NIPER
RAEBARELI

SYLLABUS

M. Tech. Medical Devices

M. Tech. Medical Devices

Course Code	Course Name	Credits
	Semester-I	
MD-510	**Cell, Molecular Biology and Bioinformatics in Medical Devices Perspective**	**2**
MD-520	**Foundation of Human Biology for Medical Devices**	**2**
MD-530	Medical Devices & Diagnostic Equipments	2
MD-540	**IoT and Machine learning in Medical Devices**	**2**
¶ GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	**1**
* GE-510	Biostatistics	2
GE-511	Seminars	1
LG-510	General Laboratory Experience	3
	Total Credits	**15**
	Semester-II	
MD-610	**Basics in Biosensors and Bioelectronics**	**2**
MD-620	**Materials in Biomedical Devices/Engineering**	**2**
MD-630	In Vitro Diagnostics	2
MD-640	**Regulatory Perspectives of Medical Devices**	**2**
** BT-630	Immunology and Immunotechnology	2
GE-611	Seminars	1
LS-610	General Lab Experience in the Area of Specialization	4
	Total Credits	**15**
	Semester-III	
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
	Semester-IV	
TH-698	Thesis	9
TH-699	Defense of Thesis	3
	Total Credits	**12**
	Grand Credits (I to IV Semesters)	**50**

Note:

* Common in all disciplines.
** Common between BT, MD
¶ Common in PA, PE, RA, PC, RT, MD

Courses marked in bold are mandatory as per the LSSSDC guidelines.

-Semester I-

MD-510: Cell, Molecular Biology and Bioinformatics in Medical Devices Perspective
(2 Credits)

1. **Cell Structure and Functional Organization in Diagnostic Context:** Overview of cell as the basic unit of life, Prokaryotic vs. eukaryotic cells with diagnostic relevance, Structure and function of cellular organelles: nucleus, mitochondria, ER, Golgi, lysosomes, peroxisomes, exosomes, cytoskeleton, Application of cell-derived components (e.g., exosomes) in diagnostics, Cell cycle (G1, S, G2, M phases) and its significance in disease diagnosis and drug screening.

2. **Cell Signaling and Receptor Biology in Device Targeting:** Cell surface and intracellular receptors: types and mechanisms, Orphan receptors and signal transduction pathways, Second messengers, hormones, and growth factors, Role of receptor-ligand interaction in biosensor design and targeted diagnostics.

3. **Molecular Basis of Disease: Cancer, Viral Diagnostic Biomarkers:** Tumor biology: oncogenes, proto-oncogenes, tumor suppressor genes, Models and markers for cancer diagnostics, Viral diagnostics with emphasis on HIV/AIDS, Enzyme-based diagnostic platforms and biomarker quantification using medical devices.

4. **DNA Structure and Its Analysis in Diagnostics:** Structural forms of DNA: A-, B-, Z-, P- and triplex DNA, Analytical techniques: UV-Vis spectrophotometry, CD spectroscopy, AFM, electron microscopy, Applications of DNA structural analysis in nucleic acid-based diagnostics and lab-on-chip systems

5. **Gene Expression and Translational Control Mechanisms:** Replication, transcription, and translation in prokaryotes and eukaryotes, Role of enzymes and cofactors in these processes, Relevance of gene expression profiling in personalized diagnostics and device-assisted detection, Post-translational modifications and their detection using bio-devices.

6. **Bioinformatics for Medical Device Applications:** Introduction to databases: GenBank, EMBL, Protein Data Bank (PDB), Tools for sequence alignment: BLAST, Clustal Omega, Protein structure visualization tools: PyMOL, Chimera, Predictive algorithms for biomarker discovery and device design using bioinformatics

Recommended Books

1. *Molecular Cell Biology by Harvey Lodish*

2. *Molecular Biology of the Cell by Bruce Alberts*
3. *Mount, D. W. (2004). Bioinformatics: Sequence and Genome Analysis. 2nd Edition. Cold Spring Harbor Laboratory Press.*
4. *Lesk, A. M. (2019). Introduction to Bioinformatics (5th ed.). Oxford University Press.*

MD-520: Foundation of Human Biology for Medical Devices (2 Credits)

