

**S. P. Mandali's**  
**RamnarainRuia Autonomous College**  
*(Affiliated to University of Mumbai)*



**RUIA COLLEGE**  
Explore ● Experience ● Excel

**Syllabus for PG Biotechnology**

**Program: M.Sc II**

**Program Code: Biotechnology(RPSBTK)**

(Credit Based Semester and Grading  
System for academic year 2021-2022)

## PROGRAM OUTCOMES

| PO          | PO Description   |
|-------------|--|
|             | <b>A student completing Master's Degree in Science program will be able to:</b>  |
| <b>PO 1</b> | Demonstrate in depth understanding in the relevant science discipline. Recall, explain, extrapolate and organize conceptual scientific knowledge for execution and application and also to evaluate its relevance.   |
| <b>PO 2</b> | Critically evaluate, analyze and comprehend a scientific problem. Think creatively, experiment and generate a solution independently, check and validate it and modify if necessary.   |
| <b>PO 3</b> | Access, evaluate, understand and compare digital information from various sources and apply it for scientific knowledge acquisition as well as scientific data analysis and presentation.  |
| <b>PO 4</b> | Articulate scientific ideas, put forth a hypothesis, design and execute testing tools and draw relevant inferences. Communicate the research work in appropriate scientific language.  |
| <b>PO 5</b> | Demonstrate initiative, competence and tenacity at the workplace. Successfully plan and execute tasks independently as well as with team members. Effectively communicate and present complex information accurately and appropriately to different groups.  |
| <b>PO 6</b> | Use an objective, unbiased and non-manipulative approach in collection and interpretation of scientific data and avoid plagiarism and violation of Intellectual Property Rights. Appreciate and be sensitive to environmental and sustainability issues and understand its scientific significance and global relevance. |
| <b>PO 7</b> | Translate academic research into innovation and creatively design scientific solutions to problems. Exemplify project plans, use management skills and lead a team for planning and execution of a task.   |
| <b>PO 8</b> | Understand cross disciplinary relevance of scientific developments and relearn and reskill so as to adapt to technological advancements.   |

## PROGRAM SPECIFIC OUTCOMES

| PSO          | Description  |
|--------------|--|
|              | <b>A student completing Master's Degree in Science program in the subject of Biotechnology will be able to:</b>  |
| <b>PSO 1</b> | Perceive the fundamental and advanced concepts in depth in the areas of biochemistry, molecular biology, immunology, medical microbiology and applying the conceptual knowledge to address the real time problems and exploring plausible solutions. |
| <b>PSO 2</b> | Annotate the vast amount of biological data by retrieving, processing and analyzing through various tools of bioinformatics and biostatistics.   |
| <b>PSO 3</b> | Criticize and assess the phases encountered from laboratory to premarketing stages in clinical research along with reviewing case studies.   |
| <b>PSO 4</b> | Identify local and global environmental issues and establish scientific strategies to devise economical solutions converging towards sustainable development   |
| <b>PSO 5</b> | Comprehend the process of patent documentation .Employ the relevance of legal and ethical implications in intellectual property rights, GMO ,developmental biology and other fields of biotechnology.  |
| <b>PSO 6</b> | Outline, execute ,Analyze experimental procedures and research proposal thus ameliorate their scientific writing temperament and soft skills consequently refining their abilities to troubleshoot any research problems.                            |
| <b>PSO 7</b> | Deduce the underlying principle of nanotechnological and biotechnological processes and develop the skills to offer contemporary solutions.  |

## PROGRAM OUTLINE

| YEAR | SEM | COURSE CODE               | COURSE TITLE  | CREDITS        |
|------|-----|---------------------------|---|----------------|
| I    | I   | RPSBTK101                 | Biochemistry  | 4              |
|      |     | RPSBTK102                 | Immunology  | 4              |
|      |     | RPSBTK103                 | Molecular Biology   | 4              |
|      |     | RPSBTK104                 | Biophysical and biochemical techniques                            | 4              |
|      |     | RPSBTKP101,102,103,104    | Practicals based on all four papers                               | 2 credits each |
|      | II  | RPSBTK201                 | Metabolism  | 4              |
|      |     | RPSBTK202                 | Immunology  | 4              |
|      |     | RPSBTK203                 | Bioprocess Technology   | 4              |
|      |     | RPSBTK204                 | Bioinformatics, phylogenetics and vitamins                        | 4              |
|      |     | RPSBTKP201 and RPSBTKP204 | Practicals based on all four papers<br>Research project (inhouse) | 2 credits each |
| II   | III | RPSBTK301                 | Nanotechnology  | 4              |
|      |     | RPSBTK302                 | Medical Microbiology  | 4              |
|      |     | RPSBTK303                 | GMO and Environment   | 4              |
|      |     | RPSBTK304                 | Developmental Biology   | 4              |

