paradigm shift in the whole gamut of higher education such that it is based on first and foremost identifying the outcomes of the learning required for a particular subject of study, and then planning all components of higher education so as to achieve these outcomes. The learning outcomes are the focal point of the reference to which all planning and evaluation of the end learning is compared and further

modifications are made to fully optimize the education of the individuals in a particular subject. For the subject of bio science the outcomes are defined in terms of the understanding and knowledge of the students in biology and computer application in biology and the practical skills the students are required to have to be competitive biologists. So, that they are able to play their role as Biologist. The curriculum developed and the teaching and the evaluation tasks are such that the students are able to apply their knowledge and training of Applied medical Biotechnology and Clinical research to solve the problems of medical biotechnology as these exist or appear from time to time in the society.

3. Aim & Objectives of the course:

The aim and objectives of the M.Sc. Applied Medical Biotechnology& Clinical Research course program essentially focuses on developing the skills of students for a successful career.

1. The course structure emphasizes to put enough effort in theory as well as laboratory work so as to gain thorough knowledge of the subject.
2. The course includes project work that would develop and nourish the scientific approach and research attitude of the students.
3. Genetic engineering, Biotechnology, Bioinformatics, Immunotherapy are the new horizons of the interdisciplinary subject in biology which might provide solutions to various problems of the society. The course work is essentially framed to acquaint the students with all the recent advances in this field.
4. It is compulsory & essential for the students to read research papers, publications and deliver seminars that would better help them to know the recent advances in the subject and also develop the communication skills.
5. The program is designed in such a way that it is essential for the students to read original publications, put enough efforts in laboratory work for practical and project, be acquainted with all the recent advances in the field like Bioinformatics, drug designing and develop all the skills for a successful career

4. Postgraduate attributes in life science:

Broaden the outlook and attitude, develop the current skills and abilities, and learn

1. New one to do extremely well in studies and career, grow into responsible global citizens. Contour the academic career of the students, make them employable, enhance
2. To shape one's life and also that of colleagues and peers. Demonstrate behavioral attributes for the enhancement of soft skills, socialistic
3. Research insight and support the participation in co-curricular and extracurricular activities. Instill skills and abilities to develop a positive approach and be self-contained
4. Approach and leadership qualities for successful career and nurture responsible human

being.

5. Provide highly skilled and knowledgeable human resources for agricultural Sector, food industry, dairy industry, medical and paramedical field, pharmaceutical and research institutes

5. Qualification Descriptors:

The following may serve as the important qualification descriptors for a PG degree in Applied medical Biotechnology & clinical research:

1. Knowledge of the diverse places where biological science is involved.
2. Understanding of diverse biological processes.
3. Advanced skills and safety issues related to handling of Microbes, Animals and Plants Good laboratory practices etc.
4. Advanced skills in working with microbes such as pilot scale culturing, downstream processes, diagnostics etc.
5. Generation of new knowledge through research projects
6. Ability to participate in team work through biological projects.
7. Ability to present and articulate their knowledge of biology.
8. Knowledge of recent developments in the area of biology.
9. Analysis of data collected through study and projects / dissertations / reviews / research surveys.
10. Ability to innovate so as to generate new knowledge.
11. Awareness how some biology leads may be developed into enterprise.
12. Awareness of requirements for fruition of a biology-related enterprise.
13. Ability to acquire intellectual property rights.

6. Programme Learning Outcome

1. A advanced and systematic or coherent understanding of the academic field of Science, its different learning areas and applications, and its linkages with related disciplinary areas/subjects.
2. The skills and knowledge gained has intrinsic beauty, which also leads to proficiency in analytical reasoning. This can be utilized in modeling and solving real life problems.
3. Procedural knowledge that creates different types of professionals related to the disciplinary including professionals engaged in research and development, teaching and government/public service
4. Skills in areas related to one's specialisation area within the disciplinary and current and emerging developments in the field of Science
5. Demonstrate relevant generic skills and global competencies such as (i) problem solving skills that are required to solve different types of problems with well-defined solutions, and tackle

open-ended problems that may cross disciplinary-area boundaries;

6. Communication skills involving the ability to listen carefully, to read texts and research papers analytically and to present complex information in a concise manner to different groups/audiences
7. Analytical skills involving paying attention to detail and ability to construct logical arguments using correct technical language
8. ICT skills
9. Personal skills such as the ability to work both independently and in a group.

7. Teaching learning processes:

The teaching learning processes incorporate a variety of modes and a regular use of ICT. These are listed below:

1. Classroom Teaching for topics which are intensely information-based. This a very regular feature of all the courses in Biotechnology
2. Power Point slides for topics which involve information related to intricate biological pathways such as metabolic pathways in Plant, Animal and Microorganisms. Use of Power Point presentations are also made whenever the lectures are to be summarized in a crisp and pointwise manner to highlight salient / important conclusions from the topics.
3. Classroom Discussions are a regular feature while teaching. The students are drawn into impromptu discussions by the teacher during the process of teaching.
4. Video Displaying, both real-time and animations, are used for topics which require 3D dimensional viewing of the biological mechanisms to drive the point home. These have proved to be very helpful while teaching concepts of molecular biology like DNA replication, transcription and translation. These are also used to convey complexities of antigen-antibody interactions and generation of antibody diversity during the teaching of Immunology.
5. Model Making is also used especially for understanding and building a perception of the students for the structures of viruses which cannot be seen by a light microscope and can be seen only under expensive equipment like electron microscopes.
6. Laboratory Practical are an integral part of every course included in PG programme in Biotechnology. The is also a daily affair for PG students of Biotechnology
7. Problem Solving is encouraged during the laboratory work.
8. Group Activity as well as discussions with the laboratory supervisor/ among the

students themselves/ Mentor is also encouraged during laboratory work.

9. Project Work is included in the programme where students work individually or in groups to design experiments to solve/answer a problem suggested by the Mentor or identified by the students in consultation with the Mentor. The students are mentored regularly during the duration the project is in progress.
10. Presentations by the Students are regularly done. The students are mentored in presentation of data, interpretation of data and articulation with the students/teachers/Research Scholars during their presentation.
11. Presentation by Experts in different specialties of Biotechnology are arranged to broaden the horizons of the students.
12. Interaction with Experts is also encouraged during/after presentations to satisfy/ignite curiosities of the students related to developments in the different ares of Biotechnology.
13. Visit to Industries/Laboratories related to Biotechnology like fermentation, food, diagnostics etc. are organized to acquaint the students with real-life working environments of the professional Biotechnology with a view to broaden their perspective of the subject of Biotechnology

8. Assessment Methods:

It is important that the students of PG Applied Medical Biotechnology and Clinical Research program achieve the desired results in terms of the learning outcomes to be professionally sound and competitive in a global society. Achieving the desired learning outcomes is also imperative in terms of job employment leading to a happy and prosperous individual further leading to a happy and prosperous family and thereby a happy and prosperous society or nation. The assessments tasks are pivotal to get an authentic feedback for the teaching learning process and for mid-course corrections and further improvements in future. The assessment tasks are carried out at various stages of the duration of the PG Applied Medical Biotechnology and Clinical Research programme like Mid-term assessments, End-term assessments, Semester examinations, Regular assessments, viva-voce etc. The assessment tasks are listed below:

1. Multiple Choice Questions (MCQ) are one of the predominant forms of assessment tasks. This task is used during all kinds of term and semester examinations.
2. Short-Answer Questions during term and semester examinations are used to assess the ability of the student to convey his thoughts in a coherent way where prioritization of the information in terms of their significance is tested.

3. Surprise Quizzes are regularly used during continuous assessment while the teaching learning process is continuing which prepares the student to quickly recall information or quickly analyze a problem and come up with proper solutions.
4. Visual/Pictorial Quizzes are used to sharpen the comprehension of the students after looking at all the components of a system.
5. Impromptu Opinions on Biotechnological problems are sought from student during regular teaching learning which help them to think quickly in a given context. This help build their ability to come up with solutions to problems which the students might not have confronted previously.
6. Problem Solving question are generally given during the laboratory work.
7. Data Interpretation is also another assessment task which is used to develop analytical skills of the students. This assessment is used during laboratory work as well as during conduction of project work.
8. Analytical Skills are assessed during work related to several experiments like enzyme kinetics, growth of bacteria and bacteriophages, mutation frequencies.
9. Paper/ Project presentations are used to assess the articulation skills of the student. These are carried out both during the duration of the teaching learning processes as well as during end-Semester examinations.
10. Report Writing is used to assess the keenness of the students for details related to Biotechnology while visiting laboratories / industries as students invariably are required to submit a report after such visits.
11. Assignment Writing are used to assess the writing abilities of the students during midterm vacations.
12. Viva-voce during the laboratory working hours and during laboratory examination are used to assess the over-all knowledge and intelligence of the students.

M.Sc. APPLIED MEDICAL BIOTECHNOLOGY AND CLINICAL RESEARCH CURRICULUM

Total number of Credits: 90

Code No.	Course	Hours/Week			Credits	Maximum Marks		
		Lecture	Tutorial	Practical		CA	SEE	Total
SEMESTER 1								
Core	Core 1 Cell and Molecular Biology	4	0	0	4	40	60	100
Core	Core 2 Applied Medical Biochemistry	3	0	2	4	40	60	100
Core	Core 3 Medical Microbiology	4	0	0	4	40	60	100
Core	Core 4 Medical Microbiology Practical	0	0	4	2	40	60	100
DSE	DSE 1 Human Genetics and Developmental biology	4	0	0	4	40	60	100
DSE	DSE 2 Biostatistics, Epidemiology & Public health	4	0	0	4	40	60	100
SEC	Soft Skill 1/ Sector Skill Course	2	0	0	2	40	60	100
		21	**0**	**6**	**24**			
SEMESTER II								
Core	Core 5 Animal Biotechnology	4	0	0	4	40	60	100
Core	Core 6 Medical Immunology	4	0	0	4	40	60	100
Core	Core 7 Advanced Medical Lab Technology	4	0	0	4	40	60	100
Core	Core 8 Animal Biotechnology Practical	0	0	4	2	40	60	100
Core	Core 9 Medical Immunology and Medical lab Technology Practical	0	0	4	2	40	60	100
DSE	DSE 3 Human Physiology	4	0	0	4	40	60	100
SI	Internship	0	0	4	2	40	60	100
SEC	Soft Skill 2/ Sector Skill Course	2	0	0	2	40	60	100
		18	**0**	**12**	**24**			

SEMESTER III								
Core	Core 10 Genetic Engineering	4	0	0	4	40	60	100
Core	Core 11 Molecular Modelling and Drug Designing	4	0	0	4	40	60	100
Core	Core 12 Medical coding and Pharmacovigilance and Safety Monitoring	4	0	0	4	40	60	100
Core	Core 13 Genetic Engineering and Drug Designing practical	0	0	4	2	40	60	100
DSE	DSE 4 Stem Cell Biology	4	0	0	4	40	60	100
DSE	DSE 5 Biomedical Instrumentation	4	0	0	4	40	60	100
SEC	Soft Skill 3/ Sector Skill Course	2	0	0	2	40	60	100
		22	**0**	4	**24**			
SEMESTER IV								
Core	Core 14 Research Methodology, IPR & Bioethics	4	0	0	4	40	60	100
GE	----------	4	0	0	4	40	60	100
Core	Project Work	0	0	20	10	40	60	100
		8	**0**	**20**	**18**			

CA - Continuous Assessment , SEE - Semester End Examination

List of Discipline Specific Elective Courses

1. Human Genetics and Developmental Biology
2. Nano and Pharmaceutical Biotechnology
3. Biostatistics, Epidemiology and Public Health
4. Biomedical Waste Management
5. Human Physiology
6. Project Management and Business Development
7. Stem cell Biology
8. Clinical Operations & Clinical Data Management
9. Biomedical Instrumentation
10. Tools and Model Organisms in Biomedical Research

List of Generic Elective Courses

1. Biomedical Waste Management
2. Biotechnology and Human Welfare
3. Environmental Biotechnology
4. Mushroom Cultivation and Medicinal Plant Gardening

List of Skill Enhancement Courses

1. Soft Skill I
2. Soft Skills II
3. Soft Skills III

List of Sector Skill courses

1. Clinical Research I
2. Clinical Research II
3. Clinical Research III

Syllabus
Core Courses

CELL AND MOLECULAR BIOLOGY 4 0 0 4

Course Objective (**Skill Development**)

To understand the basics of cell and molecular biology such as cell organelles, cell cycle and genetic materials

Unit- I **12**

CELLULAR ORGANIZATION

Cell theory, Classification cell types- Prokaryotic and Eukaryotic cells, structure and organization- plant and animal cell. cellular organelles and function – Plasma membrane – Properties and functions, cell wall, mitochondria, chloroplast, peroxisomes, Golgi complex, Endoplasmic reticulum and lysosome.

Unit- II **12**

CELL COMMUNICATION

Cell junctions-Types, Active and passive. Cell signaling and Signal transduction. Cell Cycle and its molecular mechanisms, regulation - Mitosis and Meiosis- Cancer and molecular basis of cancer cell behavior. Oncogenes and tumour suppressor genes - apoptosis

Unit- III **12**

GENETIC MATERIAL

DNA as genetic material**,** structure of Nucleic acids –DNA and RNA types – Methods of replication - Mechanism of Prokaryotic and Eukaryotic Replication, DNA replication and regulation - DNA damage and repair- Light and Dark reaction- Mutation and its types

Unit- IV **12**

TRANSCRIPTION & TRANSLATION

Transcription in Prokaryotes and Eukaryotes – Mechanism- Processing of mRNA, tRNA and rRNA – Post transcriptional Modification. Translation in Prokaryotes and Eukaryotes – Mechanism - Regulation of translation - co and post translational modifications. Genetic code

Unit- V **12**

GENE REGULATION

Regulation of Gene expression – positive and negative regulation – Protein targeting- Vesicular transport and protein import into cell organelles - Mitochondria, chloroplast and nucleus. Recombination – Homologous and Non – homologous recombination -Transposon and retrotranspons.

