SYLLABUS

M.Tech. in Medical Devices

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH GUWAHATI
SilaKatamur (Halugurisuk), P.O.: Changsari
Dist: Kamrup, Assam, Pin: 781101, Assam, India
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M.Tech. in Medical Devices

Course No.	Course Name	Credits
Semester-I		
MD-510	Medical Imaging & Processing	2
MD-520	Medical Instrumentation (Diagnostic, Therapeutic & Surgical)	2
MD-530	Biosensors	2
MD-540	Computer Application (CAD & CAM)	2
GE-510	Biostatistics	2
GE-511	Seminar	1
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
LS-510	Medical Instrumentation Laboratory	2
LS-520	Pre-clinical Studies Laboratory	1
	TOTAL CREDITS	**15**
Semester-II		
MD-610	Bioengineering (Neuro, tissue etc.) and regenerative devices	2
MD-620	Drug Delivery Engineering	2
MD-630	Biomaterials	2
MD-640	Biomedical Signal Processing	2
MD-650	Artificial Intelligence in Medical Devices	2
MD-660	Regulatory in Medical Devices	2
LS-610	Bio and Pharmaco-engineering Laboratory	1
LS-620	Biomedical devices Laboratory	1
LS-630	Medical devices Testing Laboratory	1
	TOTAL CREDITS	**15**
Semester-III		
Project		
TH-598	Synopsis	5
TH-599	Presentation	3
	TOTAL CREDITS	8
Semester-IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	TOTAL CREDITS	**12**
GRAND TOTAL CREDITS (I to IV Semesters)		**50**

M.Tech. in Medical Devices
SEMESTER - I

MD-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, Neighbours 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

Recommended Books:

Text Books:

1. R.C. Gonzalez and Wintz Paul, "*Digital Image Processing*", 4th Edition, Addision 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*", 3rdEdition, Lippincott Williams & Wilkins, 2012.
2. Rangaraj M. Rangayyan, "*Biomedical Image Analysis*", CRC Press, 2004.

MD-520: Medical Instrumentation (Diagnostic, Therapeutic & Surgical) (2 Credits)

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 Analysers - Pulse-oximeter, Blood pH measurement, Measurement of blood PCO2 & PO2, 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. Immunodiagnostics 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, sigmoidscope, endoscopic retrograde

cholangiopancreatography (ERCP).

8. Ophthalmic and thoracic surgical devices

Ophthalmoscope, laryngoscope, bronchoscope, oesophagoscope.

9. Urological surgical devices

Cystoscope, urethroscope, resectoscope, ultrasonic and electronic lithotroptor.

Recommended Books

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. 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 AsiaEdition, 1st Edition Authors: Nader Rifai A. Rita Horvath Carl T. Wittwer; HardcoverISBN: 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 WilkinsMolecular Diagnostics, 3rd Edition by George P. Patrinos, Wilhelm Ansorge, Phillip B.Danielson Hardcover ISBN: 9780128029718; eBook ISBN: 9780128029886.
4. AcademicPressDavid Wild. The Immunoassay Handbook, 4th Edition: Theory and Applications ofLigand 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, LatestEdition
7. Leslie Cromwell, Fred J Weibell and Erich A Pfeiffer. Biomedical Instrumentation,New Delhi 2000

MD-530 - Biosensors: (2 Credits)

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.

Recommended Books

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

MD-540: Computer Application (CAD &CAM) (2 Credits)

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 Programing: 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.

