

## Medical Devices

## M.Tech

<b>Semester – I</b>		
<b>Course Code</b>	<b>Course name</b>	<b>Credits</b>
MT-510	Medical Imaging & Processing	2
MT-520	Medical Instrumentation (Diagnostic, Therapeutic & Surgical)	2
MT-530	Physiology of Human Body	2
MT-540	Biostatistics and data science	1
MC-511	Spectral Analysis	2
MT-550	Computer Application (CAD & CAM)	1
MT-560	Intellectual Property Rights (IPR) & Ethics	1
MT-570	Biomedical devices and systems	1
MT-580	Pharmacopeial method of analysis	1
LS-510	Medical Instrumentation Laboratory	2
LS-520	Pre-clinical Studies Laboratory	1
<b>Total Credit</b>		16

<b>Semester – II</b>		
<b>Course Code.</b>	<b>Course name</b>	<b>Credits</b>
MT-610	Bioengineering (Neuro, tissue etc.) and regenerative devices	2
MD-620	Drug Delivery Engineering	2
MD-630	Biomaterials	2
MD-640	Biosensor	1
MT-650	Artificial Intelligence in Medical Devices	2
MT-660	Regulatory in Medical Devices	1
MT-670	Plasma technology for Biomedical applications	1
MT-680	Biomedical Signal Processing	1
LS-610	Bio and Pharmaco-engineering Laboratory	1
LS-620	AI & Machine Learning Laboratory	1
<b>Total Credit</b>		14

<b>Semester – III</b>		
<b>Course Code.</b>	<b>Course name</b>	<b>Credits</b>
TH-598	Industry exposure and/or professional training	5
TH-599	Research and thesis work	3
MT-810	Seminar	1
<b>Total Credit</b>		9

<b>Semester – IV</b>		
<b>Course Code.</b>	<b>Course name</b>	<b>Credits</b>
TH-698	Industry exposure and/or professional training	6
TH-699	Research and thesis work	3
MT-910	Seminar	1
MT-920	Communication skills & personality development	1
<b>Total Credit</b>		11

**Grand Total (I to IV Semesters): 50**

Semester 1

# Medical Devices

## SEMESTER-I

MT-510

Medical Imaging & Processing

(2 Credits)

### 1. Medical Imaging

Introduction to Electron Microscopy, X-ray Imaging, Computed Tomography, Ultrasonography, Magnetic Resonance Imaging

### 2. Image Processing Fundamentals

Structure of the Human Eye, Image Formation in the Eye, Image Sensing and Acquisition, Basic Relationships Between Pixels, Neighbors of a Pixel, Adjacency, Connectivity, Regions, and Boundaries, Distance Measures, Image Operations on a Pixel Basis, Linear and Nonlinear Operations

### 3. Image Enhancement

Gray Level Transformations, Image Negatives, Log Transformations, Power-Law Transformations, Piecewise-Linear Transformation Functions, Histogram Processing-Histogram Equalization, Histogram Matching, Enhancement Using Arithmetic/Logic Operations, Spatial domain image Filtering, Image Sharpening, Image Transformations, Biomedical applications

### 4. Image Restoration

Noise Models, Spatial and Frequency Properties of Noise, Some Important Noise Probability Density Functions, Estimation of Noise Parameters, Image Restoration using Spatial domain Filtering, Mean Filters, Order-Statistics Filters, Adaptive Filters, Biomedical applications

### 5. Image Segmentation

Point Detection, Line Detection, Edge Detection, Thresholding, Global Thresholding, Adaptive Thresholding, Region-Based Segmentation, Region Growing, Region Splitting and Merging, Biomedical applications

### 6. Image Compression

Redundancy, Image Compression Models, Elements of Information Theory, Fundamental Coding Theorems, Lossless Compression, Variable-Length Coding, LZW Coding, Lossy Compression, Image Compression Standards

#### Text Books:

1. R.C. Gonzalez and Wintz Paul, "*Digital Image Processing*", 4<sup>th</sup> Edition, Addison Wesley, 2018.
2. A.K. Jain, "*Fundamental of Digital Image Processing*", Prentice Hall India Learning Private Limited, 2015.

#### Reference Books:

1. J.T. Bushberg, J.A. Seibert, E.M. Leidholdt, J.M. Boone, "*The Essential Physics of Medical Imaging*", 3<sup>rd</sup> Edition, Lippincott Williams & Wilkins, 2012.
2. Rangaraj M. Rangayyan, "*Biomedical Image Analysis*", CRC Press, 2004.

**1. Clinical Laboratory Instruments**

UV-Vis Spectrophotometer, Colorimeters, Flame Photometers, Glucometer, Electrophoresis Techniques & apparatus, ELISA reader, RIA units, Auto Analyzer- Biochemical tests Detection and quantification of biochemical parameters, turbidometry. Blood Gas Analyzers - Pulse-oxygenometer, Blood pH measurement, Measurement of blood PCO<sub>2</sub> & PO<sub>2</sub>, Blood cell counters - methods of Cell counting, types of Blood cell counters. Special topics in microscopy in diagnosis.

**2. Immuno and Molecular Diagnostics**

Introduction, antigen-antibody binding and assays; Immunoassays –types [RIA, ELISA, Chemiluminescent IA, FIA] and specific applications; Immunohistochemistry -principle and techniques. Immunodiagnosics for detection of infectious agents. Overview of Molecular diagnostics. Real Time PCR, principle, instrumentation and application.