Total Hours 60

Course Outcome:

- CO-1: Remember the cell structure, biomembrane organization and its functions. Remember the various cell organelles.
- CO-2: Understand about cell cycles of mitosis and meiosis and well versed with cell signaling, communications and gain knowledge about cancer biology
- CO-3: Illustrate about nucleic acid functions and structures
- CO–4: Explain the replication, transcription and translation mechanism
- CO–5: Analyze about the regulation of gene expression

TEXT AND REFERENCE BOOKS:

1. Bruce Alberts, D. Bray, J. Lewis, M. Raff, Roberts and J.D. Watson, Molecular Cell Biology, , Garland Publishing Inc., New York. 2nd Edition, 1994.
2. Darnell, J and H. Lodish Baltimore, Molecular Cell Biology, American Books, Inc., New York. 1994.
3. Gerald Karp, Cell and Molecular Biology- Concepts and Experiments, Wiley International Edition, New York. 4th edition2005.
4. Watson, J.D., N.H. Hopkins, J.W. Roberts, J. Steitz and A.M. Weiner, Molecular Biology of Gene. IV Edition, The Benjamin Cummings Publishers Inc., California. 1987.
5. Benjamin Lewin, Genes VI, BejaminLewin, Oxford University Press, U.K. 6th edition, 1998.
6. Thomas D. Pollard, William C. Earnshaw and Jennifer Schwatny Saunders. Cell Biology, 2nd edition, 2007.
7. Geoffrey M. Cooper and Robert E. Hausman. The Cell: A Molecular Approach, ASM Press and Sinauer Associates, Inc., 5th edition, 2009.

APPLIED MEDICAL BIOCHEMISTRY 3 0 2 4

Course Objective: (Skill Development)

The course has been designed to expose the student to Medical biochemistry and clinical disorders caused by abnormality of biomolecules.

UNIT I BIOMOLECULES 9

Classification of carbohydrates with examples. Structure and biological importance of sugar derivatives – glycosaminoglycans, glucoproteins, proteoglycans and lipopolysaccharides. Classification of amino acids and proteins. Structural organizations of proteins. Classification of lipids. Biological significance of phospholipids, spingomyelin, eicosanoids, glycosphingolipids and lipoproteins.

UNIT II METABOLIC DISORDERS 10

Disorders of carbohydrate metabolism: Outline of glycolysis, glycogenesis, glycogenolysis, conversion of glucose to fructose and galactose. Diabetes mellitus – types, causes, diagnosis and treatment, Fructosuria, hereditary fructose intolerance, Galactosemia and Glycogen storage diseases. **Disorders of amino acid metabolism**: Outline of amino acid transamination, deamination and decarboxylation. Aminoacidurias – PKU, tyrosinemia, cystinuria, homocystinuria and maple syrup urine disease. **Disorders of lipid metabolism**: Outline of transport of fatty acids and beta oxidation. Carnitine transporter deficiency and deficiency of acyl co-A dehydrogenases. Gaucher's disease, Tay-Sach's disease, Niemann-Pick's disease, Fabry's disease, Wolman's disease. lipoproteinemias and Atherosclerosis.

UNIT III ENZYMES AND HORMONES 9

Diagnostic enzymology: Enzymes and isoenzymes. Significance of SGOT, SGPT, LDH, Creatine kinase, gamma glutamyltransferase, lipase, amylase, acid and alkaline phosphatase, glucose -6-phosphate dehydrogenase, pyruvate kinase. Hormones: Pituitary gland hormones, Neurohypophyseal hormones, Thyroid gland hormones, Adrenal gland hormones – glucocorticoids and mineral corticoids, parathyroid hormones – parathormone and calcitonin, pancreatic hormones – Insulin and glucagon. Biological role and disorders.

UNIT IV BIOCHEMISTRY OF CLINICAL DISEASES 8

Scope of clinical biochemistry, Diabetes mellitus, atherosclerosis, fatty liver, and obesity, hormonal disorders, aging, inborn errors of metabolism organ function tests.

UNIT V BIOENERGETICS 9

Bioenergetics- and biological oxidation – general concept of oxidation and reduction, electron transport chain, oxidative phosphorylation, uncouplers and theories of biological

oxidation and oxidative phosphorylation. High energy compounds, ATP cycle, Calculation of ATP during oxidation of glucose and fatty acids.

Total Hours: 45

Course Outcome:

- CO – 1: Remembering the basics of important bimolecular classification, structure, function and its significance
- CO – 2: Understand the disorders of carbohydrate metabolism, amino acid and lipid metabolism
- CO – 3: Make use of enzymes, types & their catabolic activity and different hormones, their biological role & its deficiency disorders
- CO – 4: Analyze the scope of clinical biochemistry and clinical disorders.
- CO–5: Evaluate the importance Bioenergetics, ATP and other high energy compounds.

TEXT & REFERRENCE BOOKS:

1. Bhagavan, N.V, Ha. Chung-Eun, Essentials of medical biochemistry: with clinical cases, 2nd ed. Amsterdam; Boston: Elsevier Academic Press, 2015.
2. Alberts, B.D., Bray, K., Hoplein, A., Johnson, J., Lewis, M., Raff, K Robert and P. Walter, Essential of cell Biology, 2nd edition, 2003.
3. Trevor Palmer, "Enzymes: Biochemistry, Biotechnology and Clinical Chemistry", Harwood Publisher, 2001.
4. Verma, P.S. and Agarwal, V.K. "Cell Biology", S. Chand Publication, 2008.
5. Arumugam, N., Meyyan R.P., "Cell Biology and Molecular Biology", Saras publication, 2014.
6. Lehninger. A.L., D.L. Nelson and M.M. Cox, "Principles of Biochemistry", Worth Publishers, New York, 1993.
7. Lodish, H. Berk, A., Kaiser, Krieger, Scott, Bretscher, Ploegh and Matsudaria, P. "Molecular Cell Biology". Media connected, 6th edition. W. H. Freeman and company, 2008.

APPLIED MEDICAL BIOCHEMISTRY PRACTICAL 3 0 2 4

Course Objective: (**Skill Development**)

The course aims to provide an advanced understanding of the core principles and topics of Biochemistry and their experimental basis, and to enable students to acquire a specialized practical knowledge.

List of Experiments

1. Introduction to measurements: balances and pipetting.
2. Preparation of solutions of given normality and its standardization.
3. Colorimetry and to prepare buffer solutions in the pH range 1.0 to 14.0.
4. Identification of constituents of normal and abnormal urine.
5. Estimation of Urea in the given serum sample.
6. Estimation of Cholesterol in given serum sample.
7. Estimation of protein in the given clinical sample by Lowry's Method
8. Enzyme assays (LDH, β-galactosidase, acid phosphatase, arginase, succinic dehydrogenase) time, temperature, pH:
9. Thin Layer Chromatography: lipids,
10. Thin Layer Chromatography: amino acids.

Total Hours 15

Course Outcome:

- CO-1: Remember the function, handling, maintenance and application laboratory equipments.
- CO-2: Remember the preparation of buffer, solution with expected concentration, normality and standardization in preparation of laboratory reagents. Remember to use colorimetry in preparation of standard chemicals.
- CO-3: Find the normal and abnormal constituents of body fluids eg urine and to know the operation and application of spectroscopy in evaluation of biomolecules.
- CO-4: Demonstrate the estimation of protein and assays of different enzymes and influence of time, temperature and pH.
- CO-5: Illustrate the laboratory analysis of some biomolecules in serum samples and application of TLC in separation of biomolecules.

TEXT & REFERENCE BOOKS:

1. Dayananda K S, Protein Purification: Theory and Techniques, Viva Books, 2007.

2. Prakash M., C.K. Arora, “Biochemical techniques”, Anmol Publications (I) Ltd New Delhi. 1998
3. Raymond P.W. Techniques and Practice of Chromatography (Chromatographic Science Series), CRC Press; 1st edition by Scott, 1995.
4. Jayaraman J, “Laboratory Manual in Biochemistry” (5th reprint) New Age International Publishers Mumbai, 1996.
5. David T. Plummer, An Introduction to Practical Biochemistry”, 3rd Edition. Tata McGraw Hill Publishing Company Ltd. New Delhi.2004.
6. Bruce A. White, Methods in Molecular Biology, Chapman and Hall, 1997.

MEDICAL MICROBIOLOGY 4 0 0 4

Course Objective: (**Skill Development**)

- To provide the knowledge about various microbes and their structure, Morphology, pathogenesis and diseases caused by Microorganisms.

UNIT 1 FUNDAMENTALS OF CLINICAL MICROBIOLOGY 12 Hrs

History of microbial diseases, Pathogens and their classification: Prokaryotic and eukaryotic microorganisms, Host-pathogen interactions: basic terms and concepts, Methods of isolation and identification of microorganisms, Microbiology laboratory safety, Sterilization and disinfection, General epidemiology, Basics of immunology.

UNIT 2 CLINICAL BACTERIOLOGY 12 Hrs

Bacteria as pathogen: pathogenesis and its evolution, Identification of bacterial pathogens, Morphology and fine structure of bacteria, Virulence factors, Human disease and infection caused by bacteria in the following: respiratory track, urinary track, genital tract, gastrointestinal track, blood stream, nervous system, Epidemiology of bacterial diseases, Antibacterial agents.

UNIT 3 CLINICAL MYCOLOGY & VIRUS 12Hrs

Classification of medically important fungi, General aspects of fungal diseases, Fungi as human pathogens, Antifungal agents. Structure, components and classification of animal viruses, Replication, Viral protein synthesis, Viral pathogenesis and defense mechanisms, Viruses as human pathogens: Genetics, history, epidemiology, diagnosis, and treatments, Sub viral pathogens: viroids and Prions.

UNIT 4 CLINICAL PARASITOLOGY 12 Hrs

Parasites: basic concepts and classification, medically important protozoans and Helminths, Pathogenesis and Diagnosis, Antiparasitic agents.

UNIT 5 CASE STUDIES IN CLINICAL MICROBIOLOGY 12 Hrs

Common food borne, water borne, air borne, vector borne infectious diseases in India: bacterial diarrhoea, Hepatitis, Typhoid, Dengue and Malaria, Tuberculosis, Normal microbial flora of human, Hospital infections, Infections in transplant patents, Biological warfare's and terrorism.

Total Hours 60

Course Outcome:

CO –1. Interpret the knowledge of microbial diseases, pathogens related to the human body.
CO –2. Understand the pathogenesis, symptoms, and infections
CO –3. Make use of medically important viruses and fungus.
CO –4. Analyze the diseases caused by parasites
CO –5. Create case studies in different field.

TEXT & REFERENCE BOOKS

1. Brooks G.F., Carroll K.C., Butel J.S and Morse S.A, Jawetz, Melnick and Adelberg's Medical Microbiology, McGraw Hill Publication, 24th edition, 2007.
2. Goering R, Dockrell H, Zuckerman M and Wakelin D, Mims' Medical Microbiology, Elsevier, 4th edition, 2007.
3. Willey J.M., Sherwood L.M., and Woolverton C.J, Prescott, Harley and Klein's Microbiology, McGraw Hill Higher Education,7th edition, 2008.
4. Lansing M. Prescott, John P. Harley and Donald A. Klein, Microbiology, McGraw-Hill Company, Newyork., 5th edition, 2001
5. Ananthanarayan, R., and Paniker, C.K.J. Textbook of microbiology, Orient Blackswan publishing., 10th edition, 2017
6. Ryan & Ray, Sherris Medical Microbiology: An introduction to Infectious diseases, McGraw Hill. 4th edition, 2003.

MEDICAL MICROBIOLOGY PRACTICAL 0 0 4 2

Course Objective: (**Skill Development**)

Standardize the appropriate methods for the examination of microbiology specimens and for the presumptive and definitive identification of microbial pathogens.

Medical Microbiology

1. Laboratory precautions and Safety- Instructions
2. Haemocytometer counting – RBC, WBC
3. Microscopy- Different types
4. Types of culture method Streak plate, Pour plate, Stab & Slant preparation.
5. Optimization of growth rate of bacteria : PH, Temperature, Corban, Nitrogen Sources.
6. Staining Techniques
7. Hanging drop technique.
8. Biochemical Test- IMVIC test
9. Isolation of Microorganisms from Urine and stool sample.
10. Isolation & Enumeration of Microorganism from Air, Water and Soil.
11. Isolation of microorganisms from clinical samples.
12. Antibiotic sensitivity Test - Kirby Bauer method.

Total Hours 30

Course Outcome:

- CO - 1: Remember the basic knowledge different microscope handling and maintenance
- CO - 2: Demonstrate the basic techniques like sterilization, media preparation, staining and slide preparation.
- CO - 3: Understand the different type of culturing method
- CO - 4: Interpret the practical knowledge on collection of different clinical specimens and environmental specimen.
- CO -5: Make use of the biochemical technique for identification of microbes and antibiotic sensitivity study to inhibit the growth

TEXT & REFERENCE BOOKS:

1. David Specter and Goldman. Basic Methods in Microscopy: Protocols and Concepts from "Cells: a Laboratory Manual, Cold Spring Harbor Laboratory Press, U.S. 1st edition, 2005.

2. Robert Weaver, “Molecular Biology”, McGraw-Hill, 5th edition, 2011.
3. Gunasekar, P. “Laboratory Manual in Microbiology”. New Age International Private Ltd. Publishers, New Delhi, 1995
4. PoonamBachheti and Aruna Singh. Histopathology, Vayu Education of India, 2012.
5. Naigaonkar.A.V. and M.D.Burande. A manual of Medical Laboratory Technology,NiraliPrakasan,Third Edition,Pune,India.2004.
6. Dubey, R.C. Practical Microbiology, S. Chand & Company, 2009.
7. Betty.A.F,Daniel.F.S and A.S.Weisfeld, Bailey and Scott’s Diagnostic Microbiology, Mosby(Elsevier), 2002.
8. James G. Cappucino Natalie Sherman, Microbiology - A Laboratory Manual, Wesley California, England. 4th Edition, 1999.

ANIMAL BIOTECHNOLOGY 4 0 0 4

Course Objective: (Employability)

The objectives of this course are to introduce students to the principles, practices and application of animal biotechnology, animal genomics and molecular breeding animals.

UNIT -I **12**

ANIMAL CELLS

Aseptic techniques, elements of aseptic environment, safety and risk assessment, biohazards. Culture media, types of media. Physical, chemical and metabolic functions of different constituents of culture medium; role of carbon dioxide, serum, growth factors, glutamine in cell culture; serum and protein free defined media and their applications.

UNIT –II **12**

CELL CULTURE

Primary cell culture: isolation of tissues from chick embryo, mouse and human biopsies. Methods of maintenance of tissues, continuous and established cell cultures. Organ culture: types and limitations, histotypic and organotypic cultures. Cell separation techniques, cryopreservation. Cell-cell interaction. cell death – apoptosis and its determination.

UNIT-III **12**

CELL TECHNIQUES

Gene transfer method in Animal, Cyotoxicity assays, characterization of cultured cells, molecular techniques in cell cultures: in situ hybridization, cell fusion methods, production of monoclonal antibodies, somatic cell hybridization and cell cloning and selection.