|  |  |            |                               |   |
|--|--|------------|-------------------------------|---|
|  |  | RPSBTKP301 | Practicals based on RPSBTK301 | 2 |
|--|--|------------|-------------------------------|---|

|  |           |                          |                                |                |
|--|-----------|--------------------------|--------------------------------|----------------|
|  |           | RPSBTKP302               | Practicals based on RPSBTK302  | 2              |
|  |           | RPSBTKP303               | Practicals based on RPSBTK303  | 2              |
|  |           | RPSBTKP304               | Practicals based on RPSBTK304  | 2              |
|  | <b>IV</b> | RPSBTK401                | Nanotechnology                 | 4              |
|  |           | RPSBTK402                | IPR & protection of inventions | 4              |
|  |           | RPSBTK403                | Clinical Studies               | 4              |
|  |           | RPSBTK404                | Biostatistics                  | 4              |
|  |           | RPSBTKP401 to RPSBTKP404 | Project                        | 2 credits each |

**SEMESTER III****Course Code: RPSBTK301****Course Title: PTC and ATC****Academic year 2020-21****COURSE OUTCOMES: On course completion, the student should be able to:**

| <b>COURSE OUTCOME</b> | <b>CO DESCRIPTION</b>   |
|-----------------------|---|
| <b>CO 1</b>           | Discuss the basic requirements of a tissue culture laboratory                                 |
| <b>CO 2</b>           | Design and carry out minor experiments in PTC, ATC following the required norms and protocols |
| <b>CO 3</b>           | Make use of the safety and precaution controls in these labs                                  |
| <b>CO 4</b>           | Formulate and conduct simple experiments in ATC, PTC labs                                     |
| <b>CO 5</b>           | Apply different preservation techniques in ATC and PTC  |
| <b>CO 6</b>           | Formulate and illustrate the essential methodologies in ATC and PTC                           |

**DETAILED SYLLABUS**

| <b>Course Code/<br/>Unit</b> | <b>Unit</b> | <b>Course/ Unit Title</b>  | <b>Lectures</b> |
|------------------------------|-------------|--|-----------------|
| RPSBTK301                    | I           | <b>Plant tissue culture-</b><br>Introduction to primary and secondary metabolism important pathways leading to biosynthesis of secondary metabolites in plants, Metabolic products produced from invitro culturing of plant cells, selection of plant cells/ tissues for production of a specific products, culture system in secondary plant product .Biotransformation of precursors by cell culturing, metabolic engineering for production of secondary metabolites, Hairy root culture, elicitation | 15              |
|                              | II          | <b>Plant tissue culture-II</b><br>Cryopreservation -Principle and types.<br>Germplasm conservation, Transgenic plants-<br>Edible vaccine, Golden rice  | 15              |

|  |   |    |
|--|---|----|
|  | <b>III Animal tissue culture-I</b><br>Biology of cultured cells, Culture vessels, Culture Media, Microbial contamination, cross contamination, Cryopreservation, Primary culture: Types, isolation of tissues, culturing of different cells. Cell lines: Development, Subculture and propagation  | 15 |
|  | <b>IV Animal tissue culture-II</b><br>Immortalization of cell line, cell line designation, selection of cell lines, routine maintenance, Cytotoxicity, Transformation, Culture of tumor cells, Scaffolds for Tissue Engineering: Classification of scaffold materials - examples, criteria for ideal scaffold, control of architecture, Scaffold design and fabrication techniques. Bioartificial organs: Artificial tissue and artificial skeleton. Three dimensional cell culture and tissue growth, 3D printing of tissue, cells and organs. Bioartificial heart, Bioartificial kidney. Tissue regeneration: Tissue regeneration driven by growth hormones, Stem Cells as source in regeneration of tissues, Therapeutic applications: Tissue therapy, Drug-vaccine-viral delivery in RM. Bioethical Issues. | 15 |

**References:**

1. Plant Cells in liquid culture (1991) Author : Payne Shuler, Hanser Publishers
2. Biochemistry and molecular biology of plants by Buchanan, Grissem, Jones; 1st Ed ; I.K International publishers
3. Textbook of Plant Pharmaceuticals by Chandrakant Kokate; 1 st edition; Elsevier
4. Plant Biotechnology by K.G. Ramawat , 1 st Ed. S.Chand and Company
5. Culture of Animal Cells: A Manual of Basic Techniques by Ian Freshney

