



D. Y. Patil University

# **D.Y. PATIL EDUCATION SOCIETY KOLHAPUR DEEMED UNIVERSITY**

(Declared under section 3 of the UGC act 1956)

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## ***POST-GRADUATE PROGRAM IN STEM CELL & REGENERATIVE MEDICINE***

### ***COURSE CURRICULUM***

***M.Sc.***

## ***STEM CELL & REGENERATIVE MEDICINE***

***(Choice based Credit System)***



### **BL-SC-01: Introduction**

Department of Stem cell and Regenerative Medicine offer a specialized course on M.Sc in Stem cell and Regenerative Medicine since 2011 for the aspiring candidates who are interested in the field of stem cell and regenerative medicine. The course covers basic and applied science covering various aspects of cell, molecular and developmental biology with special emphasis on stem cell biology from its origins to its current and potential application in pre-clinical and clinical fields related to various disorders.

### **BL-SC-02: Vision, Mission and Goal**

#### **Mission**

- The mission of the course is to impart in-depth knowledge on different types of stem cells and its in-vitro and in-vivo applications, scope and hope of stem cells and so on effectively.
- To advance the fundamental knowledge of stem cells and their differentiation pathways, understand how stem cells interact with tissues and organ systems of the body, and develop stem cell-based research and therapies to treat human diseases and injuries.
- To develop an Interdisciplinary course works with a strong base for success in life.

#### **Vision and Goal**

- To cultivate a broad range of interdisciplinary stem cell research (i.e., basic and translational stem cell biology research)
- To train future leaders for education, research and delivery of novel therapies using stem cells.
- To serve as a best teaching and educational center for stem cell biology and regenerative medicine.
- Develop experimental models for use of stem cells to alter physiological and developmental characteristics of tissues and organ systems involved in disease processes.
- To seek a leadership role in basic and translational stem cell research through developing innovative, multidisciplinary collaborative approaches.

#### **Outcome**

- Extensive theoretical and practical knowledge on Stem cells and Regenerative medicine in a short period of time
- Wide Job opportunities in industries, companies, Universities and other laboratories
- Increases the opportunities to pursue higher studies in foreign countries
- The course prepares students for leadership in the critically important and dynamic industries of stem cells, biotechnology and pharmaceuticals.



- They can go as lecturers/Asst professors in colleges of biotechnology, pharmacology, microbiology, and other biomedical sciences.
- They could get a vast idea about the research and development in this field, planning for their future research
- They could get jobs in hospitals where stem cell clinical trials are on.

**BL-SC-03: Syllabus**

**SEMESTER-I**

<b>Theory Papers</b>	<b>Theory marks</b>	<b>Internal marks</b>	<b>Total marks</b>
(Paper I) SC.1.1.1 Molecular Cell Biology	80	20	100
(Paper II) SC.1.1.2 Immunology	80	20	100
(Paper III) SC.1.1.3 Biochemistry	80	20	100
(Paper IV) SC.1.1.4 Developmental Biology, Anatomy and Histology	80	20	100
<b>Practical</b>	<b>Marks</b>		
(Practical I) SC.1.1.P.1 Molecular Cell Biology and Developmental Biology	80	-	80
(Practical II) SC.1.1.P.2 Biochemistry, Anatomy and Histology	80	-	80
(Practical III) SC.1.1.P.3 Industry visit and report	40	-	40
<b>Total</b>	<b>520</b>	<b>80</b>	<b>600</b>

**SEMESTER-II**

<b>Theory Papers</b>	<b>Theory paper marks</b>	<b>Internal marks</b>	<b>Total marks</b>
(Paper V) SC.1.2.1 Cell Physiology & Metabolism	80	20	100
(Paper VI) SC.1.2.2 Biomedical Instrumentation	80	20	100
(Paper VII) SC.1.2.3 Biomaterials, Medical Nanobiotechnology & Tissue Engineering	80	20	100
(Paper VIII) SC.1.2.4 Animal Models Biostatistics & Bioinformatics	80	20	100
<b>Practical</b>	<b>Marks</b>		
(Practical IV) SC.1.2.P.4 Cell Physiology, Metabolism and Biomedical Instrumentation	80	-	80
(Practical V) SC.1.2.P.5 Biomaterials, Medical Nanobiotechnology & Tissue Engineering, Animal Models, Biostatistics & Bioinformatics	80	-	80
(Practical VI) SC.1.2.P.6 Industry visit and report	40	-	40
<b>Total</b>	<b>520</b>	<b>80</b>	<b>600</b>



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### SEMESTER-III

Theory Papers	Theory paper marks	Internal marks	Total marks
(Paper IX) SC 2.3.1 Stem Cell Biology	80	20	100
(Paper X) SC 2.3.2 Disease & Applications of Stem Cells	80	20	100
(Paper XI) SC 2.3.3 Cell & tissue banking and cryopreservation	80	20	100
(Paper XIIA) 2.3.4 Clinical research, Bioethics and regulatory affairs	80	20	100
(Paper X11B) 2.3.4 Molecular Diagnostics and Therapeutics			
Practical	Marks		
(Practical VII) SC 2.3.P.7 Stem Cell Biology, Diseases and Application of Stem Cells	80	-	80
(Practical VIII) SC 2.3.P.8 Stem Cell Banking & Cryopreservation, Clinical Research, Bioethics, Regulatory affairs	80	-	80
(Practical IX) SC 2.3.P.9 Industry visit and report	40	-	40
<b>Total</b>	<b>520</b>	<b>80</b>	<b>600</b>

### SEMESTER-IV

Theory Papers	Theory paper marks	Internal marks	Total marks
(Paper XIII) SC.2.4.1 Research Methodology	80	20	100
(Paper XIV) SC.2.4.2 Entrepreneurship & Management	80	20	100
Project and Practical			
4.3 Project	350	-	350
Practical-10 Industrial visit and report	50	-	50
<b>Total</b>	<b>560</b>	<b>40</b>	<b>600</b>



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## Course Curriculum

### SEMESTER-I

#### (Paper I) SC.1.1.1-Molecular Cell Biology (60h)

- 1. Cell structure and Membrane Transport (15 hrs)**

Evolution, Prokaryotes, Eukaryotes & their organelles, Cytoskeleton, the self assembly and dynamic structure of cytoskeletal filaments, regulation of cytoskeletal filaments, molecular motors. Cell Polarity & Membrane Transport, Introduction to cell polarity, Cell-cell adhesion, Cell junction proteins, Cell-matrix adhesion, Extracellular matrix. Membrane composition and structure, Membrane fluidity ( Fluid mosaic mode) ,Active and passive transport, mediated and non-mediated transport, Carrier proteins Na<sup>+</sup> driven pumps, Na<sup>+</sup>- K<sup>+</sup> ATPase pump, Ca<sup>2+</sup>, H<sup>+</sup> pumps, Membrane potential and action potential (propagation of an impulse, saltatory conduction, chemical synapse, long term potentiation).
- 2. Cell Signaling and cell cycle regulators (15 hrs)**

Cell Signaling, feedback & crosstalk, signaling molecules & their receptors, functions of cell surface receptors: G Proteins – coupled receptors, tyrosine kinase, enzyme linked receptors, pathways of Intracellular signal transduction: C-AMP pathway, Cyclic GMP, PI3- Kinase Phospholipids & Calcium homeostasis, RAS/ RAF & MAP kinase, JAK /STAT & TGF – β/Smad pathways, NF- κB signaling, Wnt pathway, signaling based on pro-cleavage pathway (Hedgehog, Notch & SHP-2- ER signaling). An overview of the cell cycle, mitosis and meiosis, components of the cell cycle, control system, intracellular control of cell-cycle events. Programmed cell death (Apoptosis)
- 3. Central dogma theory (15 hrs)**

DNA replication: Initiation, elongation and termination in prokaryotes and eukaryotes, Gene stability and DNA repair, DNA repair enzymes, photoreactivation, nucleotide excision repair, mismatch correction, SOS repair. Recombination: homologous and non-homologous recombination, site specific recombination.