UNIT -IV **12**

EMBRYOLOGY

Collection and preservation of embryos; culturing of embryos; gametogenesis and fertilization in animals, Artificial insemination, In *vitro* fertilization and stem cell research. Ethical issues in animal biotechnology.

UNIT -V **12**

TANSGENICS, ANIMAL HUSBANDRY AND DAIRY SCIENCE

Transgenic animals; production and application; transgenic animals as models for human diseases; Breeding methods of Cattle and buffalo Milking methods and principles, Clean milk production, Feeds and feeding, Conservation of fodder, Housing for dairy animals and Common animal diseases

Total Hours 60

Course Outcome:

- CO-1: Understand about different medium for the animal cell growth and maintenance
- CO-2: Explain about culturing of different type of cells isolated from various tissue, and its interactions.
- CO-3: Illustrate the molecular techniques to understand the mechanism of cell characterization and production.
- CO-4: Make use of various techniques of animal genomics and applications like IVF, artificial insemination etc
- CO-5: Analyze about transgenic animals and breeding in animals.

TEXT & REFERRENCE BOOKS:

1. Ranga, M. M., Animal Biotechnology, II Edition, Agrobios India, Jodhpur, India. 2003.
2. Freshney, R.I., Animal Cell Culture: A Practical Approach. IV Edition, John Wiley Publications, New York. 2000.
3. Glick, B.R. and J.J.Pasternack, Molecular Biotechnology., Blackwell Science, U.K, 3rd edition, 2003.
4. Gordon, I. Laboratory Production of Cattle Embryos., CAB International, New Delhi, 2nd edition, 2003.
5. Houdebine, L.M. Transgenic Animals: Generation and Use, V Edition, CRC Press, New York, 5th edition, 1997.
6. Jenkins, N. Animal Cell Biotechnology Methods and Protocol, Humana Press, Totowa, New Jersey and Panima Publishing Corporation, New Delhi, 1999.
7. Yagasaki, K., Y. Miura, M. Hatoriand Y. Nomura, Animal Cell Technology: Basic and Applied Aspects, Vol. 13 Springer-Verlag, New York, 2008.
8. Primrose, S.B., R. M. Twyman and R. W. Old, Principles of Gene Manipulation, Blackwell Science Publishing Company, Germany, 6th edition, 2001.
9. Portner, R.,Animal Cell Biotechnology: Methods and Protocols, Vol. 24, Springer-Verlag, New York, LLC, 2007.

MEDICAL IMMUNOLOGY 4 0 0 4

Course Objective: (**Skill Development**)

- To provide the theoretical knowledge of immunological concepts and clinical research significantly related to the field of medicine.

UNIT –I **12**

INTRODUCTION

History and scope, Immunity – types, Antigen and Antibody - biology, structure and functions, super antigens, antigen- antibody interactions, primary and secondary immune response. Humoral and cell mediated immunity**.**

UNIT -II **12**

IMMUNE SYSTEM

Hematopoiesis and differentiation, Lymphocytes, Lymphoid organs**:** Primary and secondary lymphoid organs. Antigen recognition and presentation, activation of B and T lymphocytes, cytokines and their role in immune regulation. Complement system - Classical and alternate pathway.

UNIT-III **12**

HYPERSENSITIVITY, AUTO IMMUNE DISORDERS & IMMUNO DEFICIENCY DISEASES

An allergy, types of hypersensitivity. Immunology of hypersensitivity. Secondary immune response. Autoantibodies – Autoimmune diseases. Examples such as; Rheumatoid Arthritis, Myasthenia Gravis, Systemic Lupes Erythematus, Rhesus incompatibility, Protection of fetus from immune response. Immuno deficiency Diseases.

UNIT-IV **12**

TRANSPLANTATION

MLR, MHC and HLA typing, bone marrow transplantation, organ transplants, immunosuppressive therapy. Hybridoma technology and monoclonal antibodies, immuno-diagnosis and application of monoclonal antibodies in biomedical research, human monoclonal antibodies and catalytic antibodies, Xeno transplantation from various species. Immunocytochemistry – Immuno fluorescence, Immuno-enzymatic and Immuno-ferrtin techniques, immuno-electron microscopy

UNIT V **12**

VACCINES &TUMOUR IMMUNOLOGY

Vaccine technology -DNA vaccines, identification of B and T epitopes for vaccine development. Immunodiagnosis of infectious diseases, immune screening of recombinant

library. Tumour immunology: Tumour antigens, immune response to tumours, cancer immunotherapy. Immunodeficiencies – primary and secondary.

Total Hours 60

Course Outcome:

- CO-1: Remember about Fundamentals of immunity – immune response, tolerance and the concept of antigens and immunoglobulin – Immune cells and organs.
- CO-2: Understand an idea about the B and T cell recognition, Presentation and activation and about Complement system
- CO-3: Interpret the knowledge on Hyper sensitivity reactions, Auto immune disorders and Immuno deficiency diseases.
- CO-4. Utilize about MHC – HLA and its significant aspects on typing relevant to organ transplantation and Hybridoma technology
- CO-5: Explain different types of vaccines and its production and outline on tumour immunology and therapy

TEXT & REFERENCE BOOKS:

1. Tak W Mark and Mary Saunders, "The Immune Response Basic and Clinical Principles", 1st edition, AP. 2005.
2. Parslow, T.G, D.P. Sites, A.L.Terr, "Medical immunology", McGraw-Hill Publishing, 10th edition, 2001.
3. Zola H, "Monoclonal antibodies", Bios Scientific Publishers LTD., 2000.
4. Goldsby R.A., T.J. Kindt and B.A. Osborne, "Kuby Immunology", Freeman and company, 2000.
5. Roitt I, "Immunology", Blackwell Scientific Publications, 1996
6. Delves, Martin and Burton. Roitt's Essential Immunology, 11th Edition, 2006.
7. May Louise Turgeon, Immunology and Serology in Laboratory Medicine 3rd Edition 2003.
8. Ramasamy, P and R.E.B. Hanna, "Immunity and inflammation", University of Madras publications, Pearl Press Ltd., 2002.
9. Goldsby, R.A., T. J. Kindt, B. A. Osborne and W.H. J. Kuby, Immunology., Freeman and Company; USA. 5th edition, 2004.
10. Tizard, I.R., Immunology, V Edition, Saunders College Publishing, New York. 2004.

ADVANCED MEDICAL LAB TECHNOLOGY 4 0 0 4

Course Objective: (Entrepreneurship)

- To provide the analytical knowledge of clinical laboratory testing and its diagnosis.

UNIT I HEMATOLOGY 14

Specimen –definition, types. Collection and transport of specimen.Specimen preservation and storage. Hematology - Blood and its constituents, collection of blood various anticoagulants and their uses. Total Leukocyte Count(TC), Differential count(DC), Erythrocyte Sedimentation Rate(ESR) Red blood cells count(RBC), Platelet count, Packed cell volume(PCV), Mean cell volume(MCV), Hb estimation Bleeding time(BT), Clotting time(CT).Blood bank -Blood grouping(ABO system & Rh system),Identification of malarial parasites.

UNIT II CLINICALPATHOLOGY 10

Complete urine routine examination –physical, chemical and microbiological examination of urine, Culture and sensitivity. Complete routine examination of sputum and feces. Semen analysis.Examination of CSF.

UNIT III CLINICAL SEROLOGY AND IMMUNOLOGY 12

Common serological tests - Rheumatoid arthritis, Pregnancy test, Widal (slide and tube test), VDRL, HBs antigen, carbohydrate reactive protein test. Clinical manifestations and lab immunological diagnosis of AIDS, MOTT, Legionellosis, Chicken guinea, Helicobacter pylori and SARS.

UNIT IV CLINICALMICROBIOLOGY 12

Clinical manifestation and laboratory diagnosis of bacterial pathogens-Enteric pathogens (E.coli, Shigella, Samonella and Vibrio), pyogenic organisms (Staphylococcus and Streptococcus), Spirochetes (Leptospira), Mycobacterium, B. anthracis and Rickettsia.Virology, Mycology and Parasitology - Clinical manifestation and laboratory diagnosis of Rabies and Poliomyelitis, Dermatophytes and E.histolytica.

UNIT-V MOLECULARDIAGNOSTICS TECHNOLOGY 12

Molecular techniques for analysis of biochemical disorders.Assays for the diagnosis of inherited diseases. Bioinformatics tools for molecular diagnosis. Antibody based diagnosis – monoclonal antibodies as diagnostic reagents. Diagnosis of diseases by using ELISA and Western blot.DNA diagnostics – PCR and array-based diagnosis. Clinical proteomics - protein microarray for disease diagnosis.Ethics in molecular diagnosis.

Total Hours: 60

Course Outcome:

CO-1: Recall the principle and various methods of collection, transport and storage of different clinical samples and basics of hematology.
CO-2: Infer about diagnostic methods of clinical pathology specimens i.e.complete routine examination of blood, urine, sputum, feces ,CSF and semen.
CO-3: Understand the principles and procedures of different serological tests in Diagnosis.
CO-4: Summarize the interactions between bacteria, Virus, fungi and parasitic microorganisms and the humans and Clinical manifestation and laboratory diagnosis of bacterial, Viral, fungal and parasitic infections.
CO-5: Utilize the principles and techniques of molecular diagnosis and the ethics involved in molecular diagnosis.

TEXT & REFERENCE BOOKS:

1. Naigaonkar. A.V. and M.D.Burande, A manual of Medical Laboratory Technology, NiraliPrakasan, Pune, India, 3rd edition, 2004.
2. Praful.B.Godkar, Clinical Biochemistry Principles and Practice, Bhalani Publishing House, Bombay, India, 1994.
3. Anathanarayan R. and C K JayaramPaniker, Textbook of Microbiology, Ninth Edition, Jain publications, 9th edition, 2013.
4. Pradeep Kumar N.S., Manual of Practical Pathology, CBS Publishers and Distributors Pvt Ltd, New Delhi, 2011.
5. Geo. F. Brooks, Janet S. Butel and Stephen A, Medical Microbiology, Morse 23rd Edition, 2010.
6. Betty.A.F., Daniel.F.S and A.S.Weisfeld, Bailey and Scott's Diagnostic Microbiology, Mosby(Elsevier), 2002.
7. Prakash M, C.K. Arora, Biochemical techniques, Anmol publication (1) Ltd New Delhi, 1998.

ANIMAL BIOTECHNOLOGY PRACTICAL 0 0 4 2

Course Objective: (Employability**)**

To learn techniques involved in animal Biotechnology

EXPERIMENTS

1. Safety measures in Animal cell culture laboratory.
2. Designing of animal cell culture laboratory.
3. Cleaning and sterilization of glassware and plastic tissue culture flasks.
4. Preparation of tissue culture media.
5. Preparation of sera for animal cell culture.
6. Preparation of single cell suspension from Animal tissue (Primary cell culture).
7. Trypsinization of monolayer and sub culturing; Cryopreservation and thawing.
8. Cell counting and Cell viability assay
9. Staining of cells - A. Vital Staining (Trypan blue, Erythrosin B) b) Giemsa staining.
10. MTT assay.

Total Hours 30

Course Outcome:

- CO-1: List the animal tissue culture techniques and medium used in Animal Biotechnology.
- CO-2: Show to design an animal cell culture laboratory
- CO-3: Understand how to set up a primary cell culture and subculture
- CO-4: Experiment with cell counting of animal cells
- CO-5: Examine about viability and vital staining of animal cells and MTT assay in animal cell culture.

TEXT & REFERENCE BOOKS

1. Lasley JF. Genetics of Livestock Improvement. IBH, 3rd Edition., 1987.
2. Singh B. Text book of Animal Biotechnology. The Energy and Resources Institute, 2013
3. Ross CV. Sheep Production and Management. Prentice Hall., 1989.
4. Schmidt GM & Van Vleck LD. Principles of Dairy Science. WH Freeman., 1974
5. Turner HN & Young SSY. Quantitative Genetics in Sheep Breeding. MacMillan., 1969
6. Van Vleck LD, Pollak EJ & Bltenacu EAB. Genetics for Animal Sciences. WH Freeman., 1987
7. Crawford RD. Poultry Breeding and Genetics.Elsevier., 1990
8. Singh RP & KumarJ. Biometrical Methods in Poultry Breeding. Kalyani., 1994

IMMUNOTECHNOLOGY AND MEDICAL LAB TECHNOLOGY PRACTICAL 0 0 4 2

Course Objective: (Entrepreneurship)

- The objective of this course will carry out the diagnostic Techniques of serology and educate the students to learn immunological methods for disease diagnosis. Ability to carry out the diagnostic Techniques in hematology, urology, serology and standardizing the laboratory protocols responsible for diagnoses.

LIST OF EXPERIMENTS

Immunotechnology

1. Collection of Blood, Serum and Plasma, Bleeding time & clotting time estimation
2. Methods of bleeding (Eg. Tail bleeding, Intravenous, intraorbital)
3. Antigen-antibody reaction-Haemagglutination, precipitation-Widal and VDRL
4. Agglutination reactions: Determination of hemagglutination titer of IgM antibodies using human RBC
5. ELISA-DOT and plate ELISA
   Immuno Diffusion – Single, Double and Immunoelectrophoresis

Medical Lab Technology

1. ABO Blood grouping, Rh typing & Cross Matching
2. Estimation of Haemoglobin
3. Blood cell Counting: RBC, WBC, Platelets, Bleeding time, clotting time
4. Urine analysis: colour, pH, albumin, sugar (pp), deposits (pus cells, Epi cells, RBC's and crystals).
5. Identification of blood cells by study of peripheral blood smear.
6. CSF & Semen Analysis - Gross & Microscopic
7. Blood analysis: Sugar (R), Sugar (PP), Urea,Creatinine, Cholesterol, bilirubin, R.A factor.

Total hours 30

Course Outcome:

- CO-1: Understand the techniques of serological study and gain practical knowledge of immunodiagnostic methods for determination of diseases.
- CO-2: Contrast clinical diagnostic tests such as the widal test for diagnosis of typhoid and VDRL for diagnosis of syphilis will be taught to students.
- CO-3: Understand about immune diffusion techniques
- CO-4: Utilize the practical analysis of Haemoglobin, RBC, WBC, Platelets count, blood grouping from the blood sample and and Blood analysis Total Count (TC), Differential Count (DC), ESR (Erythrocyte Sedimentation Rate.

- CO-5: Test for biochemical analysis like Sugar (PP), Urea, Creatinine, Cholesterol, bilirubin, R.A factor from the blood and routine Urine analysis.