**3. Cardiovascular and respiratory devices**

Cardiac stents, valves, pacemakers, defibrillators and cardioverters. Mechanical ventilator and respiratory drug delivery devices

**4. Ophthalmic and auditory devices**

Contact and ophthalmic lenses. Implantable auditory devices (IADs).

**5. Orthotic, prosthetic and dental devices**

Spinal, hip, upper limb and lower limb orthotic and prosthetic devices. Crowns, bridges and braces.

**6. Dialysis devices**

Haemodialysis and peritoneal dialysis devices

**7. General surgical devices**

Gastroscope, colonoscope, laproscope, sigmoidoscope, endoscopic retrograde cholangiopancreatography (ERCP).

**8. Ophthalmic and thoracic surgical devices**

Ophthalmoscope, laryngoscope, bronchoscope, oesophagoscope.

**9. Urological surgical devices**

Cystoscope, urethroscope, resectoscope, ultrasonic and electronic lithotripter.

**Text Books:**

1. Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, 8th Edition, Author: Nader Rifai ISBN: 9780323530446
2. Laboratory Instrumentation, 4th Edition by Mary C. Haven, Gregory A. Tetrault, Jerald R. Schenken ISBN: 978-0-471-28572-4
3. JayantiTokas, Immunology and Molecular Diagnostics, 2015, ISBN-10 :

9789383828555; ISBN-13 : 978-9383828555

4. John G. Webster, Amit J. Nimunkar. Medical Instrumentation: Application and Design, Wiley, Latest Edition
5. Carr-Brown. Introduction to biomedical equipment technology, 2011, 1 st Edition, Pearson New York

#### **Reference books**

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics: First South Asia Edition, 1st Edition Authors: Nader Rifai A. Rita Horvath Carl T. Wittwer; Hardcover ISBN: 9788131248973
2. Clinical Chemistry: Principles, Techniques, and Correlations by Michael L. Bishop, Edward P. Fody, Larry E. Schoeff. ISBN-10 : 1451118694; ISBN-13 : 978-1451118698.
3. Lippincott Williams and Wilkins Molecular Diagnostics, 3rd Edition by George P. Patrinos, Wilhelm Ansorge, Phillip B. Danielson Hardcover ISBN: 9780128029718; eBook ISBN: 9780128029886.
4. Academic Press David Wild. The Immunoassay Handbook, 4th Edition: Theory and Applications of Ligand Binding, ELISA and Related Techniques. Hardcover ISBN: 9780080970370; eBook ISBN: 9780080970387. Elsevier Science
5. R S Khandur. Handbook of Biomedical Instruments
6. Albert M. Cook, John G. Webster. Therapeutic Medical Devices. Prentice Hall, Latest Edition
7. Leslie Cromwell, Fred J Weibell and Erich A Pfeiffer. Biomedical Instrumentation, New Delhi 2000

**1. Cell structure and Molecular Biology**

Cells as a unit of life, prokaryotic and eukaryotic cells, biomembranes, structure and basic functions of various cell organelles i.e. nucleus, ribosomes, ER, golgi, lysosomes, peroxisomes, exosomes, cytoskeleton. Nucleic acids – DNA, RNA and Protein. Overview of replication, transcription and translation. **Organization of tissues** - Cell-cell and cell-matrix interactions, cell adhesion molecules, components of the extracellular matrix, cellular junctions and role.

**2. Tools and Techniques of Cell Biology**

Histology, staining, fluorescence, confocal microscopy, TEM and SEM, Fluorescent dyes and GFP tagged proteins in visualization, FACS, cell fractionation, cell culture.

**3. Membrane Potentials and Action Potentials**

Basic Physics of Membrane Potentials, Measuring the Membrane Potential, Resting Membrane Potential of Nerves, Nerve Action Potential, Roles of other Ions During the Action Potential, Propagation of the Action Potential. Recording Membrane Potentials and Action Potentials.

**4. Organization of the Nervous System, Basic Functions of Synapses, and Neurotransmitters**

General Design of the Nervous System, Major Levels of Central Nervous System Function, Comparison of the Nervous System with a Computer, Central Nervous System Synapses, Some Special Characteristics of Synaptic Transmission

**5. Nerve & Muscle Physiology**

Classification of nerve fibres, Nerve conduction, Degeneration and regeneration in nerves, Functional anatomy of skeletal muscle, Neuro-muscular transmission and blockers, Excitation-contraction coupling, Smooth muscle, Mechanisms of muscle contraction.

**6. Sensory System :**

**The Eye** Optics of Vision, Physical Principles of Optics, Ophthalmoscope, Neural Function of the Retina, Visual Pathways, Organization and Function of the Visual Cortex, Neuronal Patterns of Stimulation During Analysis of the Visual Image, Fields of Vision; Perimetry, Eye Movements and Their Control, Autonomic Control of Accommodation and Pupillary Aperture, **The Sense of Hearing**, Tympanic Membrane and the Ossicular System, Cochlea, Central Auditory Mechanisms. Sense of Taste and Sense of Smell.

**7. Respiratory and Circulatory system**

Functional anatomy of respiratory system, Pulmonary ventilation, Alveolar ventilation, Mechanics of respiration, Pulmonary circulation, Principles of gas exchange, Oxygen & carbon-dioxide transport, Regulation of respiration, Artificial respiration. Cardio-vascular Physiology - Functional anatomy of the heart, Properties of cardiac muscle, Cardiac cycle,

Heart as a pump, Cardiac output, Generation & conduction of cardiac impulse, Electrocardiogram, Regional circulations.