Prokaryotic Transcription & Regulation, promoters, operators, Initiation, Termination, operon concept; Regulation of transcription of lactose and tryptophan, Processing of t-RNA and r-RNA ,types of RNA polymerase, 5'-Cap formation, 3'-end processing and polyadenylation in Eukaryotic, RNA Splicing.

Translation: Ribosomes composition and assembly, Universal genetic code, degeneracy of codons, termination codons, wobble hypothesis. Mechanism of initiation, elongation and termination, Transport of proteins and molecular chaperones, protein stability, protein turnover and degradation.



**4. Molecular biology of cancer**

**(15 hrs)**

Molecular biology of Cancer – Activation of oncogenes, Inactivation of tumor suppressor genes, Inappropriate expression of micro RNAs in cancer, Chromosomal rearrangements and cancer, Viruses and cancer, Chemical carcinogenesis.

**Text/Reference Books:-**

1. Bruce Alberts, Alexander Johnson, Julian Lewis, Keith Roberts, Peter Walter - Molecular Biology of the Cell, 5<sup>th</sup> edition (2007), Garland science, New York.
2. Harvey Lodish- Molecular Cell biology, 5<sup>th</sup> edition (2003), Freeman W. H. and company
3. Gerald Karp - Cell Biology, 7<sup>th</sup> edition (2013), Wiley publications.
4. E. D. P. De Robertis and E. M. F. De Robertis Jr.- Cell and Molecular Biology, Eight edition (2010), Lippincott Williams & Wilkins publication.
5. James Watson, Tania Baker, Stefan Bell, Alexander Gann, Michelle Lewin, Richard Losick - Molecular biology of the gene, 7<sup>th</sup> edition (2013), Pearson publications.

**(Paper II) SC.1.1.2 Immunology (60 h)**

**1. Basics of Immunology and humoral immune response**

**(15 hrs)**

Adaptive and Innate immunity, Humoral Immunity, Mucosal Immunity, Cellular Immunity, Cells of immune system, Memory responses, Inflammation, Vaccination, Primary and secondary lymphoid organs, Lymphocyte trafficking Immunoglobulin structure, Different classes of immunoglobulins, Functions of Ig, Immunoglobulin variability, Regulation of Ig production, Antibody specificity and affinity maturation

**2. Development of the immune system and Antigen presentation**

**(15 hrs)**

Lymphocyte development, Immune tolerance, B cell development and signaling events involved in B cell differentiation, T-cell development and signaling events involved in T-cell development. Structure of antigens, Antigen recognition, Antigen presenting cells, Antigen processing, Role of MHC and accessory molecule, Cells involved in immune effector responses, Cytokines, neuro-endocrine modulation, Genetic factors affecting immune responsiveness.

**3. The complement pathways and cell mediated immunity**

**(15 hrs)**

Complement components, complement receptors, classical pathway and alternate pathways of complement activation. T cell regulation, T cell subsets, Activation of T and B cells, Cell mediated cytotoxicity, Antibody dependent cell mediated cytotoxicity (ADCC), NK cells, LAK cells, Macrophages, activation of macrophages, Immune- adhesion molecules.



**4. Cytokine, Chemokines and Autoimmunity**

**(15 hrs)**

Lymphokines, Chemokine families, Cytokine signaling, role of chemokines in homing and inflammation, transplant immunology and immunological tolerance, acute & chronic graft rejection, natural, experimental, auto immunity, Hypersensitivity type I, II, III and IV reactions. Autoimmune disorders, Tumor immunology, Immunological techniques

**Texts/Reference Books:-**

1. Jenni Punt, Judy Owen, and Sharon Stranford - Kuby Immunology- 7<sup>th</sup> edition (2013), Macmillan publications
2. Abul K. Abbas, Andrew H. H. Lichtman, and Shiv Pillai- Cellular and Molecular Immunology, 8<sup>th</sup> edition (2014), Elsevier publications
3. Hood, Wood and Wilson - Immunology , 2<sup>nd</sup> edition (1984)
4. Ivan M. Roitt- Essential Immunology, 8<sup>th</sup> edition (1994), Blackwell Sci., Oxford.

**(Paper III) SC.1.1.3 BIOCHEMISTRY**

**(60 hrs)**

**1. Chemistry of carbohydrates**

**(15 hrs)**

Classification, properties and biological functions, Monosaccharide's- classification, properties, functions, isomerism, D & L forms, Disaccharides -Glycosidic bond, classification, composition and biological importance. Polysaccharides: Classification, properties and functions. Salic acid and blood group substances Identification tests for sugars. Characterization/identification test used for sugars, Disorders of carbohydrate metabolism, Diabetes mellitus, Glycohemoglobins, Hypoglycemia, Ketone bodies, Glucose tolerance test

**2. Chemistry of proteins**

**(15 hrs)**

Classification, properties and biological functions, Amino acid: Classification, structure and properties, amphoteric nature, isoelectric point, peptide bond formation, Protein Structure: primary, secondary, tertiary and quaternary, Oxygen transporting proteins- myoglobin, hemoglobin, collagen structure and functions.

**3. Chemistry of lipids and nucleic acids**

**(15hrs)**

Classification, properties and functions of lipids. fatty acids-composition, classification, characteristics and functions, Simple lipids-Triglycerides Conjugated lipids: phospholipids-types and functions, glycolipids lipoproteins. Cholesterol-structure, properties, occurrence and functions. Liposomes. lipids, lipoproteins and apolipoproteins-role in diseases. Experimental evidence for nucleic acids as genetic



material. Components of nucleic acids. Structure of nucleosides and nucleotides. Watson and Crick model of DNA A, B and Z forms of DNA. RNA-structure and type  
Inborn errors of nucleic acid metabolism

**4. Nutrition and organ function tests (15 hrs)**

Classification of nutrition. Composition of nutrition Caloric contents of food Daily caloric requirement-BMR, specific dynamic action and physical activity- factors affecting and significance. Formulation of diet in health and disease Balanced diet and nutritional diseases.

Urine profile Liver function tests Kidney function tests Chemical analysis of CSF Electrolyte and fluid balance and its disorders Electrolyte, blood gases and acid base balance.

**Text/Reference books:**

1. Jeremy M. Berg, Lubert Stryer, John L. Tymoczko, Gregory J. Gatto - Biochemistry, 8<sup>th</sup> edition (2015), WH Freeman publications.
2. A. L. Lehninger, D.L. Nelson and M.M. Cox- Principles of Biochemistry – 2<sup>nd</sup> edition. Worth Publishers, U.S.A 1993
3. Biochemistry by Voet Donald, Voet, Judith G. (2004) 3<sup>rd</sup> edition (J Wiley and Sons.)