TEXT & REFERENCE BOOKS:

1. James G. Cappuccino, Natalie Sherman, "Microbiology: A Laboratory Manual", Pearson Benjamin Cummings, 10th Edition, 2013.
2. Ivan Lefkovits**,** "Immunology Methods Manual: The Comprehensive Sourcebooks of Techniques", 1996.
3. Bruce A. White, "Methods in Molecular Biology", Chapman and Hall, London, New York. 1997.
4. Myers, Mika, Klein, "Microbiology and Immunology Laboratory Manual", Pearson Learning Solutions; 4th edition, 2013.
5. May Louise Turgeon, Immunology and Serology in Laboratory Medicine 3rd Edition 2003.
6. Betty.A.F,Daniel.F.S and A.S.Weisfeld, Bailey and Scott's Diagnostic Microbiology, Mosby(Elsevier), 2002.
7. Baron, E.J., Color Atlas of Diagnostic Microbiology, 1st Edition, Mosby, 1997.
8. Naigaonkar.A.V. and M.D.Burande. A manual of Medical Laboratory Technology, NiraliPrakasan, Pune,India , 3rd, Edition,.2004.
9. Pradeep Kumar N.S.Manual of Practical Pathology,CBS Publishers and Distributors Pvt Ltd, New Delhi.2011.
10. Praful.B.Godkar.Clinical Biochemistry Principles and Practice.Bhalani Publishing House, Bombay, India.1994.

GENETIC ENGINEERING 4 0 0 4

Course Objective: (Skill Development)

- To develop the fundamental theoretical knowledge in the area of genetic engineering with modern concepts and techniques.

UNIT- I **12**

Introduction to genetic engineering: Importance and outline of genetic engineering technology, organization of gene and genome, gene expression- Enzymes in genetic engineering- Endo and exonucleases – Restriction endonucleases- types, and mechanism of action, Ligases – linker, adaptor, homopolymer tailing – Polymerases – other enzymes

UNIT- II **12**

Cloning Vectors and their applications: E. Coli Vectors – Plasmids (pBR322, pUC), Bacteriophage (lambda and M13) – Cosmids and phagemids and its properties- SV40, Baculoviral vectors, Pox viral vector, Retroviral vector, Bovine papilloma viral vector - Cloning in Yeast- Expression vectors – BAC – YAC- HAC.

UNIT- III **12**

Isolation and Blotting: Plasmid isolation and purification method- nucleic acid and protein electrophoresis -nucleic acid staining and labelling - types of gene transfer- molecular probes - Selection and screening of recombinants – Blotting techniques - hybridization techniques – Autoradiography

UNIT- IV **12**

Techniques: PCR technology – concept, types, primer design- DNA synthesis - DNA sequencing methods - DNA microarray technology - Molecular markers: RFLP, RAPD - microsatellites - Chromosome walking and jumping - DNA finger printing - DNA Foot printing- RNA interference.

UNIT- V **12**

Applications: Site directed mutagenesis- Protein engineering – Expression of recombinant proteins and medicine (Insulin, Blood clotting factor VIII, tpA, Interferons); Gene therapy: Genetic engineering for human gene therapy, gene replacement/augmentation, gene correction, gene editing - Antisense technology- Recombinant vaccines- Ethical, legal and social issues.

Total Hours 60

Course Outcome:

- CO-1: Recall on enzymes in genetic engineering, basics of gene, gene cloning, and construction of genomic libraries.
- CO-2: Interpret the right clone and various modern techniques used in rDNA technology and gain knowledge on theoretical aspects of expression vectors and protein production using cloned gene, their advantages and disadvantages.
- CO–3: Utilize various molecular techniques and their application and about DNA sequencing and fingerprinting
- CO –4: Analyse about Gene transfer technologies and Forensic science
- CO –5: Improve the knowledge about Gene therapy and the importance of vaccine and protein engineering's

TEXT AND REFERENCE BOOKS:

1. Old.R.W and Primrose S.B. Principles of Gene manipulation: An introduction to genetic engineering, Blackwell Sciences, U.K, 1998.
2. Brown T.A., Gene cloning and DNA analysis, Wiley Blackwell science, 6th edition, 2010.
3. Watson, Molecular Biology of the gene, Person education, Singapore. 5th edition, 2004.
4. Kreuzer-Massey, Recombinant DNA and Biotechnology, ASM Press. 2001
5. Alcamo, I. Edward.,DNA Technology, Academic Press. 2001
6. Walker J.M. and R. Rapley, Molecular Biology and Biotechnology, Royal society of chemistry, 4th edition, 2006
7. Glick, B.R. and J.J. Pasternak, Molecular Biotechnology. Panima Publishing House, New Delhi, India, 2002.
8. Primrose, S.B. Molecular Biotechnolgy. Panima Publishing House, New Delhi, India, 2001.
9. Winnacker, E.L., Genes to Clones. Panima Publishing House, New Delhi, India, 2003.
10. Singh B.D., 2005, Molecular biology and Genetic Engineering, Kalyani publishers.2005.

MOLECULAR MODELLING AND DRUG DESIGNING 4 0 0 4

Objectives of the Course: **(Employability)**

The main goal of this course is to gain some knowledge on modern approaches used in molecular modeling. Powerful computer-based technology used to identify and design molecules for new medications greatly shortening the discovery phase of drug development by powerful computer-based technology.

Unit-1 **12**

Protein Structure Prediction Introduction, Protein Stability and Folding, Application of Hydrophobicity, Superposition of Structures, DALI methods, Evolution of Protein Structures, CASP, Secondary Structure Prediction, Homology Modelling, Fold Recognition, ROSETTA, LINUS.

Unit-2 **12**

Molecular Modeling and Dynamics Introduction, Molecular Dynamics using simple molecules, Signification of Times steps & Temperature Conformational energy calculations and molecular dynamics, docking by Energy minimization, Ramachandran Plot.

Unit-3 **12**

Drug Discovery and Development Drug Discovery Cycle, The Lead compound, Pharmacophore, Bioinformatics in drug discovery and development, chemical databases, ADME and Toxicity, Virtual Screening, Molecular Docking, Structure and Ligand Based Drug Designing, Case studies.

Unit-4 **12**

Structural Bioinformatics Tools Tools for Molecular Visualization and Analysis: RASMOL, PYMOL, VMD, SWISS-PDB Viewer. Molecular Modeling and Docking: Swiss-Model, Arguslab, Hex, DOCK and Autodock. Online Tools: Biology Workbench, Marvin Sketch, Chemskech, pubchem.

Unit-5 **12**

Quantitative tools Introduction to QSAR methodologies, Types of QSAR methods – 2D, 3D, 4D, 5D and 6DQSAR methodologies, Descriptor's classification, Application of QSAR in molecular design.

Course Outcome:

- CO-1: Understand the basics of Protein Structure Prediction
- CO-2: Identify the drugs for various diseases by insilico method.

- CO-3: Apply the basics of Molecular Modeling and Dynamics in various fields such as medicine and agriculture.
- CO-4: Analyze bioinformatics tools.
- CO–5: Evaluate the complete knowledge about various QSAR methodologies and their application

TEXT AND REFERENCE BOOKS:

1. Leach R., Molecular Modeling Principles and Application, Longman Publications, 2nd edition, 1996.
2. Baxivanis D and Foulette - Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins, Wiely Indian Edition, 2001.
3. Attwood, T,K., D J parry-Smith, Introduction to Bioinformatics, Pearson Education, 1st Edition, 11th Reprint, 2005.
4. Steffen Schulze-Kremer, "Molecular Bioinformatics: Algorithms and Applications", Walter de Gruyter, 1996.
5. Jin Xiong, Essential Bioinformatics, Cambridge University Press. 2006.
6. Rajaraman. V., Introduction to information technology. Prentice Hall of India Pvt. Ltd, New Delhi. 2003.
7. Lesk, A. M., Introduction to Bioinformatics. Oxford University Press, London. 2002.

GENETIC ENGINEERING AND DRUG DESIGNING PRACTICALS 0 0 4 2

Course Objective: (Employability)

- This course begins by introducing students to the concept of genetic engineering, examines the molecular cloning methods, the various cloning vectors and their hosts, and how to find the right vector for molecular cloning.

LIST OF EXPERIMENTS:

Genetic Engineering

1. Isolation of Genomic DNA and plasmid
2. Quantization and Estimation of nucleic acids.
3. Agarose gel electrophoresis and SDS PAGE
4. Restriction and Ligation of DNA
5. PCR (Demo)
6. Blotting Techniques

Molecular Modelling and Drug Designing

7. Sequence retrieval from biological database
8. Sequence similarity searching analysis : BLAST
9. Prediction of signal sequence using Signal
10. Pattern Search (Domains & Motifs) using Pfam
11. ORF Finder
12. Sequence translation using ExPASy translate tool
13. Characterization of retrieved
14. Phylogenetic tree construction using PHYLIP
15. Prediction of secondary and tertiary structure of protein and validation
16. Molecular visualization of proteins using RASMOL
17. Docking of small molecule with protein

Total Hours 30

Course Outcome:

- CO-1: Demonstrate the isolation of genomic and plasmid DNA. To Understand the cutting and joining for DNA
- CO-2: Illustrate about AGE and basic principles to Quantify and estimate the nucleic acids

- CO-3: Experiment with SDS Page in separation of proteins will be gained and learn about the application of Polymerase chain reaction (PCR).
- CO-4: Utilize the biological data from genbank and understand evaluation by phylogenetic tree analysis
- CO-5: Evaluate the biological data and understand the importance of docking analysis and its application

TEXT & REFERENCE BOOKS:

1. Sambrook, J, E.F. Fritsch and T. Maniatis, Molecular Cloning, A Laboratory Manual, Cold Spring Harbor Laboratory Press, New York. 2000.
2. Glover, D.M. and B.D. Hames, DNA Cloning a Practical Approach. IRL Press, Oxford. 2000.
3. James, J.G. and V.B. Rao, Recombinant DNA Principles and Methodologies. Marcel Dekker Publications, NewYork. 2001.
4. Maliga, P., Methods in Plant Molecular Biology. A Laboratory Course Manual, Cold Spring Harbour Laboratory Press, NewYork. 2000.

MEDICAL CODING AND PHARMACOVIGILANCE & SAFETY MONITORING 4 0 0 4

Course Objective: (Employability)

The paper is designed to provide basics in medical coding and to learn importance pharmacovigilance for clinical research students.

UNIT-I INTRODUCTION TO MEDICAL CODING 12

Professional over view and specific responsibilities. Standardization of coding and coding over view.History ICD and CPT. ICD – 9, ICD – 9CM, ICD -10. ICD – 9 - CM versus ICD – 10 – CM. Coding accuracy.

UNIT-II CPT CODE 12

CPT – Medical coding, structure of CPT codes. Three categories of CPT codes. Absence of codes and special cases. EM Coding.

UNIT-III PHARMACOVIGILANCE 12

Introduction, definition, aim and objective of Pharmacovigilance study. Method, Plans, procedures, scope of Pharmacovigilance study. Pharmacovigilance study in India.

UNIT-IV SAFETY MONITORING 12

Basics in pharmacogenomics process of monitoring. Safety monitoring boards. Monitoring of quality assurance. Introduction to GPP. Risk management, guidance, assessing adverse and serious adverse events. Reporting of AE & SAE.

UNIT-V PRACTICES AND SAFETY SIGNALS 12

Introduction to good reporting practices and safety signals. Case reports, Case series, data mining, and causality report. International drug monitoring procedures. Health care information for comprehensive Pharmacovigilance surveillance.

Total Hours 60

Course Outcome:

CO-1: Understand the basics in Medical Coding and transcription. Also introduced to ICD, CPT and Coding accuracy.
CO-2: Demonstrate the categories of CPT codes and coding rituals.
CO-3: Interpret the importance of Pharmacovigilance study for clinical researchers and Plans, procedures, scope of Pharmacovigilance study.
CO-4: Analyze how monitoring boards function and their responsibilities and basics of pharmacogenomics.
CO-5: Categorize the good reporting practices and safety signals and International drug monitoring procedures will also be learnt.

TEXT AND REFERENCE BOOKS:

1. Linda Campbell, Medical Transcription Fundamentals and Practice, Prentice Hall-Gale, 1993.
2. Gupta S.K, Textbook of Pharmacovigilance, Japee publications, India, 2011.
3. Ravi N Humbarwadi,Quick Learner's Pharmacovigilance,Amazon,2003.
4. Eric T Herfindel, Dick R. Gourley, Textbook of Therapeutics Drug and Disease management, 6th edition, 2012.
5. Janet woodcock, Frederick Ognibene, john overbeke, Assuring data quality and validity in clinical trials for regulatory decision making, 2003.
6. Marilyn takahashi Fortney Otis Diehl, Medical transcription guide: do’s and dont’s, 2003.

RESEARCH METHODOLOGY, IPR & BIOETHICS 4 0 0 4

Course objective: (Employability)

To provide fundamental theoretical knowledge about Research Methodology, IPR & Bioethics.

UNIT I Basics of research **10**

Objectives- Types- Significance of Research- Steps in research process Criteria for good research. Defining and formulating a research problem- Literature survey- Development of working hypothesis.

UNIT II Research design **14**

Definition and related concepts, Basic principles of experimental designs- Informal and formal experimental designs; Sampling design: Steps in sample design, Non-probability sampling and Probability sampling -random sampling; Measurement and scaling techniques- Methods of data collection - Execution of project -Processing and analysis of data- Hypothesis testing - Interpretation and report writing- Steps and layout of research report- Types of report, review paper writing and presentation.

UNIT III Qualitative and Quantitative Research **12**

Qualitative research – Quantitative research – Concept of measurement, causality, generalization, replication.Merging the two approaches.

UNIT-III IPR Introduction **12**

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.

UNIT-V Bioethics **12**

Introduction to bioethics, ethical issues in preclinical (animal) studies, & clinical studies- Ethical principles, Ethical guidelines-ICMR, Institutional Ethics - Institutional Ethics committees, Institutional review board, SOPs, ethical issues based on methodology of clinical research. The ethics of clinical research in developing countries.

Course Outcome:

- CO-1: Understand the fundamentals of research and about research problem
- CO-2: Interpret the data for research purpose, sampling and its importance
- CO-3: Explain the basics on Qualitative and Quantitative Research. Summarize two approaches
- CO-4: Utilize the importance of IPR, Copyright and other Intellectual Property
- CO-5: Analyze the patent law, International agreement, bioethics in science and WHO's patent details.