1. **Introduction to Human Biology and Medical Devices**: Overview of Human Biology, Introduction to Medical Devices and Their Importance, Basic Cell Biology, Cell Structure and Function, Cellular Metabolism.
2. **Tissues and Organ Systems**: Types of Tissues: Epithelial, Connective, Muscle, Nervous, Organization of Organs and Systems, Relevance of Tissue Engineering to Medical Devices.
3. **Cardiovascular System**: Anatomy of the Heart and Blood Vessels, Physiology of Blood Circulation, Medical Devices: Pacemakers, Stents, Artificial Hearts, Case Studies and Device Analysis.
4. **Nervous System**: Structure and Function of the Nervous System, Neurons and Signal Transmission, Medical Devices: Neurostimulators, Cochlear Implants, Case Studies and Device Analysis.
5. **Respiratory System**: Anatomy and Physiology of the Respiratory System, Gas Exchange Mechanisms, Medical Devices: Ventilators, CPAP Machines, Case Studies and Device Analysis.
6. **Renal and Digestive Systems**: Anatomy and Physiology of the Renal System, Anatomy and Physiology of the Digestive System, Medical Devices: Dialysis Machines, Endoscopes, Case Studies and Device Analysis.
7. **Integrative Physiology and Medical Devices**: Integration of Physiological Systems, Practical Applications of Medical Devices, Ethical and Regulatory Considerations, Future Trends in Medical Devices.

Recommended Books

1. *"Human Biology" by Sylvia S. Mader & Michael Windelspecht*
2. *Khandpur, R. S. (2014). Biomedical Instrumentation: Technology and Applications. McGraw Hill Education.*
3. *Marieb, E. N., & Hoehn, K. (2018). Human Anatomy & Physiology (11th ed.). Pearson Education.*
4. *Introduction to Biomedical Engineering" by John Enderle & Joseph Bronzino*

MD-530: Medical Devices & Diagnostic Equipments (2 Credits)

1. **Cardiac Pacemakers** - Cardiac pacemaker, Principle of operation, Classification of pacemakers, Cardiac defibrillators -Need for a defibrillator, Types of defibrillator-defibrillator analyzer. Cardiac valves, different types mechanical and tissue types. Angioplasty. Balloon and stent angioplasty., Stents, different types – coil, slotted tubular, drug eluting stents.
2. **Ventilators** - Need for a ventilator, Classification of ventilators, High frequency ventilators, CPAP, BiPAP, Humidifiers, Nebulizers and Aspirators, Heart lung machine. Sterilization techniques: Autoclave, Gas, Dry Heat, Radiation, Dry Steam sterilization, Need for Anesthesia – Anesthesia machine - Electronics in Anesthesia machine.
3. **Audiometry**: Common tests & procedures, audiometer. Hearing-aids: Different-types, comparison of microphones receivers & amplifiers, cochlear implants. Neonatal instrumentation: incubators, apnea monitor, photo-therapy-devices. Syringe-pump, Infusion pump.
4. **Haemodialyzers** -Artificial Kidney, Dialyzers, principle of dialyzers, Membranes of the haemodialyzers, Types of Dialysis and merits and demerits. Lithotripters - need of lithotripsy, types of lithotripter systems, techniques, applications and limitations. Endoscopy, Laparoscopy, Keyhole surgery
5. **Clinical applications of electrotherapy:** principle of surgical diathermy, surgical diathermy machine, safety aspects in electro-surgical diathermy unit, short wave diathermy, ultrasonic diathermy, microwave diathermy, Pain relief through electrical stimulation principles of cryogenic technique and application
6. **Radio Therapy**: Principles of radiotherapy, Cobalt UNIT, Treatment planning system. Types of radiation detectors, biological effects of radiotherapy.

Recommended Books

1. *John G. Webster (Editor-in-Chief), Encyclopedia of Medical Devices and Instrumentation Vol.1 to Vol.4, John Wiley and Sons, 1988.*
2. *Khandpur R. S., Handbook of Bio-Medical Instrumentation, Tata McGraw Hill, 2nd Ed., 2003.*
3. *Raghbir Singh Khandpur (2014). Handbook of Biomedical Instrumentation (3rd ed.). Tata McGraw-Hill Education.*

MD-540: IoT and Machine learning in Medical Devices (2 Credits)

1. **Introduction to IoT**: Overview of IoT in Healthcare, Definitions and importance, Key components and architecture of IoT systems, Case studies of IoT in medical applications