**(Paper IV) SC.1.1.4 -Developmental Biology and Histology (60 h)**

**1. Developmental Biology and clinical embryology (15 hrs)**

Introduction of animal development, Scope of development biology, stages of animal Development, Evolution of development, Techniques used to study mechanisms of development.

Differentiation of germ cells and gametogenesis, Fertilization and implantation Stages of human embryonic development, Congenital malformations and teratogenesis Reproductive failure and infertility and assisted reproduction

**2. Fate mapping And regeneration: (15 hrs)**

Fate Mapping, Autonomous cell specification by cytoplasmic determinants, Specification of cell fate by progressive cell-cell interactions Establishment of body axis in mammals. Regeneration, aging and metamorphosis.

**3. Organogenesis and extra embryonic membranes (15 hrs)**

Formation of germ layers (gastrulation and neurulation up to formation of notochord) Placenta, amnion and amniotic fluid, yolk sac and allantois. The development of the



heart, vessels, bones, teeth, mammary gland, digestive tract & its derivative and nervous system, Parturition & multiple pregnancies.

#### 4. Anatomy and Histology

(15 hrs)

**Human Systems-** Alimentary system, Cardiovascular System, Respiratory system, Digestive system, Urinary systems, Central Nervous system, Musculoskeletal System, Endocrine system, Reproductive system

**Human Histology:** Cytoplasm – Cytoplasmic matrix, cell membrane, cell organelles, cytoskeleton, cell inclusions, cilia and flagella. Nucleus – nuclear envelope, nuclear matrix, DNA and other components of chromatin, protein synthesis, nucleolus, nuclear changes indicating cell death. Cell cycle, mitosis, meiosis, cell renewal. Cellular differentiation and proliferation. Tissues of Body: Light and electron microscopic details and structural basis of function, regeneration and degeneration. The systems/organs of body – Cellular organization, light and electron microscopic features, structure function correlation, and cellular organization. Histology – microscopy, basic tissues, blood vessels, lymphoid tissue and histology of organs

#### References

1. Scott F Gilbert and J. F. Beressi- Developmental biology, 11<sup>th</sup> edition (2016), Sinauer publishers
2. John Hall Arthur Guyton- Text Book of Medical Physiology, 11th edition . (2005), Elsevier.
3. Tortora and Derrickson : Principles of Anatomy and Physiology, 11th edition . (2005) Wiley
4. Inderbir Singh : Text Book of Human Histology with Colour Atlas, 6th edition. (2011) Jaypee
5. Richard Drake A. Wayne Vogl Adam Mitchell- Gray's Anatomy for students, 3<sup>rd</sup> edition (2014), Elsevier.
6. Moore and Persaud - The developing human, clinically oriented embryology. 6<sup>th</sup> edition (1998). Saunders press.

#### SEMESTER-I

##### (Practical I) SC.1.1.P.1 Molecular cell Biology and Developmental Biology (30 h)

- 1) Preparation of temporary slides of Mitosis from Onion root tips
- 2) Preparation of temporary slides of meiosis from *Tradescantiabuds*/Datura/Testis.
- 3) Cell counting and viability
- 4) Blood smear preparation
- 5) Karyotyping analysis.
- 6) Preparation of slides of polytene chromosomes.
- 7) Microscopy techniques



- 8) Isolation of genomic DNA.
- 9) Isolation of RNA.
- 10) Estimation of DNA and RNA.
- 11) Gel electrophoresis
- 12) ABO blood grouping
- 13) Cell toxicity assay (Trypan blue indicator and MTT);
- 14) apoptosis of cells
- 15) Culture and mounting of Chick embryo.
- 16) News ring method
- 17) Shell less culture
- 18) Demonstration of Chick embryo fibroblast.

**(Practical II) SC.1.1.P.2 Biochemistry Anatomy, Histology and Immunology (30 h)**

- 1) Separation of amino acids by paper chromatography.
- 2) Separation of phospholipids by TLC technique.
- 3) Colorimetric estimation of glucose.
- 4) Colorimetric estimation of proteins.
- 5) Determination of isoelectric pH of Proteins.
- 6) Demonstration of various organ systems of mice/rat.
- 7) Spotting of bones.
- 8) Spotting and discussion of histological slides of animal tissues.
- 9) Microtome and hematoxylin and eosin staining
- 10) ABO blood grouping
- 11) Immunodiagnosics using commercial kits
- 12) Immunohistochemistry
- 13) Mixed lymphocyte reaction.

**(Practical-III) SC.1.1.P.3 Industrial visit and report**



## SEMESTER-II

### (Paper V) SC.1.2.1 CELL PHYSIOLOGY & METABOLISM (60 h)

#### 1. Carbohydrate Metabolism:

(15 hrs)

Introduction of metabolism and overview Digestion and absorption of carbohydrates. Glycolysis - aerobic and anaerobic, regulation of glycolysis. Krebs cycle and its regulation Alternate pathways of carbohydrate metabolism- Hexose Monophosphate shunt, Glyoxylate pathway. Interconversions and metabolism of other sugars (Fructose, Galactose & Mannose) Gluconeogenesis, Glycogenesis and glycogenolysis and their regulation. Regulation of blood glucose and homeostasis. Disorders associated with carbohydrate metabolism-glycogen storage diseases, galactosemia.

#### 2. Lipid and Protein Metabolism:

(15 hrs)

Digestion and absorption of lipids.  $\beta$ -oxidation of fatty acid and regulation. Energy yields from fatty acid oxidation. Synthesis of fatty acid and regulation. Synthesis of triacylglycerides. Role of acyl carnitine. Ketone bodies - formation and utilization. Disorders of lipid metabolism (Ketosis, Niemann Pick disease, Gaucher's disease, hypercholesterolemia, hyper and hypolipoproteinemia, fatty liver, obesity and atherosclerosis) Classification and biological importance of proteins. Digestion and absorption of Protein Amino acid metabolism (Transamination, Deamination, urea cycle) and its significance, Disorders associated with Protein metabolism – phenylketonuria, albinism, alkaptonuria

#### 3. Enzymes:

(15 hrs)

Biochemical nature of Enzyme, Characteristics of enzymes. Enzyme substrate complex. Concept of active centre, binding sites, and ES complex formation. Enzyme activity, international units, specific activity, turnover number. Activation energy. Transition state theory. Mechanism of Enzyme Catalysis. Enzyme kinetics: Michaelis-Menten Equation Significance of  $V_{max}$  and  $K_m$ . Factors affecting enzyme activity. Enzyme inhibition - types of inhibitors - competitive, non-competitive and uncompetitive, Allosteric enzymes. Diagnostic importance of Enzyme & Enzyme pattern in diseases. Structure function relations: Lysozyme, ribonuclease, trypsin, Immobilized enzyme

#### 4. Hormones, Vitamins and Minerals:

(15 hrs)

General classification of hormones - synthesis, structure, secretion, metabolism and mechanism of action of pancreatic, thyroid, parathyroid, pituitary, adrenal. Hormonal control of spermatogenesis, menstrual cycle, pregnancy and lactation. Prostaglandins



and functions of Prostaglandins. Cell membrane and intracellular receptors for hormones. Secondary messengers.