## **8. Renal Physiology & Fluid Balance**

Body fluid compartments, Water balance; regulation of fluid balance, Urine formation, Regulation of extracellular sodium & osmolarity, Renal mechanisms for the control of blood volume, blood pressure & ionic composition, Regulation of acid-base balance, Renal failure

### **Text book and Recommended Book**

1. Textbook of Medical Physiology by Guyton and Hall, 14th Edition, ISBN-13 : 978-0323597128
2. Guyton & Hall Physiology Review by John E. Hall, 3rd Edition, ISBN-13 : 978-1455770076
3. Lippincott® Illustrated Reviews: Physiology by Robin R. Preston and Thad E. Wilson. 2nd Edition, ISBN/ISSN: 978-1496385826
4. Ganong's Review of Medical Physiology, 26th Edition, ISBN 978-1-260-12240-4
5. Medical Physiology by Walter Boron Emile Boulpaep, 3rd Edition. ISBN: 9780323427968



**1. Statistics**

Introduction and its role and uses, Collection, Organization, Graphics and pictorial representation of data, Measures of central tendencies and dispersion, Coefficient of variation

**2. Probability**

Basic concepts, Common probability distributions and probability distributions related to normal distribution

**3. Sampling**

Simple random and other sampling procedures, Distribution of sample mean and proportion

**4. Estimation and Hypothesis testing**

Point and interval estimation including fiducial limits, Concepts of hypothesis testing and types of errors, Student-t and Chi square tests, Sample size and Power.

**5. Experimental design and analysis of variance**

Completely randomized, randomized blocks, Latin square and factorial designs, Post-hoc procedures

**6. Correlation and regression**

Graphical presentation of two continuous variables, Pearson's product moment correlation coefficient, its statistical significance, Multiple and partial correlations, Linear regression, Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope, Introduction to multiple linear regression model, Probit and logit transformations

**7. Non-parametric tests**

Sign, Mann Whitney U, Wilcoxon matched pair, Kruskal Wallis and Friedman two way Anova tests, Spearman rank correlation

**8. Statistical techniques in pharmaceuticals and medical devices**

Experimental design in clinical trials, Parallel and Crossover designs, Statistical test for bioequivalence, Dose response studies, Statistical quality control.

**Reading material**

1. Mathematics and Biostatistics, Second Edition, 2007-2008, G. K. Jani, Atul Prakashan
2. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition, 2004, Sanford Bolton
3. Biometry, Third Edition, 1995, Robert R. Sokal and F. James Rohlf
4. Introduction to the Practice of Statistics, Fifth Edition, 2004, David S. Moore and George P. McCabe
5. Experimental Design in Biotechnology, 1989, Perry D. Haaland

**1. Ultra Violet (UV), visible and fluorescence spectroscopy:**

- a) **Energy levels and selection rules:** Definitions, molecular orbital approach for energy absorption, various modes of transitions.
- b) **Correlation of structural variation with UV absorption:** Factors influencing the position and intensity of absorptions, Inductive and resonance effects, effect of ring size, influence of stereochemical factors.
- c) **Predicting UV absorption:** Woodward-Fieser, Fieser-Kuhn and Nelson rules
- d) **Other factors:** Non-conjugative effect, solvent effect, S-Cis band.
- e) Theory and Instrumentation, Factors affecting fluorescence, the relation between the intensity of fluorescence and concentration, measurement of fluorescence, Quenchers and Application.

**2. Infrared (IR)spectroscopy**

- a) **Characteristic regions of the spectrum:** Various modes of vibrations, Energy levels
- b) **Correlation of structure with IR spectra:** Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency.
- c) **Applications:** Determination of stereochemistry. Spectral interpretation with examples.

**3. Nuclear Magnetic Resonance (NMR)spectroscopy:**

- a) **Fundamentals:** Physical basis, magnetic nuclei, resonance, relaxation processes, signal-sensitivity.
- b) **Instrumentation:** Continuous-Wave (CW) instrument, Pulsed Fourier Transform (FT) instrument, Functions, Relation with sensitivity, Sampling.
- c) **<sup>1</sup>H NMR, correlation of structure with spectra:** Chemical environment and shielding, chemical shift and origin of its concept, reference compound, local diamagnetic shielding and magnetic anisotropy, relation with chemical shift, chemical and magnetic non-equivalence, spin-spin splitting and its origin, Pascal's triangle, coupling constant, mechanism of coupling, integral, NMR solvents and their residual peaks, protons on heteroatoms, quadrupole broadening and decoupling, effect of conformations and stereochemistry on the spectrum, Karplus relationship, diastereomeric protons, Heteronuclear coupling to F and P, virtual coupling, long range coupling-epi, peri, bay effects. Shift reagents-mechanism of action, spin decoupling and double resonance. Explanation of spectra of some compounds and drugs.
- d) **<sup>13</sup>C NMR correlation of structure with spectra:** Chemical environment, shielding and carbon-13 chemical shift, calculation, proton-coupled C Spectra, Proton-decoupled C spectra, Nuclear Overhauser Enhancement (NOE), Problem with integration, Distortion less Enhancement by Polarization Transfer (DEPT), Heteronuclear coupling for carbon

to deuterium, carbon to F, carbon to P. Explanation of spectra of some compounds and drugs.

#### 4. Mass spectrometry (MS)

Molecular ion and metastable peak, fragmentation patterns, nitrogen and ring rules, McLafferty rearrangement, Different ionizations modes: EI, CI, FAB, ESI, APCI, APPI MALDI and other techniques, applications.