TEXT AND REFERENCE BOOKS:

1. Joao Meidanis, Carlos Setubal, Computational Molecular Biology, Cengage Learning 2007.
2. Neeraj, P., and Khusdeep, D, Intellectual Property Rights. India, IN: PHI learning Private Limited, 2014.
3. Nithyananda, K.V., Intellectual Property Rights: Protection and Management, India, IN: Cengage Learning India Private Limited, 2019.
4. Tom L Beauchamp, JerffryKhan, LeRoy Walters, Anna C Mastroanni, Contemporary issues in Bioethics, Wadsworth Publishing, 2013.
5. Ahuja, V.K., Law relating to Intellectual Property Rights, India, IN: Lexis Nexis, 2017.
6. Lesk, Introduction to Bioinformatics, OUP. Bios Scientific Publishers Ltd, 2001.
7. Cynthia Gibas and Per Jambeck, Developing Bioinformatics Computer Skills, SPD, 2001.
8. Atwood, Introduction to Bioinformatics, Pearson Education.1999.

PROJECT /DISSERTATION AND VIVA-VOCE 0 0 20 10

Course Objective: (Skill Development)

Students have to do the research work in the field of medical biotechnology based on their own interest or research guide interest in a particular topic for a period of 6 months duration from the university or any research industries or research laboratories. After the completion of project work, the student should submit the dissertation in the university prescribed format and then attend the Viva-voce exam.

- Student should do research on their own interest or research guide interest on any biotechnology topic for 6 month in the university or any industries or laboratories.
- The candidates shall undertake the major project work in the Sixth Semester either in the Department concerned or in industries, institutes or any other organizations and the project report shall be submitted at the end of the Sixth semester.
- In case the candidate undertakes the project work outside the Department, the Staff concerned within the Department shall be the Main guide and the Staff/scientist under whom the work is carried out will be the Co-guide. The candidate shall bring the attendance certificate from the place of project work carried out.
- After the research, he/she should submit the detailed reports about the research in a dissertation and should present in an external examiner.
- Evaluation is based on work done, quality of report, performance in viva-voce, presentation etc.
- The report will be evaluated by duly appointed teaching faculty from head of department

Syllabus
Discipline Specific Elective Courses

HUMAN GENETICS AND DEVELOPMENTAL BIOLOGY 4 0 0 4

Course Objective: (Skill Development)

- Human Molecular Genetics is a vast field that provides information of Genetic Material, general principles and applications of cloning and molecular hybridization. The paper provides comprehensive knowledge on the structure, function and evolution of human genes and genome.

UNIT-I INTRODUCTION 12

Mendelian principles - Human Genome, Basic concepts of Human Genome, Organization of the human genes, Human gene expression, Gene Silencing, Repetitive DNA and its types, linkage, linkage group, recombination maps in diploids.

UNIT-II POPULATION GENETICS 12

Inheritance of quatitative traits, genetic basis and influence of environment. Principles of population genetics; Hardy-Weinberg law and its application for autosomal genes.Organization and mutational analysis of lac and arabinose operons.Transposons in Eukaryotes.Molecular basis of spontaneous and induced mutations.

UNIT- III NUCLEIC ACID 12

Structure and function, Physical and chemical structure of DNA, DNA Replication. Different types of RNA and their Structure. RNA transcription factors and gene expression, Post transcriptional RNA processing, Post Translational modifications.

UNIT-IV EMBRYOGENESIS 12

Molecular and cellular biology of fertilization: acrosome reaction and signal transduction, monospermy and species specificity. Egg activation, early cleavages and blastocyst formation in mammals.Gastrulation in mammal's formation of primitive streak, morphogenetic movements and neural induction.

UNIT-V ORGANOGENESIS 12

Organogenesis and foetal development.Pattern forming genes and expression in Drosophila and mammalian embryos. Development of mammalian brain- cerebral cortex cell lineages Lens development – fiber differentiation, programmed morphogenetic histogenetical cell death (apoptosis). Erythropoeisis, Myelopoeisis. Ageing.

Total Hours: 60

Course Outcome:

- CO-1: Remember about Mendelian principles, Human genome and its organization.

- CO-2: Explain Gene silencing, linkage, recombination in diploids, population genetics, Hardy Weinberg and its applications with operons, transposons and types of mutation.
- CO-3: Recall the structure of DNA and RNA with transcription and translation – post transcriptional and post translational modifications.
- CO-4: Understand the embryology, blastulation, gastrulation and neural induction.
- CO-5: Analyze the developmental aspects of Drosophila and mammals.

TEXT AND REFERENCE BOOKS:

1. Gilbert S.F., Developmental biology, Sinauer, 7th edition, 2003.
2. Ricki Lewis, Human Genetics-Concepts and Application, Ninth Edition, McGraw-Hill College Publishers, 2009.
3. Phundan Singh, "Molecular genetics", Ibdc Publishers, 2010.
4. Sabyasachi Roychoudhuri, "A Textbooks of Genetics and Molecular Biology", New Central Books Agency; 1st edition, 2011.
5. Sarin, "Genetics", - Tata McGraw hill, 1991.
6. Nussbaum, Robert L., Roderick R. McInnes, and Huntington F. Willard. Genetics in Medicine. Philadelphia: Saunders, 7th edition, 2007.
7. Glossary." Genetics Home Reference.. U.S. National Library of Medicine. 14 Mar. 2008
8. Freeman, Scott, and Jon C. Herron. Evolutionary Analysis. Upper Saddle River: Pearson: Prentice Hall, 4th edition, 2007.
9. Wolpert L, Beddington R, Jessell T, Lawrence P, Meyerowitz E, Smith J. Principles of development. Oxford university press, 2nd edition, 2002.

NANO AND PHARMACEUTICAL BIOTECHNOLOGY 4 0 0 4

Course Objective: (Employability)

To know about the advance in Nano technology, and its application in Pharmaceutical industries.

UNIT –I INTRODUCTION TO NANOTECHNOLOGY 12

Nanostructures, Biointerface, Bioconjugation, and Biomatrix, Nanoclusters, Self – Assembly of Nano materials.Nanopolymers and Nanofibres.Bioactivenanomaterials in bone grafting and tissue engineering – Inorganic/ polymers Nanocomposites for dental restoration and bone replacement applications.

UNIT –II NANOMATERIALS 12

DNA based artificial Nanostructures; Fabrication, properties and applications. Nucleic acid engineered Nanomaterials and their applications. Protein pattering for application in Biomaterials and biodevices.Vesicles and liposomes in sensor technology – Self – Assembling Nanostructured injectable polymeric gels for drug delivery.

UNIT –III PHARMACEUTICAL BIOTECHNOLOGY 12

Introduction, Microbes in Pharmaceutical industry.Formulation of Biotech products including biopharmaceutical Considerations (Microbiological considerations).Site specific delivery of Protein Drugs.

UNIT –IV PEPTIDE CHEMISTRY 12

Protein engineering, Peptide chemistry and Peptidomimetics, Catalytic antibodies, Glycobiology and Biosensors.Impact of biotechnology on drug discovery.(Gene therapy – ex vivo and in vivo gene therapy).Hematopoietic Growth Factors, chemical description, pharmacology, Pharmaceutical Concerns, clinical and Practice aspects.

UNIT –V PHARMACOLOGY AND FORMULATIONS 12

Vaccines, Modern Vaccine Technologies, Pharmaceutical aspects. Monoclonal Antibody, Based Pharmaceuticals, Development of Antibody Based Therapeutics. Formulation of monoclonal antibody – Based Therapeutically.

Total Hours: 60

Course Outcome:

- CO-1: Understand the basic knowledge and introduction about Nano technology. Understand about Nanostructures, Nanopolymers, Nanofibres and their uses, bone grafting, dental restoration and bone replacement.

- CO-2: Demonstrate about the DNA based artificial Nanostructures; Fabrication, Nanobased Protein patterning, sensor technology and polymeric gel.
- CO-3: Identify the importance of microbes in pharmaceutical technology.
- CO-4: Classify Protein engineering, Peptide chemistry and Peptidomimetics, Catalytic antibodies, Glycobiology, hematopoietic growth and Biosensors.
- CO-5: Explain antibody based therapeutics, formulation of monoclonal antibody and vaccine development.

TEXT AND REFERENCE BOOKS:

1. Charles Poole, Frank Owens, Introduction to Nanotechnology Publisher: Wiley India Private Limited, 2007.
2. Leo Shargel, Andrew B. C. Yu, Susanna Wu-Pong and Yu Andrew B.C. Applied Biopharaceutics and pharmacokinetics. McGraw – Hill companies, 2004.
3. ManasiKarkare, Nanotechnology: Fundamentals and Applications, I K International Publishing House Pvt. Ltd, 2008.
4. Charles Poole, Frank Owens, Introduction to Nanotechnology, Wiley, 2007.
5. Sambamurthy K, Ashutosh Kar, Pharmaceutical Biotechnology, New Age International Pvt Ltd Publishers, 2006.
6. Chandrakant Kokate, Pramod H.J., SS Jalalpure, Textbooks of Pharmaceutical Biotechnology (Kindle Edition), Elsevier, 1st edition, 2011.
7. Daniel Figeys (Ed.). Industrial proteomics; Applications for Biotechnology and Pharmaceuticals. Wiley and sons, Incorporated, 2005.
8. Kayser,O.and R.H. Muller. Pharmaceutical Biotechnology – Drug discovery and clinical applications. Wiley – VCH, 2004

BIOSTATISTICS, EPIDEMIOLOGY AND PUBLIC HEALTH 4 0 0 2

COURSE OBJECTIVE: (Skill Development)

- Students will understand the importance of Statistics in Biological Sciences, Epidemiology & Public Health.

UNIT I STATISTICAL METHODS **8**

Measures of Central tendency -Mean, Median, Mode– Measures of Dispersion- Range, Quartile Deviation, Standard Deviation and Coefficient of variation. Correlation and regression analysis: Correlation: Types of Correlation-Methods of studying correlation-Regression: Regression Lines and Regression equations - simple problems.

UNIT II TESTING OF HYPOTHESIS: **7**

Introduction-Tests of Significance for small samples: t-test -F-test (variance –Ratio test), Chi-Square tests -Analysis of Variance: One way and Two Way Classifications Basic Principles of Experimentation – Completed Randomized Design – Randomized Block Design- Latin Square Design

UNIT- III EPIDEMIOLOGY **5**

Epidemiology Definition and Concepts of Epidemiology, Types and use of Epidemiology, Concepts of Health and Disease, Disease investigation and prevention.

UNIT-IV EPIDEMIOLOGY OF DISEASES **5**

Health and Diseases: Communicable and Non – communicable diseases, Occupational disorders, Role of Genetics in Health and Disease, Role of nutrient and health, Environment and health issues. Diabetes, Aids, Cancer, COVID-19.

UNIT- V PUBLIC HEALTH **5**

General Public Health Definitions and Concepts and genesis of Public Health, Important Public Health Acts, and Health problems of developed and developing countries including India, Health Planning, Organization and functions of Health Care infrastructure, Objectives and Organization of Important national and International agencies like UN agencies in health care.

Total Hours 30

Course Outcome:

- CO-1: Remember the types of data and collection of data. The statistics like mean, mode and median. Measuring central tendency, Kurtosis will also be learnt.
- CO-2: Demnstrate percentiles, variability, standard deviation and application of the same in the sample data.

- CO-3: Understand Epidemiology Definition, Types and use of Epidemiology.
- CO-4: Explain about Communicable and Non – communicable diseases, Role of Genetics in Health and Disease, Diabetes, Aids, Cancer, COVID-19.
- CO-5: Utilize definition of General Public Health, Health problems of developed and developing countries, and International agencies like in health care.

TEXT AND REFERENCE BOOKS

1. Mariappan, P. Biostatistics: An Introduction [Kindle Edition], Pearson; 1 edition, 2013.
2. Vashisth, A.K,Textbooks Of Biostatistics, Neha Publishers & Distributors, 2008.
3. Bonita, Ruth; Beaglehole, Robert; Kjellstrom, Tord Basic epidemiology, Geneva : World Health Organization, cop. 2nd edition, 2006
4. Bhopal, Raj S. Concepts of epidemiology: an integrated introduction to the ideas, theories, principles and methods of epidemiology, Oxford : Oxford University Press, cop. 2002 - xxxviii, 317s. ISBN:0-19-263155-1.
5. Global Health : An Introductory textbook Lindstrand, Ann; Bergström, Staffan; Rosling, Hans; Rubenson, Birgitta; Stenson, Bo Studentlitteratur AB, 2006 - 326 ISBN:9144021984.
6. Gupta S.C. and V.K.Kapoor, Fundamentals of mathematical statistics, 2010.
7. Helio S. Migon, DaniGamerman, and Francisco Louzada, Statistical Inference: An Integrated Approach, Second Edition, Chapman and Hall/CRC, 2014.

BIOMEDICAL WASTE MANAGEMENT 4 0 0 4

Course Objective: (Employability)

- To provide basic knowledge about source, types, handling, collection, and disposal and also it is ensure the proper and safe management of biomedical waste.

UNIT-I-INTRODUCTION 12

Definition, Scope and importance of biomedical waste. Categories of biomedical wastes(Human Anatomical Waste, Animal Waste, Microbiology & Biotechnology Waste , Waste sharps, Discarded Medicines and Cytotoxic drugs, Solid Waste, Liquid Waste, Incineration Ash and Chemical Waste).Categorization and composition of biomedical wastes. Sources of biomedical wastes.

UNIT-II-HEALTH IMPACTS 12

Health impacts of biomedical wastes. Direct and Indirect hazards. Potential health hazards of BMW. Infectious agents in the biomedical wastes. Monitoring and controlling of cross infection (protective devices).

UNIT-III DISPOSAL TECHNOLOGY 12

Biomedical waste – Handling rules, segregation, collection, transportation, disposal-color coding and type of container for disposal of biomedical wastes. Disposal technologies (sharp disposal pit, deep burial pit and secured land fill).

UNIT-IV TREATMENT TECHNOLOGY 12

Treatment and management of biomedical wastes-on site - pre treatments, treatment-in-site and off-site (common treatment facilities).Liquid waste treatment by different technologies.Conventional treatment technologies (wet thermal and incineration) and alternative treatment technologies (microwave, Autoclave, hydroclave, ETP, EBT, plasma pyrolysis and gasification systems).treatment of non – infectious wastes by composting.

UNIT -V ENVIRONMENTAL POLICY 12

Environment and legislation policies and rules for handling and management of biomedical wastes.CPCB guidelines .WHO guidelines for biomedical wastes. Components of a hazardous waste management plan – minimization, recycling and re – use. Management of non – clinical support devices. Health and safety practices in Indian hospitals.

Total Hours: 60

Course Outcome:

CO-1: Understand the Scope and importance of biomedical wastes and types and sources of biomedical waste.