General nature, classification, sources, active forms and metabolic role, deficiency manifestations, daily requirement and hypervitaminosis of water soluble and fat soluble vitamins.

Study of macro elements (Calcium, phosphorous, Magnesium, Sodium, Potassium) and microelements (Iron, copper, manganese, Cobalt, Iodine, Zinc, Fluorine and their physiological importance.

**TEXT/ REFERENCE BOOKS:-**

- Jeremy M. Berg, John L. Tymoczko and Lubert Stryer - Biochemistry, 5<sup>th</sup> edition (2002), W.H. Freeman and Company, New York.
- A. L. Lehninger, D.L. Nelson and M.M. Cox- Principles of Biochemistry – 2<sup>nd</sup> edition (1993) Worth Publishers, U.S.A
- Voet Donald Voet, Judith G. – Biochemistry, (2004) 3<sup>rd</sup> edition J Wiley and Sons.
- C. Guyton, John E. Hall - Human physiology and mechanisms of disease, 6<sup>th</sup> edition (1997), Saunders publication.

**(Paper VI) SC.1.2.2 Bio -Medical Instrumentation**

**(60 h)**

**1. Instruments for Basic tissue Culture & Ultrasound Technique:**

**(15 hrs)**

Carbon dioxide incubators – types & functions, Laminar Air flows- Types & functions, “FACS” technique for Evaluation of Markers of Stem Cell, Instruments for Ultrasound Technique-Principles, Applications, Machines, Probes, Frequencies, Diagnostic & Interventional indications.

**2. Instruments for Cryopreservation:**

**(15 hrs)**

Mechanical and Thermal Properties of engineering materials at low temperatures; Components of Cryogenic refrigerators and liquefiers; Compressors: types, construction and characteristics; Expansion machines: characteristics of reciprocating and turbine expanders, design of J-T expander; Heat exchangers: theory, types, design approaches and selection criteria, Irreversibilities in cryogenic Heat exchangers; Safety in cryogenic systems: Design of cryogenic storage vessels, transfer devices, insulation system, valves; Characteristics of cryogenic pumps, Safety of cryogenic systems.



**3. Chromatography Techniques: (15 hrs)**

Partition and adsorption Chromatography- paper, TLC, GLC, gel filtration, ion exchange chromatography, HPLC, HPTLC, affinity chromatography, hydrophobic interaction chromatography, metal chelate chromatography, covalent chromatography, DNA cellulose chromatography and MAK hydroxyl-apatite chromatography.

**4. Electrophoresis, Spectroscopy and other Analytical Instruments: (15 hrs)**

Types of electrophoresis: moving boundary electrophoresis and zone electrophoresis (paper, cellulose -acetate electrophoresis, gel Electrophoresis (starch gel, native PAGE, disc PAGE, gradient PAGE, SDS-PAGE, agarose gel electrophoresis, Isoelectric focusing, 2D gel electrophoresis).

UV and visible, NMR, ESR, IR, Mass Spectrometry. Filters: Nitrocellulose, fiber glass, Polycarbonate filters, Hollow membrane fiber (Ultrafiltration), dialysis, reverse dialysis, freeze drying and lyophilisation. Sedimentation: Preparatory and analytical ultracentrifuges, Zonal centrifugation. (Proteins, enzymes & other biomolecules). PCR, RT-PCR, Flow cytometer.

**Text/Reference Books :-**

1. M.Arumugam- Bio-Medical Instrumentation, 1<sup>st</sup> edition (2003) Anuradha Agencies.
2. L.A. Geddes and L.E. Baker- 'Principles of Applied Bio-Medical Instrumentation', 1<sup>st</sup> edition (1975) John Wiley & Sons.
3. J. Webster- 'Medical Instrumentation, 1<sup>st</sup> edition (1995) John Wiley & Sons.
4. C. Rajarao and S.K. Guha- Principles of Medical Electronics and Bio-medical Instrumentation, 1<sup>st</sup> edition (2000) Universities press (India) Ltd.

**(Paper VII) SC.1.2.3 -Biomaterials, Medical Nanobiotechnology and Tissue Engineering**

**(60 h)**

**1. BIOMATERIALS**

**(15 hrs)**

Properties of Materials, Classes of materials used in medicine:

Metals, Polymers, Hydrogels, Bioresorbable and Biodegradable Materials, Ceramics, Natural materials, Composites, Thin films, grafts, Coatings, Medical fibers and Biological functional materials.

Host reactions to biomaterial: Inflammation, Wound healing and the Foreign body response. Systemic toxicity and Hypersensitivity. Blood coagulation and Blood-materials Interactions Tumorigenesis.

Testing biomaterials: In Vitro and In Vivo assessment of tissue compatibility. Testing of blood- material interactions. Animal model.



## **2. MEDICAL NANOTECHNOLOGY**

**(15 hrs)**

Diagnosis: Biomems Nanochips-Gene chip and Protein chip., Ultrasensitive biobarcode., Nano chip for HIV detection(targeting Cd4)., Quantum dots

Treatment: Nanorobotics, Cancer (pebble brain cancer) Nanoparticles A platforms for cancer therapy, Bucky balls .,Textiles and wound care products., Implantable material for vascular interventions, Active implantable devices and bionics., Dendrimer, Implantable materials for orthopedics and dentistry. Nanotechnology based chemotherapy (smart bomb)

## **3. NANOTECHNOLOGY IN TISSUE ENGINEERING**

**(15 hrs)**

Introduction of tissue engineering and implants Impact of nanotechnology on tissue engineering and implants: Cell transplantation (liver) Nanostructuring/Nanocoating Titanized synthetics Nano neuro knitting Development of synthetic polymer Nano- scale patterns for induction of stem cell differentiation Smart scaffolds. Nano scale tissue engineering & growth of new organs.

Preparation and use of biological scaffold.

## **4. TISSUE ENGINEERING AND ITS CLINICAL APPLICATION**

**(15 hrs)**

Reconstruction of the skeleton, bone, cartilage, teeth, Reconstruction of skeletal and cardiac muscle, urinary bladder, liver, cornea. Tracheal tissue engineering transplant, Bladder tissue engineering transplant Vein & arteries tissue engineering transplant.

### **Texts/Reference Books:-**

1. Harry F.Tibbals- Medical Nanotechnology and Nanomedicine, 1<sup>st</sup> edition (2010) CRC Press
2. Viola Vogel- Nanotechnology, volume 5 (2009),Wiley-ICH publications
3. Buddy D.Ratener, Allan S. Hoffman- Biomaterial Science: An Introduction to Material in Medicine, 3<sup>rd</sup> edition (2012), Elsevier.
4. J.J. Mao, G. Vunjak-Novakovic- Translational Approaches In Tissue Engineering & Regenerative Medicine, 1<sup>st</sup> edition (2008), Artech House, INC Publications.



**(Paper VIII) SC.1.2.4 Animal Models, Biostatistics & Bioinformatics (60 h)**

**1. ANIMAL MODELS FOR HUMAN DISEASES**

**(15 hrs)**

The animal model Concept, Classification of animal models, Classification of disease models Model body size and scaling. ,Methods for creating transgenic animals (SCID & Khank Out)

Selection of biomedical animal models: History of animal use in research. Definition of animal model. Types of animal models Legislative and legal requirements for using animals in Research choosing the right model.