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

Recommended Books:

GE-510: Biostatistics (2 Credits)

1. Statistics

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

2. Probability

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

3. Sampling

Simple random and other sampling procedures, Distribution of samplemean and proportion

4. Estimation and Hypothesis testing

Point and interval estimation including fiduciallimits, 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, randomizedblocks, Latin square and factorial designs, Post-hoc procedures

6. Correlationandregression

Graphical presentation of two continuous variables, Pearson'sproduct moment correlation coefficient, its statistical significance, Multiple and partialcorrelations, Linearregression, Regression line, coefficient of determination, intervalestimation and hypothesis testing for population slope, Introduction to multiple linearregression model, Probit and logit transformations

7. Non-parametric tests

Sign, Mann Whitney U, Wilcoxon matched pair, Kruskalwallisand Friedman two wayAnova tests, Spearman rank correlation

8. Statistical techniques in pharmaceutics and medical devices

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

Recommended Books:

1. Mathematics and Biostatistcs, Second Edition, 2007-2008, G. K. Jani, AtulPrakashan
2. Pharmaceutical Statistics: Practical and Clinical Applications, Fourth Edition, 2004, SanfordBolton
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

GE-511: Seminar **(1 Credit)**

1. Introduction, information retrieval systems
2. Writing term papers and reports

3. Organization of scientific material, thesis, dissertation, and references
4. Reading research papers
5. Skill in the oral presentation. Each student has to present a seminar before the end of the semester

Recommended Books:

GE 520 - Fundamentals of Intellectual Property (IP) and Technology Management (1 Credit)

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 propertypatents, copyrights, trademark; Factors effecting choice of IP protection; Penalities for violation; Role of IPin pharmaceutical industry;Globalramifications 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 attomeys 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-Beme 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-commercialization and commercialization-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines forresearch 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.Wadhera
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 AkashTaneja
4. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan
5. Making Breakthrough Innovation Happen by PorusMunshi
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 Rober 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

LS-510 - Medical Instrumentation Laboratory (2 Credits)

1. Introduction and Hands-on experiments for Basic electronics
2. Hands-on experiment on different Medical Devices and Evaluation

LS-520- Pre-clinical Studies Laboratory **(1 Credit)**

1. Demonstration and training on Animal handling
2. Hands-on experiment on mammalian cell lines
3. *In-vitro* Biocompatibility studies
4. *In-vivo* Biocompatibility studies
5. Hands-on on experiment on Electrocardiogram (ECG)
6. Hands-on on experiment on *in-vitro* and *in-vivo* imaging
7. Acquisition and analysis of fluorescence imaging (*in-vitro*)

M.Tech. in Medical Devices
SEMESTER - II

MD-610 - Bioengineering (Neuro, tissue etc.) and regenerative devices **(2 Credits)**

1. Module I:

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 irin 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.

Recommended Books:

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

MD 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 fed 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.

Recommended Books:

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, RapidTooling, 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, 2nd 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.

MD 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.

Recommended Books:

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

MD 640 - Biomedical Signal Processing (2 Credits)

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 innerves; rhythmic excitation of heart; Electrocardiogram, Electroencephalogram, Electromyography, Photoplethysmography and Phonocardiogram
3. Pre-processing, waveform recognition, morphological studies and rhythm analysis, Application ofsignal processing techniques for extraction of physiological parameters; introduction to wavelets &time frequency models and their applications

Recommended Books:

1. Rangaraj M. Rangayyan, Biomedical Signal Analysis, 2 nd Edition, Wiley-IEEE Press,

2016

2. M. J. Roberts and G. Sharma, Fundamentals of Signals and Systems, 2 nd edition. McGraw-HillEducation, 2017.

3. V. Oppenheim, A. S. Willsky, and H. S. Nawab, Signals and Systems, 2 nd 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.

MD-650: Artificial Intelligence in Medical Devices (2 Credit)

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.

Recommended Books:

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, 2nd 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)

MD-660: Regulatory in Medical Devices (2 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, Effective of medical device, Adulteration, Misbranding.

Recommended Books:

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; 1st 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.

LS 610 - Bio and Pharmaco-engineering Laboratory (1 Credit)
1. Fabrication and evaluation of engineered filaments/biofilamentsthrough 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 - Biomedical Devices Laboratory (1 Credit)
Development and Characterization of Medical devices prototype. Student needs to select/identify area and take them as minor project work

LS 630 - Medical Devices Testing Laboratory (1 Credit)
Testing of Medical devices for Mechanical and Electrical properties as per IS/ISO/IEC/ASTM standards