CO-2: Interpret the health impact caused by biomedical wastes and infectious agents, monitoring and controlling the cross infection due to biomedical wastes.
CO-3: Make use of handling rules, segregation, collection, transportation, disposal of biomedical waste. Also about disposal techniques of biomedical wastes will be acquired.
CO-4: Examine the different technologies of treatment and management of biomedical wastes and alternative treatment technologies on biowaste management.
CO-5: Evaluate environment and legislation policies and rules for handling and management of biomedical wastes, CPCB guidelines and WHO guidelines.

TEXT AND REFERENCE BOOKS:

1. Bhide, A.D and B.B.Sundaresan, "Solid Waste Management – Collection, Processing and disposal" Mudrashilpa Offset Printers, Nagpur, 2001.
2. Sharma – Holistic approach to Hospital Waste Management published by Dept. of Hospital Administration – AIIMS, New Delhi, 2006.
3. Hosetti, B.B. Prospects and perspective of solid waste management, New Age International Publisher, 2006.
4. Glynn Henry.J and Gary. W. Heinke, "Environmental Science and Engineering", Pretice Hall of India, 2004.
5. Bhide. A.D and B.B.Sundaresan, "Solid Waste Management – Collection, Processing and disposal" Mudrashilpa Offset Printers, Nagpur, 2008.
6. Glynn Henry.J and Gary. W. Heinke, "Environmental Science and Engineering", Pretice Hall of India, 2004.
7. GoelS. L, Health Care System and Hospital Administration, Balaji World of Books 2009.
8. ISHA. Current Issues in BMW Waste Handling, Bangalore, 2011.

HUMAN PHYSIOLOGY 4 0 0 4

Course Objective: (Skill Development)

This course covers the fundamental principles of human biology with emphasis on the morphology, physiology and disorder of body systems.

UNIT I MEDICAL TERMINOLOGY INTRODUCTION 12

Human body structure-Useful terms to describe body parts and activities Directional terms-Planes of the body-Body cavities- Cells, Tissues, and Membranes.

UNIT II HUMAN CIRCULATORY SYSTEM 12

Blood -Composition of blood- Plasma- Red blood cells-White blood cells: development and function- Bone marrow -Clotting pathway(s)-Functions of the lymphatic system.

UNIT III RESPIRATORY SYSTEM 12

Introduction to the respiratory system-Mechanics of ventilation- Respiratory volumes and capacities- Conducting airways-Nose and nasal cavities- Pharynx- Larynx and trachea-Bronchi, bronchial tree, and lungs.

UNIT IV DIGESTIVE SYSTEM 12

Functions of the digestive system-General structure of the digestive system-Organs of the digestive system-Mouth-Pharynx and esophagus-Stomach-Small and large intestines-Accessory organs (salivary glands, tongue, and pancreas, liver).

UNIT V HUMAN URINOGENITAL SYSTEM AND SENSES 12

Functions of the excretory system-Components and function of the - urinary system-Kidneys. Nervous System -Functions of the nervous system .The Senses- Vision -Taste-Touch-Smell- Pain Pathways - The Reproductive System -Male reproductive system - Hormonal control- Female reproductive system.

Total Hours: 60

Course Outcome:

CO-1: Recall the hierarchical architecture of the human body and gain knowledge about cell, tissues and membranes.
CO-2: Understand circulatory system and composition of blood, blood clotting mechanism and the functions of lymphatic system.
CO-3: Demonstrate the organs and organ structure of respiratory system and the mechanism of respiration.
CO-4: Analyze the structure and function of digestive system and associated organs.
CO-5: Classify the structure, function and components of excretory system, reproductive system, Nervous system and senses of different types.

TEXT AND REFERNCE BOOKS:

1. Kenneth L.Jones,Louis.W.Shainberg and Curtis.O.Byer. The Human Body, Canfield Press, Harper and Row Publishers, Sanfrancisco.1971.
2. Peter Jones , The Complete Guide to Human Body,VIth Edition,2013
3. UnglaubSilverthorn, Human Physiology: An Integrated Approach Plus Mastering A&P with e - Text, University of Texas, Austin, 2011.
4. Browder, Leon W., Carol A. Erickson, and William R. Jeffery. *Developmental Biology*, 3rd Ed. Philadelphia, PA: Harcourt College Publishing, 1991.
5. Saladin, Kenneth S. *Anatomy and Physiology,* New York: McGraw-Hill, 2nd edition, 2001.
6. Berne, Robert M., and Matthew N. Levy. *Physiology,* St. Louis,MO: Mosby, 4th edition, 1998.
7. Ganong, William F. *Review of Medical Physiology,* 19th ed. Stamford, CT: Appleton and Lange, 1999.

PROJECT MANAGEMENT AND BUSINESS DEVELOPMENT 4 0 0 4

Course Objective: (Employability)

To provide the concepts of project Management and Business Development

UNIT-I INTRODUCTION TO PROJECT MANAGEMENT 12

Project management – frame work; concept of a project, capital expenditure, Importance& difficulties, Phase of capital budgeting, feasibility study: overview. Resource allocation: elementary investment strategy, portfolio planning tools, strategic position& action evaluation.

UNIT-II FINANCIAL FORMULATION 12

Financial identification& formulation- scouting for project idea, preliminary screening and project rating index. Market& demands analysis- market survey, characterization of market, forecasting & planning, profit potential of industries; porter model. Technical analysis- analysis of inputs, technology, product mix, capacities, location, civil works, charts, lay outs, work schedule.

UNIT-III INTRODUCTION TO BUSINESS PLAN 12

Business plan preparation- sources of product for business -pre feasibility study- criteria for selection of products- ownership-capital- budgeting project profile preparation- matching entrepreneur with the project- Feasibility report preparation and evaluation criteria.

UNIT-IV INTRODUCTION TO PROJECT MANAGEMENT 12

The triple constraints in project management, project management activities, project management objective, project management documents, project control variables, project management & clinical trials, role of project management in clinical trials, major roles of a project manager in a CRO , ensuring project success.

UNIT-V INTRODUCTION TO BUSINESS DEVELOPMENT 12

Introduction & stages of business development-start-up phase, growth phase, maturity phase, decline phase. Outsourcing in clinical research, reasons for outsourcing to contract research organization, the India advantage, scope and future of CRO , list of clinical research organization in India , list of it companies offering service in clinical research. Role of business development manager.

Total Hours: 60

Course Outcome:

CO–1: Understand the project management – frame work; concept of a project, capital expenditure and resource allocation.

CO– 2: Relate about scouting for project idea, preliminary screening and project rating index and Technical analysis.
CO– 3: Demonstrate business plan preparation- sources of product for business.
CO – 4: Show the constraints in project management, project management activities, project management objectives.
CO –5: Explain the stages of business development-start-up phase, growth phase, maturity phase, decline phase, Outsourcing in clinical research and reasons for outsourcing to contract research organization.

TEXT AND REFERENCE BOOKS:

1. Richard A. Billows, Principles of project management, 2005.
2. Hisrich, "Entrepreneurship", Tata McGraw Hill, New Delhi, 2001.
3. Dennis Lock. The Essentials of Project Management, Gower Publishing Ltd. 2006**.**
4. Khanka S.S. Entrepreneurship development", S. Chand and company limited, New Delhi, 2001.
5. Clifford Gray and Erik W. Larson. Project management – The managerial approach, 2002.

STEM CELL BIOLOGY 4 0 0 4

Course Objective: (Skill Development)

To learn the basic and advanced topics in stem cell biology and its application in healthcare.

UNIT I: BASICS OF STEM CELL BIOLOGY 12

Origin of stem cells.Early development of embryo.Unique properties of stem cells. Formation of stem cells - Totipotent, Pluripotent, and multipotent cells. Types of stem cells - embryonic stem cells, adult stem cells, induced pluripotent stem cells, and cancer stem cells. Similarities and differences between embryonic and adult stem cells.

UNIT II: EMBRYONIC STEM CELLS 12

Introduction to ESCs and related ethical issues. Mouse embryo derived cells – EC, ES, EG, TS and NTES cells. Naive and primed ESCs, primate and mouse ESCs. Lab tests for ESCs, isolation of human ESCs and stem cell niche. Applications of Embryonic stem cells.

UNIT III: ADULT STEM CELLS 12

Somatic stem cells-test for identification of adult stem cells- adult stem cell differentiation-trans differentiation-plasticity-different types of adult stem cells-liver stem cells-skeletal muscle stem cells-bone marrow derived stem cells – Stem cell specific transcription factors - Induced pluripotent cells.

UNIT IV: STEM CELL SIGNALING 12

Tumor stemcells, Common signaling pathways in cancer and ESCs. Pathways involved in cancer and stem cell renewal. Pathways involved in stem cell differentiation.

UNIT V: APPLICATIONS OF STEM CELLS 12

Autologous approaches to tissue engineering – biological and translational challenges. Stem cell treatment for Parkinson's disease, burns, spinal cord injury and heart diseases. Recent developments in stem cell research and therapy. Stem cell-based gene therapy and benefits to human.

Total Hours 60

Course Outcome:

CO-1: Understand the basic knowledge in stem cells, types of stem cell and importance of stem cell research.
CO-2: Interpret the knowledge on embryonic stem cells and its application.
CO-3: Explain about adult stem cells, types, characteristics and its application.
CO-4: Utilize the role of signal pathways in cancer stem cell proliferation.
Co-5: Evaluate the applications of stem cells in treatments of diseases.

TEXT & REFERENCE BOOKS

1. Sell S. “Stem Cells Handbook”, Humana Press, Second Edition , 2004.
2. Lanza R and Atala A. “Essentials of Stem Cell Biology”, Academic Press, Third Edition, 2014.
3. Daniel R. Marshak “Stem cell biology” Cold Spring Harbor Laboratory Press., 2001
4. Bendall S.C, Stewart M.H and Bhatia M. Human Embryonic Stem Cells: Lessons from Stem Cell Niches in Vivo, Regenerative Medicine, 3: 365-376., 2008
5. Ann A. Kiessling, “Human Embryonic Stem Cells” Jones and Bartlett Publishers, Inc., second edition, 2006.

CLINICAL OPERATIONS & CLINICAL DATA MANAGEMENT 4 0 0 4

Course Objective: (Employability)

- To make the student to understand the methodology involved in Clinical Operations and Clinical Data Management.

UNIT-I PRE SCREENING OF CLINICAL TRIALS 12

Pre-screening of patients. Ride identification benefits risk assessment, review protocol compliance. Continuous review, investigator and staff qualifications, records confidentiality GMP quality systems.

UNIT-II PROTOCOL DESIGNING 12

Designing of protocol, CRF, e-CRF, IB, ICF, SOP. Report writing and publications. Clinical trials site and monitoring, document processing.

UNIT-III REGULATION OF CLINICAL RESEARCH 12

Regulation in clinical research, patents US regulatory structure, IND, NDA, ANDA, drug approval. EMEA organization and functions, India regulating systems, schedule Y- rules and regulations.

UNIT-IV CLINICAL MONITORING 12

Clinical study design – Treatment – Studies, Observational studies and seasonal studies. Clinical Monitoring and functional clinical monitor, monitoring activity.

UNIT-V CLINICAL TRIAL MANAGEMENT 12

Clinical Trial Management System (CTMS), Software for CTMS study, SaaS. Legal issues in managing clinical data Health care informatics. Effective data presentation.

TOTAL HOURS: 60

Course Outcome:

CO-1: Understand about preclinical procedures and assessment methods in clinical studies and GMP quality systems.
CO-2: Relate how to design a protocol and report preparation and publication.
CO-3: Identify how to get approval for various regulatory processes and about US regulatory structure and Indian regulatory structure, schedule Y etc.
CO-4: Analyze how to design a clinical research study and Monitoring methods and responsibilities.
CO-5: Explain about Clinical Trial Management System (CTMS) and management of clinical data and software used.

TEXT AND REFERENCE BOOKS:

1. Gupta S.K., Basic Principles of Clinical Research and Methodology Institute of Clinical research (India), 2007.
2. Susanne Prokscha. Practical Guide to Clinical Data Management. Taylor & Francis, 2nd edition, 2007.
3. Rondel R.K., S.A Varley, C.F Web. Clinical Data Management, John Wiley and Sons, 2nd edition, 2000.
4. Ravindra B. Ghoojand Sachin C. Itkar. Essential of Clinical Research, Nirali Prakashan, Publications 2010.
5. Pal.T.K and Sangita Agarwal, Clinical Research, CBS publishers and Distribution, 2009.
6. John I. Gallin and Frederick P. Ognibene, Principles and practice of clinical research,3rd edition,2012.
7. Vishal Bansal Parar, Clinical Research Fundamental and Practice,Medical Publisher, 2010.
8. Jaypee brothers.Basic Principles of Clinical Research and Methodology, Medical Publishers (P) Ltd., 2009.

BIOMEDICAL INSTRUMENTATION 4 0 0 4

Course Objectives (Employability)

• Learn about the scope of biomedical instrumentation and its applications, various bio-potential electrodes and equivalent circuits and various biochemical analytical techniques used in the laboratories.

UNIT I BIOPOTENTIAL & ELECTRODES 12

Origin of bio potential and its propagation. Electrode Circuit Model and Motion Artifact, Electrode-electrolyte interface, electrode–skin interface, half-cell potential, impedance, Polarization effects of electrode – non-Polarizable electrodes. Types of electrodes - surface, needle and micro electrodes and their equivalent circuits. Recording problems measurement with two electrodes, Biochemical Transducers.

UNIT II ELECTRODE CONFIGURATIONS & BIO AMPLIFIERS 12

Biosignals characteristics – frequency and amplitude ranges. ECG –Einthoven's triangle, standard 12 lead system. EEG – 10-20 electrode system, unipolar, bipolar and average mode. EMG– unipolar and bipolar mode. Need for bio-amplifier - single ended bio-amplifier, differential bio-amplifier – right leg driven ECG amplifier. Isolation amplifiers – transformer and optical isolation - isolated DC amplifier and AC carrier amplifier. Chopper amplifier. Power line interference, need for Band pass filtering.

UNIT III MEASUREMENT OF NON-ELECTRICAL PARAMETERS 12

Temperature, respiration rate and pulse rate measurements. Blood Pressure: indirect methods - auscultatory method, oscillometric method, direct methods: electronic manometer, Pressure amplifiers - systolic, diastolic, mean detector circuit. Blood flow and cardiac output measurement: Indicator dilution, thermal dilution and dye dilution method, Electromagnetic and ultrasound blood flow measurement.

UNIT IV BIO-CHEMICAL MEASUREMENT & ANALYTICAL TECHNIQUES 12

Biochemical sensors - pH, pO2 and pCO2, Ion selective Field effect Transistor (ISFET), Immunologically sensitive FET (IMFET), Blood glucose sensors - Blood gas analyzers, colorimeter, flame photometer, spectrophotometer, blood cell counter, auto analyzer (simplified schematic description).