#### Text Books

1. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to spectroscopy. 2008. Cengage Learning ISBN-10 : 8131529169, ISBN-13 : 978-8131529164
2. Dyer JR. Applications of absorption spectroscopy of organic compounds. 1978. Prentice Hall, Mumbai, India, ISBN-10 : 8120302524, ISBN-13 : 978-8120302525
3. Jürgen H. Gross. Mass Spectrometry: A Textbook. 2<sup>nd</sup> edition, 2011. ISBN-10 3-540-40739-1, Springer-Verlag Berlin Heidelberg, Germany ISBN-13 978-3-540-40739-3

#### Reference books

1. Neil E. Jacobsen, NMR Spectroscopy explained, 2007, John Wiley & Sons, Inc., Hoboken, New Jersey. ISBN 978-0-471-73096-5
2. Jack Cazes, Ewing's Analytical Instrumentation Handbook. 2005. Marcel Dekker, Madison Avenue, New York, U.S.A. ISBN-10 : 1482218674, ISBN-13 : 978-1482218671
3. Spectrometric Identification of Organic Compounds by Robert M. Silverstein, Francis X. Webster & David J. Kiemie

**MT-550****Computer Application (CAD &CAM)****(1 Credit)**

Introduction and components of Computer aided design (CAD)/Computer aided manufacturing (CAM); 3D Modeling and Viewing: Modeling operations and strategies;

Modeling Aids and Tools; Mass and Geometric Properties; Assembly Modeling: Bottom-up, top-down assembly approaches, Mating conditions, subassemblies, assembly analysis (Motion study); Engineering Drawing: Drawing structures, Angle of projections, Annotations, Tolerances, Manufacturing information; Product Data Exchange; Computer Aided Process Planning (CAPP): Significance, Architecture of a CAPP systems, CAPP approaches; Part Programming: Data exchange, Machine tool, Programming steps, Toolpath Planning, 2D and multi-axis, Post processing the Data; CAD/CAM Programming: Macros, CAD/CAM API functions; Introduction to CAE; Structural analysis, Thermal analysis.

<b>S. No.</b>	<b>Module</b>	<b>Number of Lectures</b>
<b>1</b>	Introduction and components of Computer aided design (CAD)/Computer aided manufacturing (CAM); Product life Cycle, Scope, GUI and Menu of a CAD/CAM software	1
<b>2</b>	3D Modeling and Viewing; Modeling entities & features, Modeling operations and strategies	2
<b>3</b>	Modeling Aids and Tools; Entity selection, transformation, measurement, color, material	2
<b>4</b>	Mass and Geometric Properties; Area, Volume, Centroid, inertia, etc.	1
<b>5</b>	Assembly Modeling; Bottom-up, top-down assembly approaches, Mating conditions, subassemblies, assembly analysis (Motion study)	2
<b>6</b>	Engineering Drawing; Drawing structures, Angle of projections, Annotations, Tolerances, Manufacturing information	2
<b>7</b>	Product Data Exchange; IGES, STEP, ACIS & DXF, STL	1
<b>8</b>	Computer Aided Process Planning (CAPP); Significance, Architecture of a CAPP systems, CAPP approaches	1
<b>9</b>	Part Programming; Data exchange, Machine tool, Programming steps, Toolpath Planning; 2D and multi-axis, Post processing the Data	2
<b>10</b>	CAD/CAM Programming; Macros, CAD/CAM API functions	1
<b>11</b>	Introduction to CAE; Structural analysis, Thermal analysis	1

**1. Intellectual property**

Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property patents, copyrights, trademark; Factors effecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications.

**2. Trade related aspects of intellectual property rights**

Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trade in Services); Protection of plant and animal genetic resources; Biological materials; Gene patenting; Biotechnology / NIPER-Guwahati drug related IPR issues; Status in India and other developing countries; Case studies and examples; TRIPS issues on herbal drugs.

**3. Nuts and bolts of patenting, copyright and trademark protection criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS**

Filing of a patent application; Precautions before patenting disclosures / non-disclosures, publication-article / thesis; Prior art search-published patents, internet search patent sites, specialized services-search requests, costs; Patent application-forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications- provisional, non provisional, PCT and convention patent applications; International patenting-requirement procedures and costs; Financial assistance for patenting- introduction to schemes by NRDC and TIFAC; Publication of patents-gazette of India, status in Europe and US; Patent annuity; Patent attorneys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infringement- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists University / organisational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information-internet sites, brochures, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Berne convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringements.

#### **4. Technology development / transfer / commercialisation related aspects**

Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialisation and commercialisation-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personnel; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory licensing excess to medicine issues; DOHA declaration, POSTWTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalisation of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPs; Related registration and marketing issues; Case studies-antiretroviral drugs and others.

#### **5. Funding sources for commercialization of technology**

Preparation of a project report, financial appraisal, business models; GOI schemes and incentives; NRDC, TePP, HGT, TDB schemes. PATSER; Venture capitalists, banks. Incubator concept Case studies with respect to IIT, CCMB, IMTECH, NIPER. Documentation and related aspects.

#### **6. Ethics and values in IP**

IP and ethics-positive and negative aspects of IPP; Societal responsibility; Avoiding unethical practices; Echo-responsibility-economic, social and NIPER-Guwahati environmental benefits of modern biotechnology; Voluntary adoption of pollution control strategies.