Improved models for animal research: Animal Models of Diabetes, Acute & chronic liver disease, Animal Model System for Studies of the efficiency of Anticancer therapies  
Ethical basis for animal use in research

**2. BASIC CONCEPTS IN BIOSTATISTICS AND SAMPLING TECHNIQUES**

**(15 hrs)**

Definition – Biostatistics, Variable Quantitative Variable, Qualitative Variable, Random Variable, Discrete random Variable, Continuous Random Variable, Examples of applications of statistics in Biology.

Sampling:

Definitions: Population Sample, Advantages of Sample Studies. Types of Samples - Convenience Sample, Random Sample. Methods of Sampling- Simple random sampling, stratified random sampling, systematic sampling, cluster sampling, multistage sampling, multiphase sampling (Definitions, merits, demerits and applications only) Sampling error.

Descriptive statistics: Types of data - Qualitative, Quantitative, Categorical, Raw and grouped data. Averages - Arithmetic mean, Geometric mean, Median, Mode (Calculations, merits, demerits and uses).

Measures of dispersion - Range, Mean deviation, Variable standard deviation, Coefficient of Variation (Computation, merits, demerits and application)

Graphical Presentation of data - Pie chart, Bar diagram, Line graph, Histogram, Frequency polygon, Frequency Curve

**3. PROBABILITY DISTRIBUTIONS, CORRELATION AND REGRESSION**

**(15 hrs)**

Sample space, Events, Definition of probability - Classical relative frequency, aximatic properties of probability (only statements). Conditional probability. Addition theorem, Multiplication theorem and Baye's theorem (only statements).

Discrete probability distributions-Binomial and Poisson (concept and list of applications.)

Continuous probability distribution-Normal distribution concept, properties and applications.

Tests of significance: Null hypothesis, Alternate hypothesis, Type I error, Type II error, Level of significance, p-value, Power of the test, Concept of test of significance. Chi-



square test, Normal test, Student's t-test (paired and unpaired). Confidence interval for arithmetic mean and proportion. One-way analysis of variance (only introduction)  
Correlation and Regression: Dependent Variable, Independent variable, Definition and properties of simple Pearsons correlation co-efficient, Test of significance of correlation co-efficient, concept of simple linear regression, scatter graph with regression line.

#### 4. BIOINFORMATICS

(15 hrs)

Protein and DNA database, Sequence alignment programs, FASTA and BLAST Searches, Gene expression analysis using microarray, MiRNA sequencing, Sequence analysis using BIOPERL, Biochemical pathway database, Finding useful resources on the www.

#### Text/Reference Books:-

1. Wayne W. Daniel, Chad L. Cross- Biostatistics: A foundation for analysis in the health science, 10<sup>th</sup> edition (2013), John Wiley & sons
2. J. Richard, Sundar P. S. S. Rao- Introduction to Biostatistics and Research Methods, 4<sup>th</sup> edition (2006), Prentice-Hall of India Pvt.Ltd. publication
3. Armitage P and Berry G - Statistical methods in medical Research, 4<sup>th</sup> edition (2008), Oxford Blackwell scientific publication
4. Sokal P R and Rohlf F. R. - Biometry: The principles and practice of statistics in Biological, 3<sup>rd</sup> edition (1981), Freeman and company Sanfransisco

#### (Practical- IV) SC.1.2.P.4 Biomaterials, Medical Nanobiotechnology and Tissue Engineering, Animal Models of Human diseases and Bioinformatics

1. Preparation of tissue engineered Alginate Capsules.
2. To study metal and polymer as Biomaterials
3. Tissue engineered composites Hydrogel.
4. Preparation of Cytodex beads.
5. Synthesis of silver NPs form different plant extracts.
6. Synthesis of gold NPs from different Plant extracts.
7. Antimicrobial activity of silver NPs.
8. Preparation decellularize procine/ bovine tracheal scaffold.
9. Preparation decellularizeprocine/ bovine arteries and vein scaffold
10. Estimation of blood glucose in Alloxan induced diabetic mice/rats by Glucometer.
11. Estimation of glucose in urine of Alloxan induced diabetic mice/rats by Urostrips method.
12. Getting an amino acid sequence, nucleotide sequence and blasting.
13. Structure analysis: secondary, tertiary and quaternary structure, bond angle, bond length, different interactions.



**(Practical- V) SC.1.2.P.5. Cell Physiology, Metabolism and Bio-Medical Instrumentation**

1. Cell fractionation and centrifugation.
2. Identification and quantitation of activity of enzymes
3. Determination of enzyme activity in presence of activators.
4. Determination of enzyme activity in presence of inhibitors.
5. Determination of optimum pH of enzyme
6. Determination of optimum temperature of enzyme
7. Determination of  $K_m$  of enzyme
8. Column Chromatography of proteins.
9. Isolation of Starch and characterization.
10. Estimation of Cholesterol.
11. Determination on alpha amino nitrogen of amino acid.
12. UV-spectrophotometer estimation of Protein.
13. Cell cycle analysis
14. Live cell imaging by microscopic technique

**Demonstration experiments**

- A. FISH
- B. Cell tracing technique
- C. Real time PCR
- D. Microarray
- E. 2D PAGE
- F. Mass spectrophotometry
- G. Zeta analysis.
- H. DLS

**(Practical- VI) SC.1.2.P.6 Industrial visit and report**

**SEMESTER-III**

**(Paper- IX) SC.2.3.1 Stem cell Biology**

**1. Introduction and basic biology of stem cells**

**(15 hrs)**

Stem cell evolution, Historical perspective - with model systems, Stemness basic, Type of stem cells, Embryonal carcinoma cells: Teratomas and Teratocarcinoma, Stem cell markers, Stem cell niches, Trans-differentiation, Growth Factors and Paracrine mechanism and action of stem cells, Cell stage to blastocyst formation, Implantation, gastrulation, properties and characterization of embryonic stem cells, Types of adult stem cells: Bone marrow, adipose tissue, cord blood, placenta etc, Differentiation and trans-differentiation of stem cells, regulation of stem cell niche in different adult tissues.



**2. Isolation of Pluripotent stem cell and molecular mechanism of Self renewal and differentiation (15 hrs)**

Isolation and maintenance of embryonic stem cell isolated from: Mouse, Human, Primate, Avian, Xenopus, Serum and feeder free culture of embryonic stem cells Alternate method of isolation of embryonic stem cell lines, Isolation and maintenance of Trophoblast, characterization of embryonic stem cells, Extracellular signaling involved in embryonic vs adult stem cells, Genetic regulation of stem cell fate, Telomerase and its regulation, cell cycle and their regulators: embryonic vs adult cells, Symmetric and asymmetric division.