2. **Introduction to Machine Learning:** Basics of machine learning, Types of machine learning (supervised, unsupervised, reinforcement learning), Applications of machine learning in healthcare, Ethical and Regulatory Considerations, Data privacy and security in healthcare, Ethical issues in AI and IoT in healthcare
3. **IoT Devices and Sensors in Medical Applications:** Types of IoT Devices, Wearable devices, Implantable devices, Remote monitoring devices, Sensors & Data Acquisition, Types of sensors (biometric, environmental), Data acquisition techniques, Challenges in sensor data collection, Communication Protocols & Standards, Wireless technologies (Bluetooth, Wi-Fi, Zigbee, etc.), IoT protocols (MQTT, CoAP, etc.), Interoperability and standards in medical IoT
4. **Machine Learning Techniques for Medical Data:** Data Preprocessing and Feature Engineering, Data cleaning and preprocessing, Feature selection and extraction, Handling missing data and imbalanced datasets, Supervised Learning Algorithms, Regression and classification techniques, Evaluation metrics (accuracy, precision, recall, etc.), Case studies of supervised learning in medical applications, Unsupervised Learning Algorithms, Clustering techniques (k-means, hierarchical clustering, etc.), Dimensionality reduction techniques (PCA, t-SNE, etc.), Case studies of unsupervised learning in medical applications
5. **Integration of IoT and Machine Learning:** Data Integration and Management, Data integration from multiple IoT devices, Real-time data processing and storage, Cloud and edge computing in medical IoT, Machine Learning Model Deployment, Model training and validation, Model deployment on IoT devices, Continuous monitoring and updating of models, IoT Platforms and Frameworks

Recommended Books

1. *Artificial Intelligence and Machine Learning for Healthcare. By Chee-Peng Lim, Ashlesha Vaidya, Yen-Wei Chen, Tejasvi Jain, Lakhmi C. Jain*
2. *Internet of Things for Healthcare Technologies. Springer Singapore by Chinmay Chakraborty, Bhaskar Krishnamachari, Raghvendra Kumar, and Pranab Shreewastava.*
3. *Moulick, S. R. (2020). Internet of Things in Biomedical Engineering. Academic Press.*
4. *Cook, D., & Das, S. K. (2020). Smart Environments: Technology, Protocols and Applications.*

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 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 Organization), WIPO (World Intellectual Property Organization) 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 Page 9 of 15 materials; Gene patenting; Biotechnology / 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 / nondisclosures, 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 / organizational 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; Trademarks 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 / commercialization 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 for research students, scientists and related personal; 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, POST WTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalization 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, and 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 environmental benefits of modern biotechnology; Voluntary adoption of pollution control strategies

Recommended Books

1. *Molecular Cell Biology by Harvey Lodish*
2. *Molecular Biology of the Cell by Bruce Alberts*
3. *Mount, D. W. (2004). Bioinformatics: Sequence and Genome Analysis. 2nd Edition. Cold Spring Harbor Laboratory Press.*
4. *Lesk, A. M. (2019). Introduction to Bioinformatics (5th ed.). Oxford University Press.*

GE-510 Biostatistics (2 Credits)

1. **Statistics**: Introduction, 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 models. Probit and logit transformations.
7. **Non-parametric tests:** Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal Wallis and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.
8. **Statistical techniques in pharmaceutics:** Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control

Recommended books:

1. *Fundamentals of Biostatistics by Bernard Rosner*
2. *Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon*
3. *Statistical Misconceptions by Huck*

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. Skills in oral presentation.

Each student has to present a seminar before end of the semester

LG-510 General Laboratory Experience-15 hours/week (3 Credits)

1. **Section A: Basic Biosciences & Biochemistry**

   Microscopy Techniques

   Buffer Preparation and pH Titration

   Protein Estimation using Bradford and Lowry Assay

Standard curve preparation and sample quantification

Hemoglobin, hematocrit, and glucose estimation

RBC/WBC counting using hemocytometer

2. **Hands-on training:** Key software tools such as MATLAB, COMSOL, SolidWorks, and LabVIEW, essential for design, simulation, and analysis in the field of medical devices.
3. **Section B: Basic Instrumentation & Sensors**

Spectrophotometer Calibration and Absorbance Analysis

pH and Conductivity Sensor Calibration

Use of glass pH electrodes and conductivity probes

Electrochemical Measurements

Signal Acquisition and Noise Filtering

Use of data acquisition systems (DAQ) and basic signal filtering

Visualization using MATLAB or Arduino/NI LabVIEW

Fabrication of a Simple Resistive Biosensor

4. **Section C: Materials & Fabrication**

Polymer Characterization by FTIR or UV-Vis

Functional group analysis of medical-grade polymers (e.g., PDMS, PLA)

