

Semester III

(Paper 9) SCRM.2.3.2 Stem cells: Diseases and applications (60 hrs)

Unit I. 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

Unit II. 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, Types of diabetes and stem cell applications.

Unit III. Stem cell in Genetic diseases and Immunological diseases (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 Cell Therapy for muscular dystrophies.

Unit IV. Stem cell and Tumors/Malignancy (15hrs)

CART cell therapy, NK & dendritic cell therapy for solid tumors, Hematopoietic stem cell transplantation for malignancies, lymphoma, leukemia and myeloma

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 10. SCRM.2.3.3. Biomaterials, Tissue engineering and 3 D bioprinting. (60 h)

Unit 1. Properties of Materials, Classes of materials used in medicine (15 hrs)

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

Unit 2. Host reactions to biomaterial and testing of biomaterials (15hrs)

Inflammation, Wound healing and the Foreign bodyresponse. 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,

Unit 3. Tissue Engineering And Its Clinical Application (15hrs)

Reconstruction of the skeleton, bone, cartilage, teeth, Reconstruction of skeletal and cardiac muscle, urinary bladder, liver, cornea. Tissue engineering transplants: Trachea, Bladder, arteries.

Unit 4. 3D Printing technology (15hrs)

3D printing design, its types and advantages, use of CT/MRI images for 3D printing, 3D printing and its clinical applications, Bio ink for 3D printing of Bone, cartilage, skin, arteries and heart

References

1. Buddy D. Ratener, Allan S. Hoffman- Biomaterial Science: An Introduction to Material in Medicine, 3rd edition (2012), Elsevier.
2. J.J. Mao, G. Vunjak-Novakovic- Translational Approaches In Tissue Engineering & Regenerative Medicine, 1st edition (2008), Artech House, INC Publications.

(Paper 11) SCRM .2.3.4. Clinical Research, Bioethics and Regulatory affairs (60 hrs)

Unit I Clinical Research:

(15 hrs)

Introduction to Clinical Research, Terminologies and definition in Clinical Research, Origin and History of Clinical Research, Difference between Clinical Research and Clinical Practice, Types of Clinical Research, Clinical Trials in India – The National Perspective, Pharmaceutical Industry – Global and Indian Perspective, Clinical Trial market, Career in Clinical Research.

Unit II Bioethics:

(15 hrs)

Introduction to bioethics: Social and ethical issues in biotechnology. Principles of bioethics. Ethical conflicts in biotechnology- interference with nature, unequal distribution of risk and benefits of biotechnology, bioethics vs business ethics.

Emerging issues: Biotechnology's Impact on Society; DNA on the Witness Stand - Use of genetic evidence in civil and criminal court cases; Challenges to Public Policy – To Regulate or Not to Regulate; Improving public understanding of biotechnology products to correct misconceptions.

Unit III Biosafety:

(15 hrs)

Biosafety: Definition of bio-safety, Biotechnology and bio-safety concerns at the level of individuals, institutions, society, region, country and world with special emphasis on Indian concerns. Biosafety in laboratory institution: laboratory associated infection and other hazards, assessment of biological hazards and level of biosafety. Bio safety regulation: handling of recombinant DNA products and processes in industry and in institutions (Indian context).

**Unit IV Intellectual Property Rights (IPR):
(15 hrs)**

Introduction to IPR, Types of IP: Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications, Protection of New GMOs; International framework for the protection of IP. IPs of relevance to Biotechnology and few Case Studies; Introduction to History of GATT, WTO, WIPO and TRIPS.

Indian Patent Act 1970 and Recent Amendments.

Patent application- forms and guidelines, fee structure, time frames; Types of patent applications: provisional and complete specifications; PCT and convention patent applications.

References

1. Fleming, D.A., Hunt, D.L., (2000). Biotechnology and Safety Assessment (3rd Ed) Academic press. ISBN-1555811804,9781555811808.
2. Thomas, J.A., Fuch, R.L. (1999). Biotechnology and safety assessment (3rd Ed). CRC press, Washington. ISBN: 1560327219, 9781560327219
3. Biotechnology - A comprehensive treatise (Vol. 12). Legal economic and ethical dimensions VCH. (2nd ed) ISBN-10 3527304320.
4. Encyclopedia of Bioethics 5 vol set, (2003) ISBN-10: 0028657748. 8. Thomas, J.A., Fuch, R.L. (2002). Biotechnology and safety Assessment (3rd Ed) Academic press.
5. Singh B.D. Biotechnology expanding horizons. Kalyani Publishers, Year: 2019
6. Law and Strategy of biotechnological patents by Sibley. Butterworth publication. (2007) ISBN: 075069440, 9780750694445.
7. Intellectual property rights- Ganguli-Tat McGrawhill. (2001) ISBN-10: 0074638602,
8. Intellectual Property Right- Wattal- Oxford Publication House. (1997) ISBN:0195905024.
9. Kuhse, H. (2010). Bioethics: an Anthology. Malden, MA: Blackwell.

(Paper 12) SCRM .2.3.4 Cell & Tissue Banking and Cryopreservation (60 hrs)

Unit I. 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

Unit II. 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.

Unit III. Tissue banking

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

Unit IV. 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

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.

(Practical 11) SCRM .2.3.P.1. Stem cells: Diseases and applications

- 1.Characterization of stem cells .
- 2.Embryo culture and in-vitro fertilization techniques .
- 3.Embroid body formation
- 4..Differentiation of stem cells into various lineages
- 4.Cancer stem cell-isolation
5. Case studies of stem cell therapy for various diseases

(Practical 12) SCRM .2.3.P.2. Biomaterials and Tissue engineering and 3D Printing

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. Decellularize procine/ bovine tracheal scaffold.
6. Preparation and decellularize procine/ bovine arteries and vein scaffold

(Practical 13) SCRM .2.3.P.3. Clinical research, bioethics and regulatory affairs

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

(Practical 14) SCRM .2.3.P.4. Cryopreservation and tissue banking.

1. Processing of different organ tissues, Tissue preservation procedure, Validation and checking/quality control, Sterilization, disinfection and decontamination Cord blood collection, processing and testing, Registration of cord blood units, Search, issue and release for transplantation, HLA typing and other related issues.
2. 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 and storage, 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.
3. Cryopreservation, Properties of Cryogenic fluids, approaches to the study of thermodynamic cycles, Isothermal, Adiabatic and Isenthalpic processes.
4. Production of Low Temperatures: Liquefaction systems, ideal, Cascade, Linde Hampson and Claude cycles and their derivatives; Refrigerators: Stirling, Gifford-McMahon cycles and their derivatives.
5. Cryogenic Insulations: Foam, Fibre, powder and Multilayer. Effects of Freezing on Cells, Thawing & Post Thaw Handling, use of Cryoprotectants

(Practical 15) SCRM .2.3.P.5. Project Synopsis.