**Practicals**  
**RPSBTKP301**

| Course code | Title   | Credits |
|-------------|---|---------|
| RPSBTKP301  | <ol style="list-style-type: none"> <li>1. Media preparation (MS, B5 and coconutwater)</li> <li>2. Seed sterilization: Physical &amp; Chemical methods. Check the efficiency of seed sterilization using both the methods.</li> <li>3. Explant preparation, inoculation &amp; initiation of tissue culture.</li> <li>4. Callus induction and characterisation</li> <li>5. Subculture of callus and plantlet establishment</li> <li>6. Synthetic seed</li> <li>7. Somatic embryogenesis</li> <li>8. Establishment of suspension cultures. (Periodic subculture of callus can be done on solid media/ semisolid media / liquid media)</li> <li>9. Dissection of chick embryo</li> <li>10. Monolayer formation (fibroblast) and passaging.</li> <li>11. To assay the radical scavenging activity of tissue hydrolysate- DPPH method</li> <li>12. Techniques for cell preservation</li> <li>13. Karyotyping with Giemsa staining</li> <li>14. Observation of Normal and transformed cell line</li> <li>15. Toxicology MTT Assay</li> </ol> | 2       |



**Course Code: RPSBTK302**

**Course Title: MEDICAL MICROBIOLOGY**

**Academic year 2020-21**

**COURSE OUTCOMES: On course completion, the student should be able to:**

| COURSE OUTCOME | CO DESCRIPTION   |
|----------------|--|
| CO 1           | Explain the basics of medical microbiology   |
| CO 2           | Comment and appreciate the significance of this field                              |
| CO 3           | Develop an understanding of various disease related issues of medical microbiology |
| CO 4           | Analyse and interpret the molecular techniques involved in medical microbiology    |
| CO 5           | Formulate and develop molecular diagnostic techniques for various infections       |
| CO 6           | Determine the role of biofilms in the field of medicine                            |

### DETAILED SYLLABUS

| Course Code/<br>Unit | Unit | Course/ Unit Title  | Lectures |
|----------------------|------|---|----------|
| RPSBTK302            | I    | <b>Cytogenetics</b><br>Chromosomal disorders, Karyotyping, G-banding, Chromosome analysis, variations, Chromosome painting, Molecular Cytogenetics, FISH, CGH   | 15       |
|                      | II   | <b>Medical microbiology</b><br>Infections of Respiratory tract- Pneumonia, GI tract infection- , Shigella, Vibrio, Salmonella<br>Nosocomial- S.pyogenes, Klebsiella. Viral infections HIV, Hepatitis(ELISA). Fungal- Candidiasis.<br>Parasitic: Malaria, Leishmania and Dengue, Ebola, SARS, Nipah, CoronaVirus | 15       |
|                      | III  | <b>Molecular diagnostics</b><br>Introduction to molecular diagnostics, pros and cons, importance, molecular techniques, amplification based techniques (probe, signal and target  | 15       |

|  |    |  |    |
|--|----|--|----|
|  |    | amplification). Molecular diagnostics for Pneumonia, Tuberculosis, Pseudomonas, HIV, Hepatitis. Candidiasis  |    |
|  | IV | <b>Biofilms</b><br>Biofilms in medicine: Outline specifications:<br>Stages in biofilm formation, Quorum sensing,<br>biofilm in medical devices- implants & treatments,<br>biofilms in pathogenesis, biofilm forming organisms-<br><i>E.coli, Pseudomonas spp, S.aureus</i> | 15 |

**References:**

1. Industrial Microbiology an Introduction Michael, Neil, John & Gary
2. Diagnostic Microbiology 5th edition Elmer Koneman, Stephen Allen Lippincott
3. Molecular Microbiology: Diagnostic Persing, Tenover, ASM press Washington
4. Principles & Practice (2004) Versalone DC
5. Pharmaceutical microbiology 7th ed., (2004) Hugo Russell's Edited by Stephen P. Denyer, Hodges and Sean P. Gorman

**Practicals****RPSBTKP302**

| Course code | Title  | Credits |
|-------------|--|---------|
| RPSBTKP302  | 1. Medical diagnostic - Identification of organisms from specimens (Salmonella, Shigella, Klebsiella pneumoniae,).<br>2. Staining of Biofilms<br>3. ELISA for Hepatitis,<br>4. PCR based diagnosis for Malaria | 2       |

**Course Code: RPSBTK303**

**Course Title: GMO AND ENVIRONMENT**

**Academic year 2020-21**

**COURSE OUTCOMES: On course completion, the student must be able to:**

| <b>COURSE OUTCOME</b> | <b>CO DESCRIPTION</b>   |
|-----------------------|---|
| <b>CO 1</b>           | Explain the importance GMOs and GM crops                                      |
| <b>CO 2</b>           | Elaborate on the development of GMOs to date                                  |
| <b>CO 3</b>           | Describe the use of genetic modification in agriculture                       |
| <b>CO 4</b>           | Discuss the potential risks & benefits of human activities on the environment |
| <b>CO 5</b>           | Discuss the potential risks & benefits associated with GMO crop consumption   |
| <b>CO 6</b>           | Articulate the concept of bioremediation of waste from different industries   |