Hydrogel Fabrication and Swelling Studies

Crosslinked PVA or gelatin-based hydrogels for controlled release

Surface hydrophilicity assessment of coated vs. uncoated surfaces

Mechanical Testing of Materials (Tensile or Compression)

Cleanroom Protocols and Sterility Testing

Basics of cleanroom entry, gowning procedures, and sterility indicators

-Semester II-

MD-610: Basics in Biosensors and Bioelectronics	**(2 Credits)**

1. **Introduction to Bioelectronics in Medical Devices:** Overview of bioelectronics and its role in healthcare, applications in diagnostic and therapeutic devices, introduction to system biology and synthetic biology principles relevant to biosensor design. Basics of electric circuits with biomedical relevance; review of Kirchoff's laws and circuit models used in biosensor interfacing.
2. **Sensors and Transducers in Medical Devices:** Fundamentals of sensors and actuators in biomedical applications; types of transducers (e.g., resistive, capacitive, piezoelectric, thermal);

applications in diagnostic devices such as glucometers, wearable pressure sensors, and implantable stimulators. Case studies from commercial medical devices.

3. **Bio-potential Electrodes and Signal Interfaces:** Electrode-electrolyte interface theory, types of electrodes: polarizable vs. nonpolarizable; signal distortion and filtering techniques; electrodes for ECG, EEG, EMG; microelectrode design in implantable and wearable biosensors; electrode configuration for medical imaging and monitoring devices.
4. **Bioelectric Amplifiers and Signal Conditioning Circuits:** Design and characteristics of bio-amplifiers: noise reduction, CMRR, isolation; analog front-end circuits for bio signal acquisition. Application of amplification systems in ECG, EMG, and EEG acquisition devices. Integration with ADCs and embedded systems.
5. **Biosensors for Diagnostics and Therapeutics:** Principles and classification of biosensors (enzyme-based, immunosensors, DNA sensors, cell-based sensors); transduction mechanisms: electrochemical, optical, mechanical, and thermal; design considerations for diagnostic accuracy, stability, and sensitivity in point-of-care and wearable devices.
6. **Advanced Biomedical Sensing Technologies:** Modern sensors for physical and chemical measurands: potentiometric and ion-selective electrodes, amperometric sensors, microcantilevers, piezoelectric biosensors, and nano-enabled biosensors. Immunoassay-based devices (e.g., ELISA chips), thermal flow and pressure sensors in IVD, infusion pumps, and ventilators.

Recommended Books

1. *Tran Minh Canh, Biosensors, Chapman and Hall, London 1993, [ISBN: 978-0-412-48190-1]*
2. *D. G. Buerk, Biosensors: theory and applications Lancaster: Technomic Publications, 1993, [ISBN: 9780877629757]*
3. *Albert Szent-Györgyi, Bioelectronics: A Study in Cellular Regulations, Defense, and Cancer, Academic Press, 2014 | ISBN-13: 978-1483247267*
4. *Vo-Dinh, T. (2008). Biomedical Photonics Handbook: Biosensors and Bioelectronics (Vol. II). CRC Press.*
5. *Grieshaber, D., MacKenzie, R., Vörös, J., & Reimhult, E. (2008).*
6. *Electrochemical Biosensors – Sensor Principles and Architectures. Sensors, 8(3), 1400–1458.*

MD-620: Materials in Biomedical Devices/Engineering (2 Credits)

1. **Introduction**: Cellular nanostructures, Multilayer Thin Film: Polyelectrolyte multilayers
2. **Colloidal nanostructures**: Characterization, Therapeutic and diagnostic nano-carriers like solid

lipid nanoparticles, biopolymeric nanoparticles, carbon nanotubes, polymeric nanofibers, quantum dots, magnetic nanoparticles and gold nanostructures

3. **Stimuli responsive materials**: in situ gels, nanocomposites, self-assembly to form coated colloids and smart capsules.
4. **Biomaterials classification**: Cell-Material Interactions, Protein Adsorption, Implant rejection, inflammation and foreign body response, Implant Infection
5. **Testing of biomaterials:** Biocompatibility, Biodegradation, Mechanical properties.
6. **Tissue engineering:** regenerative biomaterials, diagnostic and biomedical devices applications of biomaterials