#### **Recommended books**

1. Law Relating to Intellectual Property by B.L. Wadhwa
2. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012)
3. Patent Agent Examination by Sheetal Chopra and Akash Taneja
4. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan
5. Making Breakthrough Innovation Happen by Porus Munshi
6. Innovation X- Why a Company's Toughest Problems are its Greatest Advantage by Adam Richardson
8. Legal Drafting for the Layman by Nabhi Kumar Jain
7. How to Write and Publish a Scientific Paper by Robert A Day
8. Concise Law Dictionary-with Legal Maxims, Latin Terms and Words and Phrases by Justice Y.V. Chandrachud
9. Biomedical Research- From Ideation to Publication by G. Jagadeesh and others

**MT-570**

**Elective 1; Biomedical Devices and Systems**

**(1 Credit)**

Introduction to biomedical devices and their requirements; Engineering approaches to clinical challenges, clinical problems requiring implants and devices for solution; Materials used in medicine; Implantable devices and materials: Vascular and cardiovascular devices, stents, orthopedic implants, cochlear implants; Wearable devices: ventricular assist devices, osteoarthritis, rehabilitation devices; Minimally invasive devices and techniques: suture medicated closure devices, solid/liquid embolic agents; Imaging and image-guided techniques; Gait analysis; Regulatory requirements and ISO standards for *in vitro/in vivo* testing.

### **Reading material**

#### **Texts Books:**

1. Paul H. King, Richard C. Fries. Design of Biomedical Devices and Systems. CRC press, Boca Raton, 2009
2. J.B. Park and J.D. Bronzino. Biomaterials: Principles and Applications. CRC Press. 2002. ISBN: 0849314917

#### **Reference Books**

1. T. M. Wright, and S. B. Goodman. Implant Wear in Total Joint Replacement: Clinical and Biologic Issues, Material and Design Considerations. American Academy of Orthopaedic Surgeons, 2001.
2. Buddy D. Ratner, Allan S. Hoffman, Frederick J. Schoen, Jack E. Lemons. Biomaterials Science: An Introduction to Materials in Medicine, Academic Press, 2004, USA
3. James Moore and George Zouridakis. Biomedical Technology and Devices Hand Book. CRC press, Washington DC, 2004
4. Aimé Lay-Ekuakille and Subhas C. Mukhopadhyay, Wearable and Autonomous Biomedical Devices and Systems for Smart Environment. Springer-Verlag Berlin, 2010
5. Andrés D. Lantada. Handbook on Advanced Design and Manufacturing Technologies for Biomedical Devices. Springer London 2013
6. David D. Zhou and Elias Greenbaum. Implantable Neural Prostheses 1. Devices and Applications. Springer, London, 2009
7. ASM Handbook Volume 23, Materials for Medical Devices

**MT-580**

**Elective 2; Pharmacopoeial Methods of Analysis**

**(1 credit)**

1. ICH Q4 Pharmacopoeial harmonization process: Current Status.
2. Study of different parts of various pharmacopoeias.
3. Limit tests: Tests for arsenic, lead, chloride, sulfate, and heavy metals.
5. Microbiological tests and assays: Antimicrobial (preservative) effectiveness testing, microbial limit tests, sterility test, vitamins assay (zone of exhibition), antibiotics assays, bacterial endotoxin test,
6. Leachables and extractables.

**Reference books:**

1. The Indian Pharmacopoeia, Indian Pharmacopoeia Commission, Ghaziabad.
2. The British Pharmacopoeia, Stationary Office British Pharmacopoeia Commission, London.
3. The United States Pharmacopoeia-National Formulary, Board of Trustees, Rockville.
4. The European Pharmacopoeia, Directorate for Quality of Medicines of the Council of Europe.



**LS-510**

Medical Instrumentation Laboratory

**(2 Credits)**

1. Hands on experiment on different Medical Devices and Evaluation

**LS-520**

Pre-clinical Studies Laboratory

**(1 Credit)**

2. Animal handling and its anatomy
3. Hands on experiment on mammalian cell lines
4. *In-vitro* Biocompatibility studies
5. *In-vivo* Biocompatibility studies
6. Hands on experiment on Electrocardiogram (ECG)
7. Hands on experiment on *in-vivo* imaging (anatomical, functional and molecular imaging)
8. Acquisition and analysis of florescence imaging

# Semester 2

# Medical Devices

## SEMESTER-II

**MT-610**

**Bioengineering and regenerative devices (2 Credits)**

**1. Module 1:**

Introduction to tissue Engineering and Artificial Organ. Applications of tissue engineering- Bionics and prosthetics.

**2. Module II:**

Potential Biomaterials for Regenerative Devices. Optimization of Biomaterial composition, Design and fabrication of implantable devices/scaffold- Electrospinning, Rapid Prototyping, 3D Printing. Self-Assembling, Prosthetic devices.

**3. Module III:**

Stem Cell Basics: types-sources, and therapeutic Application, Stem cell Expansion. Stem cell Growth Kinetics and influencing factors, Stem Cell Differentiation -bone, cartilage, neural tissue, Cell signaling Molecules, Stem Cell Characterisation,

**4. Module IV:**

Bioreactor - importance, basic configurations and design, Static and Dynamic bioreactor systems for cell seeding and culturing, Factors influencing regenerative device production-mechanical, electrical and fluid flow.

**5. Module V:**

Stem Cell- biomaterial interaction- cell adhesion, migration & aggregation, generation of tissue construct devices for transplantation & the in vitro and in vivo ( animal model) assessment,

**6. Module VI:**

Case studies –bone, cartilage, joints (knee & hip joints) and neural tissue regenerative devices, Ethical & Safety Issues,tutorials, Student presentations.