### **DETAILED SYLLABUS**

| <b>Course Code/<br/>Unit</b> | <b>Unit</b> | <b>Course/ Unit Title</b>  | <b>Lectures</b> |
|------------------------------|-------------|--|-----------------|
| RPSBTK303                    | I           | <b>Introduction to GMOs</b><br>Genetically modified microorganisms, examples and methods, Humulin, ice minus bacteria, GM bacteria in bioremediation, use of PCR as a GMO identification tool, risks and controversies related to use genetically modified microorganisms. Proteins based assay methods, Toxicological evaluation. | 15              |
|                              | II          | <b>GMO crops</b>   | 15              |

|  |     |  |    |
|--|-----|--|----|
|  |     | GE crops' Arabidopsis as a model plant for studies in genetic engineering; Protocols on food and feed safety assessments, acute oral safety study in rats and mice, sub chronic feeding study in rodents, protein thermal stability, pepsin digestibility, livestock feeding |    |
|  | III | <b>Solid waste management</b><br>Solid waste treatment, pollution indicators & biosensors, biodegradation of xenobiotics, pesticides, phytoremediation   | 15 |
|  | IV  | <b>Biodegradation</b><br>Biodegradation of waste from food, textile, petrochemicals, paper industries, biological detoxification, Removal of oil spillage & grease deposits, Valorization, Radioactive waste, pollution measurement by MHRD guidelines.                      | 15 |

**References:**

1. Environmental Biotechnology ( 2nd Edition, 2005) Alan Scragg Oxford University Press
2. Environmental Biotechnology- Basic Concepts and Applications (2006) Indu Shekhar Thakur I. K. International Pvt.Ltd.
3. Environmental Biotechnology M. H. Fulekar Oxford & IBH Publishing

**Practicals**  
**RPSBTK303**

| Course code | Title  | Credits |
|-------------|--|---------|
| RPSBTKP303  | <ol style="list-style-type: none"> <li>1. Bioremediation- isolation of metal tolerant organisms &amp; study their growth characteristics and pattern.</li> <li>2. GMO validation - kit based/demo</li> <li>3. Isolation of pesticides degraders</li> <li>4. Pollution indicators- Detection and Identification.</li> </ol> | 2       |

**Course Code: RPSBTK304**

**Course Title: DEVELOPMENTAL BIOLOGY**

## Academic year 2020-21

**COURSE OUTCOMES: On course completion, the student should be able to:**

| COURSE OUTCOME | CO DESCRIPTION   |
|----------------|--|
| CO 1           | Apply the key principles of developmental biology toward evaluating and analyzing primary literature in the field.   |
| CO 2           | Explain significant concepts including mechanisms by which differential gene activity controls development, mechanisms that determine cell fate and mechanisms that ensure consistency and reliability of development. |
| CO 3           | Summarize the post fertilization events.   |
| CO 4           | Explain the molecular mechanisms of sex hormone.   |
| CO 5           | Discuss the immunology of pregnancy.   |
| CO 6           | Appraise and criticize the ethical issues in embryo research.  |

## DETAILED SYLLABUS

| Course Code/<br>Unit | Unit | Course/ Unit Title   | Lectures |
|----------------------|------|--|----------|
| RPSBTK304            | I    | <b>Human Embryonic development</b><br>Human Embryonic development: Events during fertilization, in-vitro fertilization, Zona pellucida, glycoprotein, Oolemma protein and their role in fertilization, sperm, antigens and their functional significance. Molecular and biochemical events during sperm function | 15       |
|                      | II   | <b>Post fertilization events</b><br>Post fertilization events: early embryonic development, establishing multicellularity, formation of blastula, embryonic germ layer, tracking of migrating cells.   | 15       |
|                      | III  | <b>Sex hormones and Implantation</b><br>Molecular mechanism of sex hormone action and regulation of gene expression. Implantation and endometrium antigens involved in implantation.   | 15       |

|  |    |  |    |
|--|----|--|----|
|  |    | Immunology of pregnancy. Superovulation, embryo culture and embryo transfer technology   |    |
|  | IV | <b>Infertility and reproductive vaccines</b><br>Infertility and reproductive vaccines. Frontiers in contraceptive research. Cryopreservation of sex gametes and embryos. Ethical issues related to embryo research | 15 |

**References:**

1. Langman's Medical Embryology ( 9th Edition 2004) T. W.Sadler. Lippincott Williams &Wilkins
2. Essential Developmental Biology (2nd Edition 2006) J. M. W. Slack Blackwell Publishing
3. Developmental Biology (8th Edition 2006) Scott F. Gilbert Sinauer Associates, Inc

**Practicals**  
**RPSBTKP304**

| Course code | Title   | Credits |
|-------------|---|---------|
| RPSBTKP304  | 1. Candling, Observing Chick embryo- stages of development, prepared slides/ Preserved specimen<br>2. Developmental biology- Visit to laboratory/video lectures for latest development in the field. To be documented | 2       |