Recommended Books

1. *Basu B, Katti D and Kumar A. Advanced Biomaterials: Fundamentals, Processing and Applications, Wiley, 2009, ISBN: 978-0470193402.*
2. *Gero Decher, Joseph B. Schlenoff, Multilayer Thin Films;Sequential Assembly of Nanocomposite Materials WileyVCH Verlag GmbH, 2012, [ISBN: 9783527316489]*
3. *Park, J. B., & Bronzino, J. D. (2003). Biomaterials: Principles and Applications (2nd ed.). CRC Press.*
4. *Lanza, R., Langer, R., & Vacanti, J. (2013). Principles of Tissue Engineering (4th ed.). Academic Press.*

BT-630 Immunology and Immunotechnology (2 Credits)

1. **Immunity:** Innate and adaptive, immune response memory, specificity and recognition of self and non-self, immunogenicity, antigenicity, physiology of immune response, epitope analysis, synthetic peptides and immune response, immunity to virus, bacteria, fungi, Cells and Organs of the immune system
2. **Humoral immunity:** Antigen-antibody interactions, affinity, avidity, immunoglobulins, molecular mechanism of generation of antibody diversity, molecular biology of IgG.
3. **Cell mediated immunity:** T cell subsets and surface markers, T cell-dependent and independent markers, structure and function of MHC, association of MHC with disease susceptibility, structure of T cell antigen receptor.
4. **Immune memory:** B-cell memory, significance, mutations and switches in memory cells, T-cell memory, lack of mutations and switches in T-cell memory, activation, super activation, loss of memory, Concept and types of vaccines.
5. **Immune tolerance:** B-cell tolerance, reversible and irreversible tolerance, antigen induced

tolerance, induction, T-cell tolerance, partial engagement of signal transducer, self-antigens, molecular consequence of tolerance.

6. **Disorders:** Hypersensitivity reaction, immunosuppression, autoimmune disorders, its molecular mechanism, immunodeficiency disorders (AIDS), tumor immunology.
7. **Principles, methods and applications of immuno-diagnostics:** Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous and heterogenous immunoassays, fluorescence, immunoblot, immunoaffinity, immunoprecipitation, biotinylation, immunosensors.

Recommended Books

1. *Cellular and Molecular Immunology by Abdul K. Abbas, Andrew H. Lichtman and Shiv Pillai*
2. *Kuby Immunology by Thomas J. Kindt, Barbara A. Osborne, and Richard A. Goldsby*
3. *Refer to relevant research and review articles.*

MD-630 In Vitro Diagnostics (2 Credits)

1. **Introduction to In Vitro Diagnostics:** Definition, importance, and scope of IVDs in healthcare; classification of IVD devices including laboratory tests and point-of-care (POC) systems; significance of IVDs in disease diagnosis, monitoring, and personalized medicine.
2. **Analytical and Molecular Techniques in IVD:** Overview of analytical techniques: spectrophotometry, HPLC, electrophoresis (gel and capillary), ELISA. Molecular diagnostic techniques: PCR, RT-PCR, and multiplex PCR. Applications in microbial detection, cancer diagnostics, and genetic testing.
3. **Microbial Testing and Automation:** Total Plate Count (TPC), bioburden testing, selective media and microscopy for pathogen detection. Automation in diagnostic labs, rapid diagnostic tools, standardization of antigens and antibodies.
4. **Case Studies in IVD Applications:** Case 1: COVID-19 diagnostics – RT-PCR vs antigen tests. Case 2: Multiplex PCR for respiratory pathogens. Case 3: POC tests for malaria – diagnostic accuracy and field challenges.
5. **Emerging Trends and Future Directions:** Advances in microfluidics, lab-on-a-chip systems, wearable diagnostics, and remote healthcare devices. Future of personalized and decentralized diagnostics.

Recommended Books

1. *Jennings, L. K., & Lippert, M. C. (2008). Laboratory Quality Management: A Guide for Healthcare Laboratories. ASCP Press.*

2. *1. Buckingham, L. (2017). Molecular Diagnostics: Fundamentals, Methods, and Clinical Applications. F.A. Davis Company.*
3. *2. McPherson, R. A., & Pincus, M. R. (2022). Henry's Clinical Diagnosis and Management by Laboratory Methods (24th ed.). Elsevier.*
4. *3. Ghosh, N., & Sinha, S. (2022). Principles and Practice of Analytical Techniques in In Vitro Diagnostics. Springer.*
5. *Primary research articles and reviews from journals like Clinical Chemistry, Journal of Clinical Microbiology, and Analytical Chemistry.*

MD-640: Regulatory Perspectives of Medical Devices (2 Credits)