**References:**

1. Shu Q. Liu, Bioregenerative Engineering: Principles and Applications, Wiley Interscience, New York, 2007.
2. N. Hakim (ed), Artificial Organs, Springer-Verlag London, 2009, ISBN:1848822812, 9781848822818.

3. A. Hasan (ed), Tissue engineering for artificial organs: regenerative medicine, smart diagnostics and personalized medicine, Wiley VCH, 2017, ISBN 978-3-527-68993-4, 3527689931, 978-3-527-68994-1.
4. W.W. Minuth, R. Strehl, K. Schumacher, Tissue Engineering: From Cell Biology to Artificial Organs, Wiley-VCH, 2005, ISBN: 9783527311866,3527311866, 0471253944,0470844817,0471852139,3527308954,3527301984
5. R. Lanza, R. Langer, J. Vacanti, Principles of Tissue Engineering, 3 rd Edition, Academic Press, 2007, ISBN 9780123706157, 0123706157
6. Meyer, U., Meyer, Th., Handschel, J., Wiesmann, H.P., Fundamentals of Tissue Engineering and Regenerative Medicine, Springer Nature, 2009, Hardcover ISBN 978-3-540-77754-0, Softcover ISBN 978-3-662-51830-4

## **MT-620**

### **Drug Delivery Engineering (2 Credits)**

#### **1. Medical devices versus drug delivery carriers**

Strategies to prevent device-related nosocomial infections

Importance of lipid-and polymer-based antimicrobial delivery carriers in medical devices

#### **2. Drug Delivery: Targeted Drug Delivery and Novel Carrier Systems**

Drug targeting: Basics of drug targeting

Different levels of drug targeting: First order, second order and third order targeting, active and passive targeting, EPR effect, receptor-mediated endocytosis, prodrug based drug targeting, brain targeting, tumor targeting

NDDS: Fundamentals of novel drug delivery systems

Biopharmaceutics and pharmacokinetic aspects of CRDDS: Strategies and design, factors affecting controlled release drug delivery systems, computation of desired release rate and dose for CRDDS. Pharmacokinetic design for DDS; in-vitro/in-vivo considerations. Intermittent zero order and first-order release

#### **C. Additive Manufacturing (AM) Engineering**

3D Printing in Drug Delivery: Introduction, Classification of AM technologies, Advantages, AM versus Pharmaceutical Conventional manufacturing processes.

AM Technologies: Vat polymerization, powder bed fusion, Material extrusion, Material jetting, etc.

AM for various Engineered Drug Delivery Systems: Oral solid dosage forms, Transdermal patches, Drug delivery implants, Delivery to other routes.

AM Materials: Details with drug delivery application domains.

Bio printing for in vitro drug testing: Bioprinted organ-on-a-chip models and cell-laden models.

Product Evaluation & Quality for drug delivery engineering perspective: Stability, Safety, Efficacy, Scalability of AM technology, AM ecosystem, Regulatory challenges, Cost-effectiveness.

#### **Reading material:**

1. Biofilm Eradication and Prevention: A Pharmaceutical Approach to Medical Device Infections, Author: Tamilvanan Shunmugaperumal, First published: 29 June 2010, Print ISBN:9780470479964 | Online ISBN:9780470640463.
2. Introduction to Biopharmaceutics, by Gibaldi, M.

3. Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Niazi, S.K.
4. Modeling in Biopharmaceutics, Pharmacokinetics, and Pharmacodynamics: Homogeneous and Heterogeneous Approaches, by Macheras, P. and A. Iliadis.
5. Applied Biopharmaceutics & Pharmacokinetics, by Shargel, L., S. Wu-Pong.
6. Lan Gibson, David W. Rosen and Brent Stucker, Additive Manufacturing Technologies: Rapid Prototyping to Direct Digital Manufacturing, Springer, 2010.
7. Andreas Gebhardt, Understanding Additive Manufacturing: Rapid Prototyping, Rapid Tooling, Rapid Manufacturing, Hanser Publisher, 2011.
8. C.Y. Liaw, M. Guvendiren, Current and emerging applications of 3D printing in medicine, *Biofabrication* 9 (2017), 024102.
9. Drug Delivery: Engineering Principles for Drug Therapy, W. Mark Saltzman, Oxford University Press, 2001
10. Drug Delivery: Fundamentals and Applications, Anya M. Hillery and Kinam Park, 2<sup>nd</sup> Edition, CRC Press, 2016
11. M. Palo, J. Hollander, J. Suominen, J. Yliruusi, N. Sandler, 3D printed drug delivery devices: Perspectives and technical challenges, *Expert Rev. Med. Devices* 14 (2017) 685-696.

### **MT-630**

#### **Biomaterials (2 Credits)**

Overview of Biomaterials and their use in Medical Devices; Physical and Mechanical requirements for Medical Device Materials; Metallic Materials; Failure Analysis of Metallic Orthopedic Implants; Hip Joint Prosthesis Fixation: Problems and Possible Solutions; Ceramic Materials; Polymeric Materials; Meta materials; Soft Tissue Replacement: Sutures, Skin, Maxillofacial Implants, and Blood Interfacing Implants; Hard Tissue Replacement: Long Bone Repair and Joints; Practical aspects of biomaterials: Introduction, Sterilization of Implants and Devices, Implant and Device Failure, Implant Retrieval and Evaluation; Fundamentals of nanotechnology and its applications orthopedic materials, regenerative medicine.