UNIT V PATIENT SAFETY 12

Physiological effects of electricity – important susceptibility parameters – Macro shock –Micro shock hazards – Patient's electrical environment – Isolated Power system –

Conductive surfaces – Electrical safety codes and standards – Basic Approaches to protect against shock, Protection equipment design, Electrical safety analyzer – Testing the Electric system

Total Hours: 60

Course Outcomes

CO-1: Students know to Design a suitable electrode for a physiological and non-physiological signal that can be measured from the human body, Types of electrodes and Biochemical Transducers.
CO-2: Students will learn how to Record the various bio signals using electrode from the human body and design a suitable bio-amplifiers for bio signal acquisition system.
CO-3: Learn to implement a various non-electrical parameters acquisition system from the human body. Gain Knowledge on Blood flow and cardiac output measurement
CO-4: Practice with different types of analytical and diagnostic tools practiced in diagnostic and clinical laboratories.
CO-5: Students will learn about Electrical safety codes and standards – Basic Approaches to protect against shock, Protection equipment design and Develop a device for patient safety.

TEXT AND REFERENCE BOOKS:

1. Leslie Cromwell, "Biomedical Instrumentation and Measurement", Prentice Hall of India, New Delhi, 2007.
2. John G. Webster, "Medical Instrumentation Application and Design", John Willey and sons, 2002.
3. Joseph J. Carr and John M. Brown, "Introduction to Biomedical equipment technology", John Willey and sons, New York, 1997.
4. Richard Aston. Principles of Biomedical Instrumentation and Measurement" Publishing Company, 1990.
5. Geddas L.A and L.E.Baker, "Principles of Applied Biomedical Instrumentation", 2004.
6. John G. Webster, "Bioinstrumentation", John Willey and sons, New York, 2004.
7. Khandpur R.S, "Handbook of Biomedical Instrumentation", Tata McGraw- Hill, New Delhi, 2003.
8. Myer Kutz – "Standard Handbook of Biomedical Engineering & Design" – McGraw-Hill Publisher, 2003.

TOOLS AND MODEL ORGANISMS IN BIOMEDICAL RESEARCH 4 0 0 4

Course Objective: (Employability)

This course has been designed to introduce the various tools and techniques and different model organisms in modern era of biology. It focuses on the principles of chromatography and various molecular biology and immunological techniques.

UNIT I: ANALYTICAL METHODS 12

Chromatography: Principle and applications of affinity, gel filtration and ion exchange chromatography, HPLC, Centrifugation: Principle and different types of centrifugation- differential, density gradient and equilibrium. Flow cytometry: Flurochromes, fluorescent probe and principle, application in biomedical science.

UNIT II: MOLECULAR BIOLOGY METHODS 12

Isolation, purification and quantification of nucleic acids; Agarose and PAGE; Hybridization techniques- Southern, Northern and Western; Restriction enzymes, Gene cloning and RFLP; Principles of PCR, RT PCR, Real time PCR;DNA sequencing- Maxim Gilbert and Sanger Methods.

UNIT III: IMMUNOLOGICAL METHODS 12

Monoclonal antibody generation, isolation of various immune cells and their functional assays, generation and applications of nude mice. ELISA - direct, indirect, competitive and sandwich ELISA, Co-immune-precipitation for protein-protein interaction studies.

UNIT IV: INTRODUCTION TO MODEL ORGANISMS 12

Definition of model organisms, Scope and importance of model organisms. Selection of model organisms for research.

UNIT V: DIFFERENT MODEL ORGANISMS 12

Brief history of model organisms, life cycle, culture conditions/maintenance, advantages and disadvantages of the organism as a model, models: Escherichia coli, Saccharomyces cerevisiae (Baker’s yeast), Caenorhabditiselegans (Nematode worm), Drosophila melanogaster (Fruit fly), Daphnia (Water flea), Daniorerio (Zebra fish) and Musmusculus (Mouse).

Total Hours: 60

Course Outcome:

CO-1: Remember various analytical tools and techniques in chromatography and centrifugation.
CO-2: Demonstrate about various molecular analytical methods such as PCR, RT PCR, Real time PCR; DNA sequencing-for biomedical research.
CO-3: Understand about monoclonal antibody generation, isolation of various immune cells and immunological techniques such as ELISA – and it types.
CO-4: Apply the knowledge on model organisms, scope, importance and selection of suitable model organisms for research.
CO-5: Categorize model organisms, life cycle, advantages and disadvantages of the organism as a model.

TEXT AND REFERENCE BOOKS:

1. Gerald Karp, "Cell and Molecular Biology: Concepts and Experiments", Wiley, 6th edition, 2009.
2. Benjamin A. Pierce. Genetics: A Conceptual Approach, W. H. Freeman, 4th edition, 2010.
3. Wilson K and Walker J, Principles and Techniques of Biochemistry and Molecular Biology, Cambridge University Press, 7th edition, 2010.
4. David Sheehan, Physical Biochemistry: Principles and Applications, John Wiley, 2nd edition, 2009.
5. Brown T.A. Gene cloning and DNA analysis, Wiley-Blackwell, 6th edition, 2010.
6. Primrose S.B. and R.M. Twyman.Human Molecular Genetics, Tom Strachan and Andrew Read; Garland Science Publishers, 3rd edition, 2003.
7. Kuby, J. Immunology, W.H. Freeman and Company, New York, 6th edition, 2006.
8. Michael R. Green and Joseph Sambrook. Molecular Cloning: A Laboratory Manual, Three-volume set Cold Spring Harbor Laboratory Press, 4th edition, 2012.
9. William S. Klug, Michael R. Cummings, Charlotte A. Spencer and Michael A. Palladino.Concepts of Genetics, 10th edition, 2012.
10. David Freifelder, Physical Biochemistry: Applications to Biochemistry and Molecular Biology, W.H. Freeman and Company, 2nd edition, 1982.

INTERNSHIP 0 0 4 2

Course Objective: (Employability)

- Students have to go for training in any medical biotechnology fields such as clinical research institutes, clinical diagnostic laboratories, Parma research industries, etc., to learn the hands-on training in the relevant field. After getting the training, the students should submit the training certificate along with detailed report to the department.
- For the benefit of the students, it has been mandatory to attend a minimum of one internship/ Mini project during semester vacation
- Student should go for Internship/ Mini project in any biotechnological industry or laboratories and learn their laboratory techniques by hands on training.
- After the Internship/ Mini project, student should submit detailed reports about the Internship/ Mini project in printed format.
- Evaluation is based on work done, quality of report, performance in viva-voce, presentation etc.
- The report will be evaluated by duly appointed teaching faculty from head of department.

Total: 30 hrs

Syllabus
Generic Elective Courses

BIOMEDICAL WASTE MANAGEMENT 4 0 0 4

Course Objective: (Employability)

This course aims to provide knowledge about source, types, handling, collection, and disposal and also it is ensure the proper and safe management of biomedical waste.

UNIT-I: Introduction to biomedical waste **12**

Introduction, Definition, Scope and importance of biomedical waste. Categories of biomedical wastes(Human Anatomical Waste, Animal Waste, Microbiology & Biotechnology Waste , Waste sharps, Discarded Medicines and Cytotoxic drugs, Solid Waste, Liquid Waste, Incineration Ash and Chemical Waste).

UNIT-II: Health impacts biomedical waste **12**

Health impacts of biomedical wastes. Direct and Indirect hazards, Potential health hazards of BMW. Infectious agents in the biomedical wastes. Monitoring and controlling of cross infection (protective devices)

UNIT-III: Handling of biomedical waste **12**

Biomedical waste - Handling rules, segregation, collection, transportation, disposal-color coding and type of container for disposal of biomedical wastes. Disposal technologies (sharp disposal pit, deep burial pit and secured land fill).

UNIT IV Treatment and management of biomedical waste **12**

Treatment and management of biomedical wastes-on site - pre treatments, treatment-in-site and off-site (common treatment facilities).Liquid waste treatment by different technologies. Conventional treatment technologies (wet thermal and incineration)

UNIT V Legislation policies and rules of biomedical wastes **12**

Environment and legislation policies and rules for handling and management of biomedical wastes. CPCB guidelines .WHO guidelines for biomedical wastes.

Total : 60hrs

Course Outcome:

- CO–1: Outline the basics, scope and importance of biomedical wastes.
- CO–2: Demonstrate the potential health hazards of biomedical wastes.
- CO–3: Understand the principles and methods of disposal of biomedical wastes and secured land fill
- CO–4: Apply different technologies of treatment and management of biomedical wastes and learn on Conventional treatment technologies
- CO–5: Evaluate the rules, policies and guidelines of biomedical wastes and understand the WHO guidelines for biomedical wastes

TEXT AND REFERENCE BOOKS

1. Bhide A. D.and B.B.Sundaresan, “Solid Waste Management – Collection, Processing and disposal” Mudrashilpa Offset Printers, Nagpur, 2001.
2. Goel S. L, Health Care System and Hospital Administration, Balaji World of Books 2009.
3. Radhakrishnan R, Biomedical Waste Management, Neha Publishers &Distributors, 2007.
4. Behera P.K., Sustainable Bio-Medical Waste Management (2 Vols.)Dominant Publishers And Distributors, 1993.
5. Hosetti, B. B. Prospects and perspective of solid waste management, 2006.
6. Glynn Henry J and Gary. W. Heinke, “Environmental Science and Engineering”, PreticeHall of India, 2004.
7. Bhide A. D and B.B.Sundaresan, “Solid Waste Management – Collection, Processing and disposal” Mudrashilpa Offset Printers, Nagpur, 2001.
8. Glynn Henry J and Gary. W. Heinke, “Environmental Science and Engineering”, Pretice Hall of India, 2004.

BIOTECHNOLOGY AND HUMAN WELFARE 4 0 0 4

Course Objective: (Employability)

This course has been designed to introduce the various techniques in modern era of biotechnology. It focuses on industrial biotechnology, agriculture and medical biotechnology and molecular techniques for forensic science.

UNIT I Industrial Biotechnology 12

Industry: protein engineering; enzyme and polysaccharide synthesis, activity and secretion, alcohol and antibiotic formation.

UNIT II Agricultural Biotechnology 12

Agriculture: N2 fixation: transfer of pest resistance genes to plants; interaction between plants and microbes; qualitative improvement of livestock.

UNIT III Environmental Biotechnology 12

Environments: e.g. chlorinated and non-chlorinated organ pollutant degradation; degradation of hydrocarbons and agricultural wastes, stress management, development of biodegradable polymers such as PHB.

UNIT IV Biotechnology in Forensic science 12

Forensic science: e.g. solving violent crimes such as murder and rape; solving claims of paternity and theft etc. using various methods of DNA finger printing.

UNIT V Biotechnology in medicine 12

Health: e.g. development of non-toxic therapeutic agents, recombinant live vaccines, gene therapy, diagnostics, monoclonal in E.coli, human genome project.

Total: 60hrs

Course Outcome:

- CO –1: Make use of the products of industrial biotechnology and agriculture biotechnology.
- CO–2 Understand the interaction between plants and microbes and the various techniques involved in environmental biotechnology.
- CO–3: Utilize the degradation of hydrocarbons and agricultural wastes
- CO–4: Explain the molecular techniques for forensic science and various methods of DNA finger printing
- CO–5: Evaluate health care products, human genome project and recombinant live vaccines

TEXT AND REFERENCE BOOKS

1. Patnaik, "Textbooks of Biotechnology", McGraw Hill Education (India) Private Limited, 2012.
2. Satyanarayana, U, "A Textbooks of Biotechnology", Bookss and Allied (p) Limited, 2013.
3. Sateesh MK, "Bioethics and Biosafety", I. K. International Pvt Ltd, 2010.
4. Sree Krishna V, "Bioethics and Biosafety in Biotechnology", New age international publishers, 2007.
5. Purohit S.S. "Agricultural Biotechnology", , Agrobios, 3rd edition, 2010.
6. Kumaresan V," Biotechnology P, Saras Publication, 2015
7. Kumaresan V, N Arumugam, Environmental Biotechnology ,Saras,2014
8. SandhyaJadhav ,A Text Book of Environmental Biology and Biotechnology 2nd Edition Vision, Publications, 2nd edition, 2012
9. Ellyn Daugherty, "Biotechnology: Science for The New Millennium", EMC Publishing, 2006.
10. Clark D.P and Pazdernik N.J. "Biotechnology-Applying the Genetic Revolution". Elsevier Academic Press, USA.2009.
11. Alan Scragg, "Environmental Biotechnology", Oxford; Second edition, 2007.

ENVIRONMENTAL BIOTECHNOLOGY 4 0 0 4

Course Objective: (Employability)

The topic represents a stand-alone, progressive topic leading the student through the key aspects of environmental microbiology prior to its subsequent application within environmental biotechnology.

UNIT I Biofuels **12**

Conventional fuels and their environmental impact – Firewood, Plant, Animal, Water, Coal and Gas. Modern fuels and their environmental impact – Methanogenic bacteria, Biogas, Microbial hydrogen Production, Conversion of sugar to alcohol Gasohol

UNIT II Bioremediation **12**

Bioremediation of soil & water contaminated with oil spills, heavy metals and detergents. Degradation of lignin and cellulose using microbes.

UNIT III Phyto-remediation 12

Phyto-remediation. Degradation of pesticides and other toxic chemicals by micro-organisms-degradation aromatic and chlorinates hydrocarbons and petroleum products.

UNIT IV Waste water treatment and biofertilizer **12**

Treatment of municipal waste and Industrial effluents. Bio-fertilizers Role of symbiotic and asymbiotic nitrogen fixing bacteria in the enrichment of soil. Algal and fungal biofertilizers (VAM)

UNIT V Biomining **12**

Biomining, Bioleaching, Enrichment of ores by microorganisms (Gold, Copper and Uranium).Environmental significance of genetically modified microbes, plants and animals.

Total : 60hrs

Course Outcome:

- CO–1: Understand the importance of conventional fuels and their environmental impacts
- CO–2: Explain knowledge relevant to the applications of Bioremediation to the environment.
- CO–2: Interpret the degradation of lignin and cellulose using microbes and water contaminated with oil spills
- CO–3: Utilize various techniques involved in Phyto-remediation and degradation of pesticides and other toxic chemicals by micro-organisms.
- CO–4: Analyze waste water treatment and the Algal and fungal biofertilizers
- CO–5: Detemine the knowledge about Bioleaching and importance of genetically modified microorganisms.