## MSC PART II

### Modality of Assessment (SEMESTER III)

#### Theory Examination Pattern:

#### A) Internal Assessment- 40%- 40 Marks

| Sr No | Evaluation type   | Marks     |
|-------|---|-----------|
| 1.    | One Assignment/Case study/Project based / written assignment/ Presentations | 20        |
| 2.    | One Class Test (multiple choice questions/objectives/ match the column)     | 20        |
|       | <b>TOTAL</b>  | <b>40</b> |

#### B) External Examination- 60%- 60Marks

##### Semester End Theory Examination:

1. Duration - These examinations shall be of **2.5 hours** duration.
2. Theory question paper pattern:
  - There shall be 4 questions each of 15 marks. On each unit there will be one question.
  - All questions shall be compulsory with internal choice within the questions.

##### Paper Pattern:

| Question | Options        | Marks     | Questions Based on |
|----------|----------------|-----------|--------------------|
| Q.1)A)   | Any 1 out of 2 |           | Unit I             |
| Q.1)B)   | Compulsory     |           |                    |
| Q.2)A)   | Any 1 out of 2 |           | Unit II            |
| Q.2)B)   | Compulsory     |           |                    |
| Q.3)A)   | Any 1 out of 2 |           | Unit III           |
| Q.3)B)   | Compulsory     |           |                    |
| Q.4)A)   | Any 1 out of 2 |           | Unit IV            |
| Q.4)B)   | Compulsory     |           |                    |
|          | <b>TOTAL</b>   | <b>60</b> |                    |

#### External Examination- 60%- 60 Marks

##### Semester End Theory Examination: (Deviation from the usual modality)

Owing to the pandemic situation prevailing in 2020 and continuing in 2021, the external examinations (Semester End) may be conducted online as per the instructions/circulars received from the University of Mumbai and Maharashtra State notifications from time to time. The conventional mode of external examination will commence again only after the declaration of normalcy by the Government authorities.

**Practical Examination Pattern:****B) External Examination: - 50Marks****Semester End Practical Examination:**

| Particulars     | Paper     |
|-----------------|-----------|
| Laboratory work | 40        |
| Journal         | 05        |
| Viva            | 05        |
| <b>Total</b>    | <b>50</b> |

**Overall Examination & Marks Distribution Pattern****Semester III**

| Course    | RPSBTK301/302/303/304 |          | Total | Grand total |
|-----------|-----------------------|----------|-------|-------------|
|           | Internal              | External |       |             |
| Theory    | 40                    | 60       | 100   | 400         |
| Practical |                       | 50       | 50    | 200         |



## SEMESTER IV

**Course Code: RPSBTK401**

**Course Title: NANOTECHNOLOGY**

**Academic year 2020-21**

**COURSE OUTCOMES:** On course completion, the students should be able to:

| COURSE OUTCOME | CO DESCRIPTION  |
|----------------|---|
| CO 1           | Discuss the basics of nanotechnology, tools used for characterizing nanomaterials and specific applications of nanotechnology |
| CO 2           | Examine the nanorobotics devices of nature  |
| CO 3           | Analyse and interpret the latest developments in nanotechnology in the field of medical sciences                              |
| CO 4           | Explain drug delivery system using nanotechnology   |
| CO 5           | Apply nanomaterials in food, cosmetics, agriculture, environment management   |
| CO 6           | Assess and appreciate the thrust in this science and feel encouraged to take it ahead in research                             |

## DETAILED SYLLABUS

| Course Code/<br>Unit | Unit | Course/ Unit Title   | Lectures |
|----------------------|------|--|----------|
| RPSBTK401            | I    | <b>Introduction, synthesis of nanomaterials</b><br>Introduction, synthesis of nanomaterials, biological methods, use of microbial systems & plant extracts, use of proteins & templates like DNA. Characterization of nanomaterials, analysis techniques, properties of nanomechanical, optical, magnetic properties, electrical conductivity, thermal conductivity. | 15       |
|                      | II   | <b>CNTs and nanomotors</b>   | 15       |

|  |     |   |    |
|--|-----|---|----|
|  |     | Carbon nanotubes, Nanorobotics devices of nature: ATP synthase, the kinen, myosin, dynein, flagella modulated motion  |    |
|  | III | <b>Nanomedicine</b><br>Nanomedicine: biopharmaceutics, implantable materials, implantable chemicals, surgical aids, diagnostic tools, nanosensors, nanoscanning, nano enabled drug delivery system, nanorobotics in medicine. | 15 |
|  | IV  | <b>Applications of nanotechnology</b><br>Application of nanomaterials in food, cosmetics, agriculture, environment management   | 15 |