1. **Introduction to Medical Device Regulations:** Classification of medical devices (Class I–III or A–D systems), Global overview of regulatory systems: US FDA, EU MDR, CDSCO (India), PMDA (Japan), Importance of regulatory science in medical device innovation, Definition and categorization of medical devices and IVDs,
2. **Indian Regulatory Framework for Medical Devices:** Role of CDSCO, ICMR, and BIS in device approval, Medical Device Rules, 2017 and amendments, Import/export licensing and product registration, Notified Bodies and clinical evaluation in Indian context.
3. **International Regulations and Harmonization:** US FDA regulatory process: 510(k), PMA, De Novo, EU MDR and CE marking, SO 13485 and ISO 14971: Quality Management and Risk Management, GHTF and IMDRF harmonization efforts.
4. **Clinical Evaluation, Quality Assurance, and Risk Management:** Design controls and Good Manufacturing Practices (GMP), Clinical trials and ethical approval processes, Risk classification and risk-benefit analysis, post-market surveillance, and adverse event reporting.
5. **Regulatory Strategies, Documentation, and Future Directions:** Technical file and regulatory submission dossier preparation, Regulatory strategy in start-ups and academic innovations, Digital health devices and emerging regulatory trends, AI-enabled and software-as-a-medical-device (SaMD) regulations

Recommended Books

1. *Roth, D. K. (2013). The Medical Device R&D Handbook (2nd ed.). CRC Press.*
2. *Sanghera, T., & Sullivan, R. (2020). Medical Device Regulatory Practices: An International Perspective. Elsevier.*
3. *Rajan, A. (2021). Medical Devices Law and Regulation in India. Universal Law Publishing.*

GE-611 Seminar	**(1 Credit)**
Students are required to submit written records and present details of the project to be pursued in semester-III and IV. This should include the purpose and basis of the project, stating aims, objectives and probable outcomes, being able to supplement these with necessary information, literature review towards it, and process for the project itself.	

LS-610 General Laboratory Experience-10 hours/week	**(2 Credits)**
1. Fabrication and Calibration of Colorimetric Glucose Sensors 2. Antigen-Antibody Based Detection (ELISA) 3. Electrochemical Detection of Biomarkers 4. Fabrication of simple electrochemical biosensor using screen-printed electrodes 5. Microfluidic Device Fabrication 6. Designing and printing of a basic Y-channel PDMS microfluidic chip 7. Fluid handling and mixing demonstration 8. Point-of-Care Diagnostic Simulation 9. RNA/DNA Extraction from Biological Samples 10. Surface Functionalization and Antibody Immobilization on Sensor Substrates 11. Quality Control and Validation of IVD Assays 12. Evaluation of accuracy, precision, specificity, and limit of detection (LoD) 13. Use of ROC curves and coefficient of variation (CV) analysis 14. Biosafety and Sample Handling 15. Proper disposal and contamination control techniques	

-Semester III-

TH598 Synopsis	**(5 Credits)**
• Involves submission of a project synopsis that captures the current status, methodology implemented, and preliminary results of the major or minor project initiated in the third semester. The project may be undertaken through: • Industrial training or internships at medical device companies or R&D organizations. • Clinical immersion programs in collaboration with healthcare institutions to address real-world medical challenges.	

- In-house research projects under NIPER faculty guidance focused on translational medical device development.
- The synopsis must reflect the technical progress made, challenges encountered, and refinement of project goals as the student prepares for continued work in Semester 4.
- Participate in industry-based training or internships at medical device companies, healthcare technology firms, or start-ups.

TH599 Presentation	**(3 Credits)**

- Students will deliver a mid-project oral presentation detailing the progress of their ongoing research or training activity.
- This includes outlining initial findings, techniques applied, learning outcomes from industry/clinical exposure, and modifications to the project timeline or objectives.
- The presentation will be evaluated by a Student Research Committee (SRC) and is intended to provide constructive feedback and ensure alignment with academic and industry standards.

-Semester IV-

TH698 Thesis	**(5 Credits)**

Students are expected to:

- Complete the execution of their research objectives.
- Analyze data, interpret results, and validate findings.
- Draw meaningful conclusions aligned with the problem statement.
- Prepare a detailed thesis document following institutional guidelines.

TH699 Defense of Thesis	**(3 Credits)**

This involves a formal oral defense of the thesis before an evaluation panel comprising internal and external examiners.

Students must:

- Present their research problems, methods, results, and implications.
- Reflect on the challenges encountered and how they were addressed.
- Highlight the translational relevance of their work in the context of medical device development.
- The defense serves as an evaluation of the student's research capabilities, communication skills, and contribution to the field.