**3. Hematopoietic and non-hematopoietic stem cells and their differentiation (15 hrs)**

Bone marrow microenvironment, Hematopoietic stem cell mobilization, mesenchymal stem cells and their properties, Hematopoietic Vs mesenchymal stem cells, Isolation of Hematopoietic and mesenchymal stem cells, Ex vivo expansion, Characterization of Hematopoietic and mesenchymal stem cells, Transcriptional regulation of Hematopoietic and mesenchymal stem cells, Side population phenotypes, endothelial progenitor cells, Multipotent adult progenitor cells, Differentiation of stem cells in-vivo and ex-vivo, Differentiation of hematopoietic stem cell lineages, Differentiation of mesenchymal stem cells in to osteoblast adipocyte, chondrocyte lineages, Transdifferentiation of mesenchymal stem cell into various lineages, differentiation into endothelial cells and stem cell mediated angiogenesis.

**4. Cancer stem cells and their regulation (15 hrs)**

Introduction to cancer, Oncogenes, Tumor suppressive gene, Metastasis, Stem cell origin of cancer, Cancer stem cells, Pathways involved in cancer stem cells and their tumor progression, cancer stem cells, pericytes and tumor angiogenesis.

**Text/Reference Books**

1. "Stem cell basics and application" Ed. By K. D. Deb and S. M. Totey, Tata McGraw Hill Pvt. Ltd, 2011.
2. "Hand book of Stem Cells" Edited by RoberLanza, Elsevier, Academic Press, 2011.
3. "Stem Cells Handbook", Edited by Stewart Sell, Human Press, 2010.
4. "Human embryonic stem cells", Edited by Arlene Y. Chiu, MahendraRao, Human Press, 2011.
5. "Stem cell therapy for organ failures", Edited by S. Indumathi, Springer Verlag, 2015



**(Paper – X) SC.2.3.2 Disease & Applications of stem cells**

**(60 hrs)**

**1. Source of stem cells for neuronal repair**

**(15 hrs)**

Application of stem cell Therapy (SCT) for degenerative neuronal diseases (Parkinson disease, Motor neuron disease) and demyelinating diseases (Multiple sclerosis). Stem Cell Therapy in stroke, Stem Cell Therapy in spinal cord regeneration, Stem Cell Therapy for muscular dystrophies

**2. Stem cell for Myocardial regeneration and Diabetes:**

**(15hrs)**

Pathology of acute myocardial infarction and chronic ischemic heart disease, Role of stem cells in acute myocardial infarction and dilated cardiomyopathy, Use of regenerative therapy: MSC, AC 133, CD34, Role of VEGF in healing, Structure of pancreas, Mechanism of insulin secretion and its action, Types of diabetes and its pathophysiology, Differentiation of ESC and adult stem cells to insulin secreting beta islet cells.

**3. Stem cell in Genetic diseases, Immunological diseases, Ophthalmology and Aging: (15hrs)**

Genetic basis of hereditary hemolytic anemias: Thalessemia, sickle cell anemia and hereditary spherocytosis. Role of stem cells in treatment of hereditary hemolytic anemias. Severe combined immunodeficiency disease (SCID), Wiskott-Aldrich syndrome, Stem cells for corneal repair/surface disorders

**4. Stem cell and Tumors/Malignancy:**

**(15hrs)**

Source of stem cells from solid tumors- Breast cancer stem cells, Brain tumor stem cells, Prostate cancer stem cells. Hematopoietic stem cell transplantation for malignancies- lymphoma, leukemia and myeloma.

**Text/Reference books**

1. "Stem cell basics and application" Ed. By K. D. Deb and S. M. Totey, Tata McGraw Hill Pvt. Ltd, 2011.
2. "Hand book of Stem Cells" Edited by RoberLanza, Elsevier, Academic Press, 2011.
3. "Stem Cells Handbook", Edited by Stewart Sell, Human Press, 2010.
4. Handbook of stem cells, Edited by Robert Lanza. Elsevier academic press.
5. Human embryonic stem cells, Edited by Arlene Y. Chiu, Mahendra Rao. Humana press.
6. "Stem cell therapy for organ failures", Edited by S. Indumathi, Springer Verlag, 2015



**(Paper XI) SC.2.3.3 Cell & tissue banking and cryopreservation**

**1. Basics of tissue banking**

What is Cell and Tissue Banking? Definition. Scope and need of Cell and Tissue Banking and Cryopreservation, Processing of different organ tissues, Tissue preservation procedure, Validation and checking/quality control, Sterilization, disinfection and decontamination

**2. Cord blood banking**

Advantage and disadvantages of cord blood banking, Regulation of cord blood banks, Donor Recruitment, Cord blood collection, processing and testing, Registration of cord blood units, Search, issue and release for transplantation, HLA typing and other related issues.

**3. Tissue banking of Skin, musculo-skeletal, Ocular, Cardiovascular tissue and sperm**

Structure of skin, Wound healing, Use of allograft, Long bone formation, growth and endochondral ossification, Bone characteristics and functions, Bone and tendons, processing storage and issue, Bone remodeling, Structure and function of the cornea, Ocular tissue transplantation, Corneal storage, processing and tissue, Eye banking, tissue processing, storage and issue of heart valves, Pericardium, Blood vessels and tissue transplantation, sperm banking indications, Culture Media, Protocols, Instrumentation, Applications

**4. Cryopreservation**

Introduction and Historical Background of Cryopreservation, Review of Basic, Thermodynamics, Properties of Cryogenic fluids, first and Second Law, approaches to the study of thermodynamic cycles, Isothermal, Adiabatic and Isenthalpic processes. Production of Low Temperatures: Liquefaction systems, ideal, Cascade, Linde Hampson and Claude cycles and their derivatives; Refrigerators: Stirling, Gifford-McMahon cycles and their derivatives. Cryogenic Insulations: Foam, Fibre, powder and Multilayer. Principles of Cryopreservation, Effects of Freezing on Cells, Thawing & Post Thaw Handling, Cryoprotectants

**TEXT/ REFERENCE BOOKS:**

1. "An Introduction to cell and Tissue Transplantation Science" published by British Blood Tranfusion Society, Manchester, 2007.
2. "Hand book of Stem Cells" Edited by RoberLanza, Elsevier, Academic Press, 2011.
3. "Stem Cells Handbook", Edited by Stewart Sell, Human Press, 2010.



4. "Human embryonic stem cells", Edited by Arlene Y. Chiu, MahendraRao, Human Press, 2011.
5. Translational Approaches: In Tissue Engineering & Regenerative Medicine", Artech House, INC Publications 2008 J. J. Mao, G. VunjakNovakovic et al (Eds).
6. Stem Cell Repair and Regeneration, Naggy, 2007, Imperial College Press N. Habib, M.Y. Levicar, L. G. Jiao, and N. Fisk.

**(Paper XII A) SC 2.3.4 Clinical research, Bioethics and Regulatory affairs (60 hrs)**

**1. Biomedical Basis of Disease and Pre-clinical Evaluation: (15hrs)**

Anatomy, Endocrinology, Oncology, Cardiology, Inflammatory/ immunological diseases, inherited diseases, Infectious diseases, introduction to preclinical studies, Use of model systems - animals, Use of model systems - in vitro systems, Use of model systems - computer generated, Toxicology, Interface with clinical protocol

**2. Experimental Methods I and II: Research and Advanced design, methodology and analysis: (15hrs)**

Developing a hypothesis, Laboratory research methodology, Clinical research methodology, Bias in research methodologies, Need for confidentiality, Research audit and evidence-based design, Medical writing, Funding academic research, Review of common study design for clinical trials, Design of randomized controlled studies, Design of Cohort studies, Sample size calculation, introductory statistics, Non-parametric analysis, Parametric analysis

**3. Research Governance, Ethics and IPR with respect to stem cell therapy: (15hrs)**

Overview of research governance, Research ethics, Gaining ethical approval, Guidelines of India, Guidelines in other countries, Religious consideration, Regulatory consideration.