**References:**

1. The Nanoscope encyclopedia of nanoscience and nanotechnology, Vol I, V and VI (2005) Dr. Parag Diwan and Ashish Bharadwaj Pentagon Press New Delhi
2. Nano forms of carbon and its applications (2007) Prof. Maheshwar Sharon and Dr. Madhuri Sharon Manad Nanotech Pvt. Ltd.
3. Biotechnanotechnology lessons from Nature (2004) David Goodsell Wiley-Liss A John Wiley and sons
4. Nanotechnology- Basic science and emerging technologies (2005) Willson Kannangava, Smith, Simmons, Raguse Overseas Press
5. Textbook of Biotechnology (2005) R. C. Dubey S. Chand and Co.
6. Nanotechnology- Principles and practices S. K. Kulkarni Capital Publishing Co.

**Course Code: RPSBTK402****Course Title: IPR & PROTECTION OF INVENTIONS****Academic year 2020-21****COURSE OUTCOMES: On course completion, the student should be able to:**

| <b>COURSE OUTCOME</b> | <b>CO DESCRIPTION</b>  |
|-----------------------|--|
| <b>CO 1</b>           | Elaborate on the rules and regulations for patenting                             |
| <b>CO 2</b>           | Distinguish between copyright, Trademark, GI and Industrial designs              |
| <b>CO 3</b>           | Interpret different case laws in biotechnology                                   |
| <b>CO 4</b>           | Discuss the roles and responsibilities of the patent officer and the institution |
| <b>CO 5</b>           | Examine various patent applications  |
| <b>CO 6</b>           | Summarize the various case studies associated                                    |

**DETAILED SYLLABUS**

| <b>Course Code/<br/>Unit</b> | <b>Unit</b> | <b>Course/ Unit Title</b>  | <b>Lectures</b> |
|------------------------------|-------------|--|-----------------|
| RPSBTK402                    | I           | <b>Introduction to Intellectual Property</b><br>Introduction to IPR; Globalization & development of GATT, WTO, TRIPS agreement; Important provisions under TRIPS (Article/s 3, 4, 31/31f) agreement; Important provisions under Geographical indications act, PVPFRA; Traditional knowledge and Bio-piracy; Differences among copyright, Trademark, GI and Industrial designs; Classification of trademark; conventional v/s non-conventional. | 15              |
|                              | II          | <b>Concept of 'prior art'</b><br>Indian patents act 1970 and rights of patentee (section 48), Principles of patent protection (sec 83); Patenting biotech inventions: objectives, concept of novelty, concept of inventive step, non-patentable objects (sec 3/4), Budapest treaty and protection of micro-organisms, moral issues in patenting biotech  | 15              |

|     |   |    |
|-----|---|----|
|     | <p>inventions; Important case laws under Biotechnology; Harvard onco-mouse case, Diamond vs Chakrabarty case, Turmeric case, Hoodia cactus case, Patent databases and patent search. International patent classification (<a href="https://www.wipo.int/classifications/ipc/en/">https://www.wipo.int/classifications/ipc/en/</a> ) Analysis and report formation</p>   |    |
| III | <p><b>Patent filing and Infringement.</b><br/>         Patent application- forms and guidelines, fee structure, time frames; Types of patent applications: ordinary patent application (provisional and complete specifications, timeline); PCT (timeline) and conventional patent applications; Patent-of-addition v/s divisional patent, publication of patents-gazette of India, status in Europe and US. Parts of a patent; How to write a claim, types of claims (independent v/s dependent claims, Markush claims, Omnibus claims, biotechnology claims, etc.), Patenting by research students, lecturers and scientists- University/organizational rules in India and abroad, credit/royalty sharing by workers and financial incentives. Patent infringement- meaning, scope, litigation, case studies and examples. Important case studies: Glivec case (section 3d), Natco v/s Bayer case of compulsory licensing</p> | 15 |
| IV  | <p><b>Important aspects of IP protection</b><br/>         IP transfer, patent filing, types of patent, types of claim, claim drafting, patent search. Exhaustion doctrine and article 6 of TRIPS agreement in conjunction with sec 48 of Indian patents act 1970; case studies; fair dealing and de minimis principle. IP enforcement (proactive vs reactive measures):-civil, criminal and custom remedies. Article 34 of TRIPS agreement Legislative structure and IP protection in India, role of IPAB. Copyright protection: Rights of copyright owner (sec 14, economic rights; sec 57, moral rights), Contract of service v/s Contract for service (sec 17) and idea expression dichotomy under Indian copyright act 1957 spring-board doctrine, doctrine of first-sale and Creative Commons (CC). Levels of trademark protection (based on trade name). Passing off v/s trademark infringement</p>                       | 15 |