TEXT AND REFERENCE BOOKS

1. Pradipta Kumar Mohapatra, "Environmental Biotechnology",I.K. International Publishing House; 1st Ed. Edition, 2007.
2. Satyanarayana, U, "A Textbook of Biotechnology", Books and Allied (p) Limited, 2013.
3. Purohit S.S. "Agricultural Biotechnology", Agrobios, 3rd edition, 2010.
4. Alan Scragg, "Environmental Biotechnology", Oxford; Second edition, 2007.
5. Hans-Joachim Jordening and Jesef Winter, "Environmental Biotechnology – Concepts and Applications", Wiley VCH, 2004.
6. Metcalf and Eddy, "Waste Water Engineering", Tata McGraw hill, 4th edition, 2003.
7. Alicia L. Ragout De Spencer, JohnF.T. Spencer. "Environmental Microbiology: Methods and Protocols", Humana Press, 2004.
8. Milton Wainwright, "An Introduction to Environmental Biotechnology", Springer, 1999.

MUSHROOM CULTIVATION AND MEDICINAL PLANT GARDENING 4 0 0 4

Course Objective: (Entrepreneurship)

To learn the cultivation of various mushrooms and to create self-employment for the students.

Unit 1: Introduction 12

Introduction to Mushroom - History of Mushroom - Ecology of Mushroom -Life cycle of Mushroom. classification of mushrooms, nutritional and dietary values of mushrooms as source such as protein, carbohydrates, fibre, vitamins and minerals, therapeutic properties, mushroom collections from field

Unit 2: cultivation techniques 12

Mushroom cultivation techniques- Erections of mushroom culture sheds and maintenance (tools, equipment and prerequisites). Fungal Isolation techniques, preparation of mother culture- pure culture, selection of stock, spawn production – mother spawn production. Basic elements for Mushroom growth and farm settings

Unit 3: Spawn Multiplication 12

Multiplication of spawn - Precautions, characters, and storage of spawn; substrate production, culturing of mushrooms; harvesting, post-harvesting processes, and key machinery and equipment required.

Unit 4: Cultivation techniques for selected mushrooms 12

Cultivation techniques for commercially viable mushrooms - paddy straw mushroom, button mushroom and milky mushroom – spawning, substrate preparation, growth, packing, and maintenance of suitable environmental conditions. Factors influencing mushroom cultivation and harvesting. Mushroom delights.

Unit 5: Medicinal Plant Gardening 12

Types of medicinal plants, Secondary metabolites- Bioactive constituents, Medicinal plants cultivation methods and gardening.

Total : 60 hours

Course Outcome:

CO –1: Student will understand about mushroom and its classification
CO –2: Illustrate about the Mushroom cultivation techniques
CO –3: Student will plan to about : Spawn Multiplication
CO –4: Student will Demonstrate about the cultivation methods of Selected mushrooms
CO –5: Explain about types of medicinal plants and its cultivation and gardening

TEXT & REFERENCE BOOKS:

1. Suman, B.C and V. P. Sharma. Mushroom Cultivation in India, Daya Publishing House. 2007

2. Subrata Biswas, M. Datta, S.V. Ngachan. Mushrooms: A Manual for Cultivation. PHI

Learning Private limited, New Delhi. 2012.

3. Singh, M., Vijay, B., and Kamal, S., and Wakchaure, G.C. Mushrooms: Cultivation, Marketing and Consumption. Directorate of Mushroom Research, Indian Council of Agricultural Research, Solan, India, p.266. 2011

4. Oei, P, and van Nieuwenhuijzen, B. Small-scale mushroom cultivation. Digigrafi, Wageningen, The Netherlands, p.86. 2005

5. Training Manual on Mushroom Cultivation Technology. United Nations - Economic And Social Commission for Asia and the Pacific, p.139.

6. Milan S. Stankovic. Medicinal Plants and Natural Product Research, MDPI publishers, Switzerland, 2020

7. M.C. Joshi. Hand Book of Indian Medicinal Plants, Scientific Publishers, 2019

SKILL ENHANCEMENT COURSE

SOFTSKILLS – I **- 2 0 0 2**

Course Objective: (Skill Development)

- To enable participants Business Communication Skills
- To enhance participants E-mail writing skills
- To impart Leadership and Team Bonding skills

Credit Hours

1. **READING COMPREHENSION AND VOCABULARY** **06**
   Filling the blanks – Cloze Exercise – Vocabulary building – Reading and answering Questions.
2. **LISTENING AND ANSWERING QUESTIONS.** **06**
   Listening and writing – Listening and sequencing sentences – Filling in the blanks – Listening and answering questions.
3. **GROUP DISCUSSIONS** **06**
   Why GD part of a selection process – Structure of a GD – strategies in GD – Team Work – Body Language
4. **CONVERSATION.** **06**
   Face to face Conversation and Telephone conversation.
5. **SELF- INTRODUCTION AND ROLE PLAY** **06**

Total **30 Hours**

Course Outcome

At the end of this course the students will be able to,

CO 1 Prioritize power of understanding and aids assimilation of vocables. Vocabulary to charge communication with educated words

CO 2 Develop comprehensive knowledge through listening leading to answering questions

CO 3 Build observation power and infuse self-confidence through group discussions

CO 4 Identify methodology for befitting constructional ability

CO 5 Experiments with inward looking and visualization of the 'otherness' of situations

Books Recommended

- Barun K. Mitra. Personality Development and Soft Skills. Oxford University Press. New Delhi.2011.
- S.P. Sharma. Personality Development. Pustaq Mahal. New Delhi. 2010.Meenakshi Raman and Sangeetha Sharma. Technical Communication. Oxford University Press. New Delhi. 2009.
- Tiko, Champa & Jaya Sasikumar. Writing with a Purpose.OUP. New Delhi. 1979

Web Source:

- https://www.skillsyouneed.com/ips/communication-skills.html
- https://blog.smarp.com/top-5-communication-skills-and-how-to-improve-them
- https://blog.hubspot.com/service/phone-etiquette

SOFT SKILLS – II **- 2 0 0 2**

Course Objective: (Skill Development)

- To enable students to develop their communication skills effectively
- To enhance students Reading, Writing, Listening and Speaking skills
- To develop their self-confidence through communication

Credit Hours

1. **PRESENTATION SKILLS** **06**
   Elements of an effective presentation – structure of presentation – voice modulation – Audience analysis – Body language
2. **SOFT SKILLS** **06**
   Time Management – Articulateness – Assertiveness – Stress management
3. **RESUME / REPORT PREPARATION / LETTER WRITING** **06**
   Structuring the resume / Report – Business letters – E-Mail Communication
4. **INTERVIEW SKILLS** **06**
   Kinds of Interviews – Required by Skills – Corporate Culture – Mock Interviews
5. **30 FREQUENTLY ASKED QUESTIONS** **06**

Total **30 Hours**

Course Outcome

At the end of this course the students will be able to,

CO1 Illustrate the essential of presentation skills, thoughts, structure, voice modulation, audience analysis and body language

CO2 Utilize the psychological skills pertaining to time management, articulation, assertion and stress management

CO3 Construct methodology for preparation of resume, reports, business letters and email communication

CO4 Appraise learners with varied skills needed for expose to interviews

CO5 Categorize the nature of questions asked usually in interviews

Books Recommended

- Barun K.Mitra. Personality Development and soft skills. Oxford University Press. New Delhi. 2011.
- S P Sharma. Personality Development. Pustaq Mahal. New Delhi. 2010.
- Meenakshi Raman and Sangeetha Sharma. Technical Communication. Oxford University Press. New Delhi. 2009

Web Sources:

- https://www.skillsyouneed.com/ips/communication-skills.html
- https://www.businessnewsdaily.com/5836-top-interviewing-skills.html
- https://gdpi.hitbullseye.com/Group-Discussion.php

SOFT SKILLS III **2 0 0 2**

Course Objective: (Skill Development)

- To enable students to develop their soft skills and Body Language
- To enhance students Reading, Writing, Listening and Speaking skills
- To develop their self-confidence to excel at Interviews

	Credit Hours
UNIT–I	**06**
Powerful Presentation	
UNIT–II	**06**
Reinforcement	
UNIT–III	**06**
Using visual aids	
UNIT–IV	**06**
Types and Methods of Presentations	
UNIT–V	**06**
Obstacles to Presentation	
Total	**30 Hours**

Course Outcome:

CO1 To develop participants social and professional skills
CO2 To help participants manage time effectively
CO3 To build a strong resume to suit corporate requirements
CO4 To face interviews confidently
CO5 To enhance their aptitude abilities

Books Recommended:

- Roz Townsend: Presentation Skills for the Upwardly Mobile, Emerald, Chennai.
- Prasad, H. M. How to Prepare for Group Discussion and Interview. New Delhi: Tata McGraw-Hill Publishing Company Limited, 2001.
- Pease, Allan. Body Language. Delhi: Sudha Publications, 1998.

Web Sources:

- https://www.skillsyouneed.com/ips/communication-skills.html
- https://venngage.com/blog/presentation-skills/
- https://gdpi.hitbullseye.com/Group-Discussion.php

SECTOR SKILL COURSE

CLINICAL RESEARCH I 2 0 0 2

COURSE OBJECTIVE: (Employability)

To understand the fundamentals in clinical research

Unit I **7 hours**

Introduction to Clinical Research, Clinical Trial Terminologies, History of Clinical research, CPCSEA Guideline & Pre-clinical Trials, Drug Discovery & Development,

Unit II **7 hours**

Introduction to Toxicity Studies, Definition of clinical trial, Different Phases of clinical research : Subtypes of Phase 1,2,3, and 4, E –clinical trial, Bioavailability & Bioequivalence Studies [BA/BE]

Unit III **6 hours**

Drug Regulations & Ethics in Clinical Research: Background of ethics, Declaration of Helsinki, Belmont Report, Informed consent Process, Nuremberg code

Unit IV **5 hours**

History of Indian regulations, Schedule – Y- Appendices, ICMR (Indian Council of Medical Research) Guidelines, Indian GCP (Good Clinical Practice), ICH GCP (International Conference on Harmonisation)

Unit V **5 hours**

Drugs & magic remedies Act 1954, Drug prices control order, CTRI-Clinical trial registry of India, Regulations for AYUSH, An Introduction to Clinical Data Management, Data Management Standards.

TOTAL 30 HOURS

COURSE OUTCOMES

CO-1: To understand the basic the guidelines for conducting pre-clinical trial and research
CO-2: Will Know about various phases of clinical trials
CO-3: Knowledge about the ethics in clinical research
CO-4: To acquire knowledge Indian regulations in clinical research
CO-5: They would have studied in detail about Indian act for drug regulation

TEXT AND REFERENCE BOOKS

1. Spriet A., Dupin-Spriet T., Simon P. Methodology of Clinical Drug Trials, 2nd Edition. Publisher: Karger.
2. SheinChung Chow, Jen-Pei Liu. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. Publisher: Wiley.
3. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Publisher: Wiley-Blackwell.

CLINICAL RESEARCH II 2 0 0 2

COURSE OBJECTIVE: (Employability)

To understand the fundamentals in clinical data management.

UNIT I **5 hours**

CDMS (Clinical Data Management System) & CTMS (Clinical Trial Management System), Conduct, Medical coding / Writing, Close Out, Pharmacovigilance

Unit II **5 hours**

Clinical Trial Documentation, Audits and Inspections, Clinical trial documents, Definition & responsibility of Principal Investigator, Audit & inspections

Unit III **5 hours**

Different types of trial design, Role of Clinical Research Organization, Site Management and Monitoring in Clinical Research, Objectives of a Clinical Research Organization,

Unit IV **5 hours**

The Definition & responsibilities and duties of Principal Investigator, Role of a Clinical Research Organization, Role of personnel in a clinical trial

Unit V **10 hours**

Assignments and Case Study Report

TOTAL 30 HOURS

COURSE OUTCOMES

CO-1: They would have studied in detail about Clinical Data Management System
CO-2: Will Know about various clinical documentation and its importance
CO-3: Students would ably understand different types of trial design.
CO-4: Students can realize the responsibilities and duties of Principal Investigator in Clinical Research Organization
CO-5: Gain experience in clinical operation

TEXT AND REFERENCE BOOKS

1. Spriet A., Dupin-Spriet T., Simon P. Methodology of Clinical Drug Trials, 2nd Edition. Publisher: Karger.
2. SheinChung Chow, Jen-Pei Liu. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. Publisher: Wiley.
3. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Publisher: Wiley-Blackwell.

CLINICAL RESEARCH III 2 0 0 2

COURSE OBJECTIVE: (Employability)

To understand the fundamentals in clinical research operations management.

Unit I: 5 Hours

Operation in CRO & SMO: Site Selection Criteria- Site Selection parameters: Location, Staffing, Qualifications, History, Clinical trial experience, Area of therapeutic experience, Site Selection Check list, Site Initiation Visit (SIV), Single Centre/Multi Centre Trial-Definition, b

Unit II: 6 Hours

Investigator's Brochure, Nonclinical Studies, Nonclinical Pharmacology, Effects in Humans, Safety and Efficacy, Marketing Experience, Summary of Data and Guidance for the Investigator, Study Protocol - The contents of a trial protocol should generally include the topics.

UNIT III: 8 Hours

Study title, Purpose of research, Study design, Procedures, Women of childbearing potential, Possible risks and benefits, Compensation, Withdrawal of the consent, Right to new information, Contact persons, Patient consent form, Patient Information Sheet, Patient visit diary, Clinical Study Report- Title Page, Synopsis, List of Abbreviations and definitions of terms, ethics.

UNIT IV: 8 Hours

Importance of Essential Documents, Pre Study Document, Financial aspects of the trial, Approval letter from the IRB, IRB Composition, Investigational product, accountability at site, Subject enrolling log, Audit certificate, Post Study Documents, Final report by investigator to IRB, Final report by investigator to regulatory authorities, Clinical study report to document results and interpretation, Study Completion documents, Study Termination/closure documents

UNIT V: 3 Hours

Study Drug Packaging and Distribution Study Drug Receipt, Dispensing, Accountability, Storage, Disposal, Regulatory Requirement.

Total : 30 hours

COURSE OUTCOMES

CO-1: They would have studied in detail clinical research operations management
CO-2: Demonstrate various Nonclinical Studies and study protocol
CO-3: Students would able to how to prepare a clinical study report.
CO-4: Gain knowledge on Essential Documents preparation in clinical operation
CO-5: Understand the drug management in stores

TEXT AND REFERENCE BOOKS

1. Business Development for the Biotechnology and Pharmaceutical Industry by Martin Austin Clinical Drug Trials & Tribulations Ebooks by James Swarbrick.
2. Clinical Research Coordinator Handbook Ebook by Deborah Rosenbaum, Michelle Dresser.
3. Clinical Trial Medicine Ebook by Richard Chin, Bruce Y. Lee.