Basic principles and acquisitions of intellectual property rights, MPPP act, manufacturing, licensing and material transfer, Biotechnology and IPR, Filing a patent, types of patent, provisional and complete specifications; PCT and convention patent applications; International patenting-requirement, Indian Patent Act 1970; Recent Amendments; Filing of a patent application; Precautions before patenting-disclosure/non-disclosure



**4. Clinical Trials and Regulatory Requirements: (15hrs)**

Phase I trials, Phase II trials, Phase III trials, Introduce the legal framework behind translational medicine, Regulatory process, Cloning Methods, Proteomics, Fundamentals of Gene expression, Identifying mutations and polymorphisms

**Reference:**

1. "Basic Principles and Acquisition of Intellectual Property Rights" by Dr. T. Ramakrishna, 2<sup>nd</sup> Edition.
2. "Biotechnology and Intellectual Property Rights" by Dr. T. Ramakrishna, 2<sup>nd</sup> Edition.
3. "Translational and experimental clinical Research" by Daniel P. Schuster & William J. Powers. Publication Lippincott Williams & Wilkins.
4. "Basic Principles & Clinical Research & Methodology" by Ed. S. K. Gupta & Forwarded by N. K. Ganguly. Institute of Clinical Research (India), Jaypee Brothers Medical Publishers (P).
5. "Clinical Trials: A Methodological Perspective" by Steven Piantasosi & Wiley Interscience, A John Wiley & Son, Inc. Publication.

**(Paper XIIB) SC. 2.3.4 Molecular Diagnostics and Therapeutics (60 h)**

**1. Host pathogen interactions in disease process (15 h)**

Protective immune response in Bacterial, Viral and Parasitic diseases; Cancer; Inappropriate Immune response; Disease pathology and clinical spectrum; Clinical diagnosis of diseases; Molecular Genetics of the host and the pathogen, Biochemical disorders; Immune, Genetic and Neurological disorders; Molecular techniques for analysis of these disorders; Assays for the Diagnosis of inherited diseases; Bioinformatic tools for molecular diagnosis Antibody based diagnosis; Monoclonal antibodies as diagnostic reagents; Production of monoclonal antibodies with potential for diagnosis; Diagnosis of bacterial, viral and parasitic diseases by using; ELISA and Western blot.

**2. DNA sequencing and diagnosis (15 h)**

Isolation of DNA; purification and analysis; DNA sequencing and diagnosis; PCR and Array based techniques in diagnosis; Single nucleotide polymorphism and disease association; Two dimensional gene scanning Isolation of proteins and other molecules associated with disease; Process and their profiling for diagnosis; 2D analysis of such proteins by sequencing individual spots by Mass Spectrometry; Protein Micro array; Present methods for diagnosis of Specific diseases like Tuberculosis, Malaria and AIDS; Ethics in Molecular Diagnosis



**3. Gene therapy**

**(15 h)**

Intracellular barriers to gene delivery; Overview of inherited and acquired diseases for gene therapy; Retro and adeno virus mediated gene transfer; Liposome and nanoparticles mediated gene delivery Cellular therapy; Stem cells: definition, properties and potency of stem cells; Sources: embryonic and adult stem cells; Concept of tissue engineering; Role of scaffolds; Role of growth factors; Role of adult and embryonic stem cells; Clinical applications; Ethical issues

**4. DNA technology and Gene Silencing**

**(15 h)**

Clinical applications of recombinant technology; Erythropoietin; Insulin analogs and its role in diabetes; Recombinant human growth hormone; Streptokinase and urokinase in thrombosis; Recombinant coagulation factors Immunotherapy; Monoclonal antibodies and their role in cancer; Role of recombinant interferons; Immunostimulants; Immunosuppressors in organ transplants; Role of cytokine therapy in cancers; Vaccines: types, recombinant vaccines and clinical applications, Antisense therapy; siRNA; miRNA and silencing, transfection techniques, Tissue and organ transplantation; Transgenics and their uses; Cloning; Ethical issues

**Texts/References**

1. Campbell, M.A and Heyer L.J.- Discovering Genomics, Proteomics and Bioinformatics, 2nd Edition (2007), CSHL Press, Pearson/Benzamin Cummings San Francisco, USA.
2. Andrew Read and Dian Donnai- New Clinical Genetics, 3<sup>rd</sup> edition (2007) Scion Publishing Ltd, Oxford shire, UK.
3. James W Goding- Monoclonal antibodies: Principles and Practice, 3rd Edition (1996), Academic Press
4. George Patrinos and Wilhelm Ansonage, Molecular Diagnostics, 1st Edition (2005), Academic Press.

**Practical - VII (SC.2.3.P.7) Stem cell Biology, Diseases and Application of Stem Cells**

**(30 h)**

1. Isolation of stem cell from cord blood
2. Isolation of stem cells from bone marrow
3. Isolation of stem cells from adipose tissue
4. Isolation of stem cells from cord tissue
5. Isolation of stem cell from endometrial tissue
6. Stem cell counting and viability checking
7. Cell proliferation assay
8. Growth curve and PDT analysis



9. Characterization of stem cells
10. Embryo culture and in-vitro fertilization techniques
11. Embroid body formation
12. Differentiation of stem cells into various lineages
13. Cancer stem cell- isolation
14. Case studies of stem cell therapy for various diseases

**Practical – VIII (SC.2.3.P.8) Clinical Research, Bioethics, Regulatory affair**

1. Presentation of clinical report of Pathological investigations in-
  - I. Blood (Glucose, Hb, Lipid profile).
  - II. Urine (Normal and Abnormal constituents).
  - III. Chest X ray.
  - IV. Liver Function tests.
  - V. Kidney Function tests (Urea, Uric acid,)
  - VI. Ultrasonography.
2. Case studies solutions
3. Technical and soft skill presentations
4. Term search
5. Development of Clinical research documents
6. SOPs development
7. CRF preparation
8. ICFs Preparation
9. Preparation of Dummy clinical research
10. Preparation of bioequivalence protocol
11. Preparation of patent draft
12. Preparation of claims in patents
13. Biosafety guidelines in biomedical field

**Practical IX (SC.2.3.P.9) Industrial visit and report**



D. Y. Patil University

#### SEMESTER-IV

#### (Paper –XIII) SC.2.4.1. RESEARCH METHODOLOGY (60 h)

- 1. Research (15 h)**  
Need and importance of Research in General and with special reference to scientific research. Criteria of selecting a Research problem-Limitations and Delimitations. Reasons for surveying related literature. Allied and critical Literature.
- 2. Hypothesis (15h)**  
Significance of Hypothesis.Types of Hypothesis.Meaning and Nature of Experimental Research.Sources of Experimental Invalidity.
- 3. Experimental Designs: (15h)**  
Introduction, Types of Experimental Design, Pre, True and Quasi Experimental designs. Research Report, Identifying research problem, funding agencies
- 4. Computer Applications (15h)**  
Introduction to spreadsheet application, features and functions, Using formulas and functions, Data storing, Features for Statistical data analysis, Generating charts/ graph and other features. Tools used may be Microsoft Excel, Open office or similar tool. Introduction to presentation tool, features and functions, Creating presentation, Customizing presentation, Showing presentation. Tools used may be Microsoft Power Point, Open Office or similar tool.  
Introduction to Internet, Use of Internet and WWW, Using search engine like Google, Yahoo etc, and Using advanced search techniques.