**References:**

1. [https://www.wipo.it/wipo\\_magazine/en/2011/03/article\\_0002.html](https://www.wipo.it/wipo_magazine/en/2011/03/article_0002.html)
2. [https://www.wipo.int/edocs/mdocs/africa/en/wipo\\_tiscs\\_znz\\_16/wipo\\_tiscs\\_znz\\_16\\_t\\_6.pdf](https://www.wipo.int/edocs/mdocs/africa/en/wipo_tiscs_znz_16/wipo_tiscs_znz_16_t_6.pdf)
3. <https://www.lexisnexisip.com/knowledge-center/totalpatent-one-and-the-usptos-seven-step-patent-search-strategy/>
4. <https://www.khuranaandkhurana.com/wp-content/uploads/2017/01/ANATOMY-OF-PATENT-SPECIFICATION.pdf>
5. [https://www.wipo.int/edocs/mdocs/aspac/en/wipo\\_ip\\_phl\\_16/wipo\\_ip\\_phl\\_16\\_t5.pdf](https://www.wipo.int/edocs/mdocs/aspac/en/wipo_ip_phl_16/wipo_ip_phl_16_t5.pdf)
6. <http://www.mondaq.com/india/x/667450/Patent/Patent+Claims+And+Their+Types>

**Course Code: RPSBTK403****Course Title: CLINICAL STUDIES****Academic year 2020-21****COURSE OUTCOMES: On course completion, the student should be able to:**

| <b>COURSE OUTCOME</b> | <b>CO DESCRIPTION</b>  |
|-----------------------|--|
| <b>CO 1</b>           | Discuss the ethical issues in human subjects research                          |
| <b>CO 2</b>           | Imagine and understand the different phases of clinical trials                 |
| <b>CO 3</b>           | Analyse the roles and responsibilities of the investigator and the institution |
| <b>CO 4</b>           | Examine various regulatory issues related to clinical studies                  |
| <b>CO 5</b>           | Recall the companies and organizations associated in this field                |
| <b>CO 6</b>           | Develop interest on medical writing and design a clinical study report         |

**DETAILED SYLLABUS**

| <b>Course Code/<br/>Unit</b> | <b>Unit</b> | <b>Course/ Unit Title</b>  | <b>Lectures</b> |
|------------------------------|-------------|--|-----------------|
| RPSBTK403                    | I           | <b>Drug discovery and Preclinical toxicology</b><br>Pre-Clinical toxicology: General Principals, | 15              |

|  |     |   |    |
|--|-----|---|----|
|  |     | Systemic toxicology, (Single dose and repeat dose toxicity studies), Carcinogenicity, Mutagenicity, Teratogenicity, Reproductive toxicity, Local toxicity, Genotoxicity, animal toxicity requirements   |    |
|  | II  | <b>Introduction to Clinical trials</b><br>Introduction to clinical trials, Historical guidelines in clinical research (Nuremberg code, Declaration of Helsinki and Belmonte report), ICH-GCP guidelines (E6-R1), Phases of clinical trials  | 15 |
|  | III | <b>Clinical study design</b><br>Clinical study methodology and regulations: Principles, types (single blinding, double blinding, open access, randomized trials and their examples), Design of protocol, CRF, e-CRF, IB, ICF and preparation of trial reports, Regulations involved (ICMR guidelines) and ethics. | 15 |
|  | IV  | <b>Medical Writing</b><br>Medical Writing: Literature search and medical articles, contract writing, publication, abstracts, bibliography, clinical study reports, principles and softwares in CDM (Clinical Data Management)   | 15 |

**References:**

1. EC R1 guidelines
2. ICMR ethical guidelines
3. D & C Rules - Schedule Y
4. Law Of Intellectual Property Rights Shiv Sahai Singh Deep & Deep Publications (p) Ltd
5. WTO And Intellectual Property Rights By Talwar Sabanna (2007) Serials Publications
6. IPR: Unleashing the Knowledge Economy (2003) Prabuddha Ganguli Tata Mcgrow Hill publication

**Course Code: RPSBTK404**  
**Course Title:BIOSTATISTICS**  
**Academic year2020-21**

**COURSE OUTCOMES: On course completion, the student should be able to:**

| COURSE OUTCOME | CO DESCRIPTION   |
|----------------|--|
| CO 1           | Calculate standard normal scores and resulting probabilities   |
| CO 2           | Interpret and explain a p-value  |
| CO 3           | Perform a two-sample t-test and interpret the results; calculate a 95% confidence interval for the difference in population means                |
| CO 4           | Discuss and interpret results from Analysis of Variance (ANOVA), a technique used to compare means amongst more than two independent populations |
| CO 5           | Analyse and interpret relative risks and odds ratios when comparing two populations  |
| CO 6           | Evaluate correlation and regression  |