#### **Reading material:**

1. ASM Handbook Volume 23, Materials for Medical Devices
2. B.D. Ratner, Alan S. Hoffman, Frederick J. Schoen, Jack E. Lemons, Biomaterials Science: An Introduction to Materials in Medicine 2004, Edition: 2nd Revised edition (ISBN-10: 0125824637 and ISBN-13: 978-0125824637)

3. J.B. Park and J.D. Bronzino. Biomaterials: Principles and Applications. CRC Press. 2002. ISBN: 0849314917
4. Joon Park, R.S. Lakes. Biomaterials: An Introduction, Springer, ISBN 978-0-387-37879-4, 2007
5. Lei Yang. Nanotechnology Enhanced Orthopedic Materials: Fabrications, Applications and Future Trends, Elsevier, 2015 ISBN: 978-0-85709-844-3

## **MT-640**

### **Biosensor (1 Credit):**

#### **1. Module 1:**

Introduction; Definition and fundamental principles; Generations of biosensors; Basic transduction system in biosensors: electrochemical, optical, acoustic, piezoelectric, and calorimetric biosensors.

#### **2. Module 2:**

Biological recognition systems / bioreceptor: antibody, Fab and Fc fragments, nucleic acid, cell, and tissue; property of materials for bioreceptor. Design engineering of biosensor and characterization techniques. BIO-MEMS, Micro / Nanofluidics

#### **3. Module 3:**

Analytical parameters: Calculation of LOD, LOQ, Dynamic Range, Selectivity coefficient, electrode/chip performance, Models of real sample analysis; Invitro, invivo, exvivoanalysis systems, sample processing, standard addition method, spike-recovery method. Case studies and tutorials.

#### **4. Module 4:**

Materials for biosensors: conducting polymers, natural / synthetic polymers, paper matrix, nanocomposite materials, metal oxides / dendrites, porous silicons, Application of biosensors for pharmaceutical testing and clinical diagnostics. Student presentations.

### **Text books and Reference books:**

1. Buerk, Donald, G., "Biosensors: Theory and Applications", CRC Press, 1995.
2. Manz, A., & Becker, H.(Eds.), "Microsystem Technology in Chemistry and Life Sciences", Springer-Verlag, New York, 1999. ISBN: 3-540- 65555-7.
3. Nanobiosensors for personalized and onsite biomedical diagnosis, ISBN No: 978-184-91-9950-6, Pranjal Chandra (Ed.) Publisher: The Institution of Engineering and Technology, Michael Faraday House, London, United Kingdom, Year: 2016
4. Next-generation point-of-care biomedical sensors technologies for cancer diagnosis, ISBN No: 978-981-10-4725-1, Pranjal Chandra, Tan Yen Nee, Surinder P. Singh (Eds.), Publisher: Springer, Singapore, Year: 2017

## **MT-650**

### **Artificial Intelligence in Medical Devices (2 Credits)**

#### **1. Use of computers in physiological data acquisition and analysis:**

Programming, storage and display of data with reference to bioelectric potentials. Applications of Microprocessor and Microcontroller in medicine. Python scripting for data analysis.

#### **2. Digital filters:**

FIR and IR type and their application to biomedical signal filtering.

#### **3. Data reduction techniques:**

Spectrum analysis.

#### **4. Intelligent computing systems in medicine:**

Introduction to Intelligence and Artificial Intelligence. Heuristic search method, knowledge Based system.

#### **5. Artificial Neural Networks:**

Introduction, Pattern and data, methods for pattern recognition tasks, Artificial neural networks: Terminology, Models of neurons, Topology. Activation and synaptic dynamics: Activation dynamic models, synaptic dynamic models, learning methods. Functional units of ANN for pattern recognition tasks: Pattern recognition problems, basic functional units, Feed forward neural networks: Analysis of pattern association networks, analysis of pattern classification networks, Feedback neural networks: Analysis of linear associative, FF



Networks. Competitive learning neural networks: Components of competitive learning network, analysis of pattern clustering network.

#### **6. Biomedical applications of ANN:**

Modelling and diagnosing the cardiovascular system, Pattern recognition of pathology images, ultrasound and magnetic resonance medical images textures analysis using ANN.

#### **7. Introduction to Imaging:**

Need of Imaging, invasive and non-invasive-imaging, concept of resolution and sensitivity. Use of electromagnetic spectrum for non invasive imaging, Importance of mathematics in imaging.

#### **8. Imaging modalities:**

Introducing modalities based on increasing mathematical complexity.

#### **9. Evolutionary computing and Genetic Algorithm (EC-GA).**

#### **10. Fuzzy Logic and its application in decision making.**

#### **11. Application of EC, GA, FL in Medical data analysis and diagnosis.**

#### **Reading material:**

1. Biomedical Informatics: Computer Applications in Health Care and Biomedicine, Editors: Shortliffe, Edward H., Cimino, James J. (Eds.), 2021. (ISBN 978-3-030-58720-8).
2. Neural Networks and Artificial Intelligence for Biomedical Engineering, M. E. Cohen, D. L. Hudson, Wiley-IEEE Press 1999, (Print ISBN:9780780334045; Online ISBN:9780470545355; DOI:10.1109/9780470545355)
3. Principles of Computerized Tomographic Imaging", A. C. Kak, M. Slaney and G. Wang. 2002 American Association of Physicists in Medicine, (DOI: 10.1118/1.1455742)
4. Introduction to the Mathematics of Medical Imaging, Charles L. Epstein, 2<sup>nd</sup> Edition, 2008, (ISBN 978-0-89871-642-9)
5. The Mathematics of Medical Imaging: A Beginner's Guide", T. G. Feeman, 2015, (ISBN 978-3-319-22664-4)

## **MT-660**

### **Regulatory in Medical Devices (1 Credit)**

#### **1. Overview of medical devices:**

Definition, Classification, Difference between drug and medical device, *In-vitro* diagnostics, Labelling of medical devices and *in-vitro* diagnostics, Overview of combination products.