#### References:

1. Panneerselvam, R.- Research methodology, Prentice hall of India, New Delhi, 2004.
2. Kothari CR- Research methodology-methods and techniques, 2<sup>nd</sup> edition (2009) New Wiley Eastern Ltd., Delhi, 2009.
3. Ranjit Kumar-Research methodology-step by step guide for beginners 1<sup>st</sup> edition (1999), Sage publications.
4. Norman K. Denzin- The SAGE handbook of qualitative research, 1<sup>st</sup> edition (2005, SAGE publications.



**(Paper- XIV) SC.2.4.2. ENTREPRENEURSHIP AND MANAGEMENT (60 h)**

**1. Introduction (15 h)**

Meaning – nature and characteristics of Management, Scope and Functional areas of management. Management V/s Administration – Roles of Management, Levels of Management. Evolution of management thought: early, contemporary and modern.

**2. Nature and purpose of planning and Organization (15 h)**

Types of plans .Decision making. Importance of planning – steps in planning & planning premises. Hierarchy of plans. Components of planning. Principles of organization, Types of organization. Departmentation Committees. Centralization Vs Decentralization of authority and responsibility. Nature and importance of staffing–Process of Recruitment and Selection.

**3. Meaning and nature of directing (15 h)**

Understanding, Supervision, motivation and leadership. Leadership styles, Motivation Theories (Abraham Maslo, Herzberg and Victor Hvrom's). Communication – Meaning and importance. Meaning and steps in controlling – Essentials of a sound control system – Methods of establishing control (in brief).

**4. Structure of a Biotechnology Company (15 h)**

Start-up of Biotechnology Company, New Product Development.Market Research.Sales &Marketing Principles.Intellectual Property Principles in Biotechnology.Health Care Overview and Role of Government in Biotechnology. Ethical and Other Legal Issues in Biotechnology

**Reference Books:-**

- P.C.Tripathi, P. N. Reddy - Principles of Management, 5<sup>th</sup> edition (2012), Tata McGraw Hill,
- Vasant Desai – Dynamics of Entrepreneurial Development & Management, 4<sup>th</sup> edition (2001), Himalaya Publishing House.
- Poornima M.Charantimath- Entrepreneurship Development Small Business Enterprises, 2<sup>nd</sup> edition (2006), Pearson Education..
- Stephen Robbins- Management, 17<sup>th</sup> Edition (2003), Pearson Education.

**(Practical-X) SC.2.4.P.10 Major Project**

**(Practical –XI) SC.2.4.P.11 Industrial visit and report**



#### **BL-SC-04: Course structure and distribution of credits**

M.Sc. Stem cell and Regenerative Medicine is on choice based credit system and consists of total 14 theory courses, 6 practical lab courses and 4 Industrial visits spread over 4 semesters along with one research project. First three semesters consists of 12 theory courses (4 theory papers in each semester), 6 practical lab courses with 3 Industrial visit. Fourth semester consists of 2 theory papers, one Industrial visit and a research project. For third semester, student can select one theory paper from groups of elective papers [(Paper XIA) SC. 2.3.4 Clinical research, Bioethics and regulatory affairs or (Paper XIIB) SC.2.3.4 Molecular diagnostics and therapeutics.

Each theory course will be of 4 (four) credits, a practical lab course will be of 4 (four) credits, Industrial visit is of 3 credits and project will be of 8 (eight) credits. A student earns 27 (twenty seven) credits per semester for first 3 semesters and 19 credits in semester 4. Total of 100 credits overall in 4 semesters.

#### **BL-SC-05: Scheme of Examination and Standard of passing:**

##### **Scheme of examination**

1. This course will have 20 % Term Work (TW)/ Internal Assessment (IA) and 80% external (University written examination of 3 hours duration for each course paper and practical examination of 3 hours duration for each practical). All external examinations will be held at the end of each semester and will be conducted by the University as per the existing norms.
2. Term work/ Internal assessment- IA (20%) and University examination (80%) - shall have separate heads of passing (i.e. 8 Marks for passing in IA and 32 Marks for passing in University examination). For Theory courses, internal assessment shall carry 20 marks and semester-end examination shall carry 80 marks for each theory course.
3. To pass, a student has to obtain minimum grade point E, and above separately in the IA and external examination.
4. The University (external) examination for Theory and Practical shall be conducted at the end of each Semester.
5. The candidates shall appear for the external examination of 4 Theory courses each carrying 80 marks of 3 hours duration and 2 practical courses each carrying 100 marks at the end of each semester.
6. The candidate shall prepare and submit for the practical examination a certified journal based on the practical course carried out under the guidance of a faculty member with minimum number of experiments as specified in the syllabus for each group.
7. The candidate shall prepare the dissertation based on the Research Project for the fulfillment of Master's Degree.



**Standard of Passing**

As per ordinances and regulations prescribed by the University for semester based credit and grading system.

**Standard point scale for grading:**

Grade	Marks	Grade Points
O	70 & above	7
A	60-69.99	6
B	55-59.99	5
C	50-54.99	4
D	45-49.99	3
E	40-44.99	2
F(Fail)	39.99 & below	1

**Grade Point Average (GPA) calculation:**

- GPA is calculated at the end of each semester after grades have been processed and after any grade have been updated or changed. Individual assignments/quizzes /surprise tests / unit tests / tutorials / practicals / project/ seminars etc. as prescribed by University are all based on the same criteria as given above. The teacher should convert his marking into the Quality-Points and Letter-Grade.
- Performance of a student in a semester is indicated by a number called Semester Grade Point Average (SGPA). It is the weighted average of the grade points obtained in all the subjects registered by the students during the semester.
- The Final remark will be decided on the basis of Cumulative Grade Point Average (CGPA) which is weighted average of the grade point obtained in all the semesters registered by the 1 earner.

$$SGPA = \frac{\sum_{i=1} C_i p_i}{\sum_{i=1} C_i}$$

$C_i$  = The number of credits earned in the  $i^{th}$  course of a semester.  
 $p_i$  = Grade point earned in the  $i^{th}$  course  
 $i = 1, 2, \dots, n$  represents number of courses for which the student is registered.

$$CGPA = \frac{\sum_{j=1} C_j p_j}{\sum_{j=1} C_j}$$

$C_j$  = The number of credits earned in the  $j^{th}$  course upto the semester for which the CGPA is calculated  
 $p_j$  = Grade point earned in the  $j^{th}$  course\*  
 $j = 1, 2, \dots, n$  represents number of courses for which the student is registered upto the semester for which the CGPA is calculated.

\* : A letter Grade lower than E in a subject shall not be taken into consideration for the calculation of CGPA.

The CGPA is rounded upto the two decimal places.