**DETAILED SYLLABUS**

| Course Code/<br>Unit | Unit | Course/ Unit Title   | Lectures |
|----------------------|------|--|----------|
| RPSBTK404            | I    | <b>Introduction to Statistics</b><br>Statistical population, sample from population, Random sample. Central Tendency: Mean, Median and Mode, Standard Deviation Confidence intervals   | 15       |
|                      | II   | <b>Gaussian distribution and normality</b><br>Gaussian Distribution and testing for normality, Non-parametric tests (Sign test, Wilcoxon test, Mann-Whitney Test, Krushkal- Whllis test,), transforming data to create Gaussian Distribution | 15       |
|                      | III  | <b>Hypothesis testing</b>  | 15       |

|  |    |  |    |
|--|----|--|----|
|  |    | Test of Significance. Hypothesis testing:-<br>Theory o errors - Type I and Type II errors,<br>Null hypothesis, P values-one v/s two tail P values, t-<br>test(paired&amp;<br>unpaired), z-test, Chi square test, contingencytable. |    |
|  | IV | <b>ANOVA</b><br>Comparing three or more groups- Introduction<br>to ANOVA, One way ANOVA, repeated measures<br>ANOVA, Friedman Test. Correlation and Regression:<br>Linear and multiple Correlation and Regression.                 | 15 |

**References:**

1. Introduction to Biostatistics (Second Edition-2005) N. Gurumani M J P Publishers
2. Basic Biostatistics (2008) B. Burt Gerstman Jones and Bartlett Publishers
3. Biostatistics: A foundation For Analysis In Health Sciences ( 7th Edition 1999) Wayne W. Daniel John Wiley & Sons Inc.
4. Fundamentals of Biostatistics (2006) Veer Bala Rastogi Ane Books India
5. Biostatistics- The Bare Essentials ( Second Edition 2000) Nosman Streiner B.C. Decker Inc.

**Practicals RPSBTKP401 to RPSBTKP404**

Students will have to undergo mandatory hands on project for 200M in an established lab/institute/industry/Parent institute for 4-6 months. Submit dissertation thesis and present it to the examiners during final exam.



## MSC PART II

### Modality of Assessment (SEMESTER IV)

#### Theory Examination Pattern:

##### A) Internal Assessment- 40%- 40Marks

| Sr No | Evaluation type   | Marks     |
|-------|---|-----------|
| 1.    | One Assignment/Case study/Project based / written assignment/ Presentations | 20        |
| 2.    | One Class Test (multiple choice questions/objectives/ match the column)     | 20        |
|       | <b>TOTAL</b>  | <b>40</b> |

##### B) External Examination- 60%- 60Marks

###### Semester End Theory Examination:

1. Duration - These examinations shall be of **2.5 hours** duration.
2. Theory question paper pattern:
  - There shall be 4 questions each of 15 marks. On each unit there will be one question.
  - All questions shall be compulsory with internal choice within the questions.

###### Paper Pattern:

| Question | Options        | Marks     | Questions Based on |
|----------|----------------|-----------|--------------------|
| Q.1)A)   | Any 1 out of 2 |           | Unit I             |
| Q.1)B)   | Compulsory     |           |                    |
| Q.2)A)   | Any 1 out of 2 |           | Unit II            |
| Q.2)B)   | Compulsory     |           |                    |
| Q.3)A)   | Any 1 out of 2 |           | Unit III           |
| Q.3)B)   | Compulsory     |           |                    |
| Q.4)A)   | Any 1 out of 2 |           | Unit IV            |
| Q.4)B)   | Compulsory     |           |                    |
|          | <b>TOTAL</b>   | <b>60</b> |                    |

#### External Examination- 60%- 60 Marks

##### Semester End Theory Examination: (Deviation from the usual modality)

Owing to the pandemic situation prevailing in 2020 and continuing in 2021, the external examinations (Semester End) may be conducted online as per the instructions/circulars received from the University of Mumbai and Maharashtra State notifications from time to time. The conventional mode of external examination will commence again only after the declaration of normalcy by the Government authorities.

**Practical Examination Pattern:**

Students will have to undergo mandatory hands on project for 200M in an established laboratory /college laboratory for 4-6 months

**Semester End Examination: (200 marks)**

| Particulars                                       | Marks      |
|---|------------|
| Guide   | 50         |
| Panel of Departmental Teachers (except the guide) | 50         |
| Internal examiner                                 | 50         |
| External examiner                                 | 50         |
| <b>Total</b>                                      | <b>200</b> |

**Overall Examination & Marks Distribution Pattern****Semester IV**

| Course                   | RPSBTK401/<br>402/ 403/404 |          |       | Grand Total |
|--------------------------|----------------------------|----------|-------|-------------|
|                          | Internal                   | External | Total |             |
| Theory                   | 40                         | 60       | 100   | 400         |
| Semester end examination |                            | 50       | 50    | 200         |

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