#### **2. Medical device regulation: Global requirements:**

Medical Device regulation in India (CDSCO), Medical Device regulation in USA (USFDA), Medical Device regulation in European Union (EMA)/European Medical Device Regulations, Medical Device Regulations-WHO.

#### **3. Regulatory requirements for medical devices and approvals:**

Regulatory requirements of biocompatibility of medical devices (ISO10993), Clinical Investigation of medical devices, Regulation of investigational medical devices, Post marketing surveillance and materiovigilance, Dossier preparation of common technical document (CTD) and eCTD submission, How to obtain a license to manufacture a medical device, Import and export of medical device and in-vitro diagnostics.

#### **4. Standards of medical devices, Quality Management Systems:**

National and international standard system for medical devices, Performance evaluation of medical devices with reference laboratories in India, Material selection for medical devices, Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Documentation Practice (GDP).

#### **5. Medical Device safety and risk management:**

Quality management system for medical devices, Total product life cycle, Effectiveness of medical device, Adulteration, Misbranding.

#### **Reading material:**

1. Medical Devices Rules, 2017, Related Guidance documents available at CDSCO websites.
2. US-FDA Regulation of Medical Devices
3. European Union Regulation of Medical Devices
4. Medical Device regulations: global overview and guiding principles, World Health Organization.

5. Book: Medical Devices: Regulations, Standards and Practices; 1<sup>st</sup> Edition, Imprint: Woodhead Publishing; Hardcover ISBN: 9780081002896 (Authors: Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo)
6. Book: Inventing Medical Devices: A Perspective from India. (Author: Jagdish Chaturvedi), Publisher: Createspace Independent Pub; (ISBN-10: 1519467184; ISBN-13: 978-1519467188).
7. Book: Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices (Authors: John J. Tobin, Gary Walsh); ISBN: 978-3-527-31877-3; Wiley-Blackwell publisher; 2008.

## **MT-670**

### **Elective 3; Plasma technology for Biomedical applications (1 Credits)**

1. Fundamental of Plasma; Introduction to the thermal and non-thermal plasma.
2. Development of plasma devices and its diagnostic: soft plasma jet, Dielectric barrier discharge (DBD) type plasma.
3. Plasma treatment methodology; Direct and Indirect treatment (plasma treated liquid), application of plasma in disease
4. Decent progress in plasma application: 2D & 3D (in-vitro) and animal model. Plasma application in tissue regeneration.
5. Cellular response and mechanisms of plasma treatment: intracellular reactive oxygen and nitrogen species(RONS), selective anticancer treatment, a potential mediator of oxidative stress cellular signalling and immune stimulation.

### **Reference Materials;**

1. Introduction to plasma physics by R.J. Goldston, Tylor & Francis group.
2. Plasma in Medicine and Biology by M. Larrossi, M.G. Kang, G. Morfill and W. Ztolz
3. Cold Plasma in Cancer Therapy by Michael Kaider, Degun Xan, Jonathan Sharma.

## **MT-680**

### **Elective 4; Biomedical Signal Processing (1 Credit)**

1. Signals: classification of signals; signal operations: scaling, shifting and inversion; signal properties: symmetry, periodicity and absolute integrability; elementary signals; Signal representation: signal space and orthogonal bases.
2. Sources of bioelectric potential, resting potential, action potential, propagation of action potentials in nerves; rhythmic excitation of heart; Electrocardiogram, Electroencephalogram, Electromyography, Photoplethysmography and Phonocardiogram
3. Pre-processing, waveform recognition, morphological studies and rhythm analysis, Application of signal processing techniques for extraction of physiological parameters; introduction to wavelets & time frequency models and their applications

#### **Texts:**

1. Rangaraj M. Rangayyan, Biomedical Signal Analysis, 2<sup>nd</sup> Edition, Wiley-IEEE Press, 2016
2. M. J. Roberts and G. Sharma, Fundamentals of Signals and Systems, 2<sup>nd</sup> edition. McGraw-Hill Education, 2017.
3. V. Oppenheim, A. S. Willsky, and H. S. Nawab, Signals and Systems, 2<sup>nd</sup> edition. Pearson, 2015.

#### **References:**

1. E.N. Bruce, Biomedical Signal Processing and Signal Modelling, John Wiley and Sons, 2001.
2. W. J. Tompkins, Biomedical Signal Processing; Prentice Hall, 1995.

## **LS-610**

### **Bio and Pharmaco-engineering Laboratory (1 Credit)**

1. Fabrication and evaluation of engineered filaments/biofilaments through extrusion mediated AM techniques.
2. Rapid prototyping using various platform technologies related to AM/3D Printing such as FDM, SLS, SLA, etc.
3. Computer-aided design, prototyping and evaluation of cutting-edge translational pharmaceutical devices to justify drug delivery applications

4. Understanding the mathematical concept behind the calculations for the estimation of pharmacokinetics parameters.
5. Evaluation of In-vitro drug release kinetics for the sustained release formulations.

**LS-620**

**AI & Machine Learning Laboratory (1 Credit)**

As per the laboratory manual