MEDICAL DEVICES

M. S. (Pharm.)

Course no.	Course Name	Credits
Semester I		
CORE SUBJECTS (ALL COMPULSORY)		
MD-510	Medical Imaging and Instrumentation	2
MD-520	Advanced Biomaterials	3
MD-530	Regulatory Perspectives of Medical Devices	2
GE-510	Bio-statistics	2
LG-510	General Laboratory Experience	2.5
GE-511	Seminar	0.5
	Total	**12**
ELECTIVE SUBJECTS (4 CREDITS)		
EL-501	Biochemical Engineering Fundamentals	2
EL-502	Biotechnology in Pharmaceutical Sciences	1
EL-503	Microbiology	1
EL-504	Industrial safety and green chemistry	1
EL-505	Computer Application in Biomedical Engineering	1
EL-506	Biological System Analysis and Control	1
EL-507	Productivity in management and reengineering	1
EL-508	Biosynthesis of Natural Products	1
EL-509	Chemotherapy of Parasitic and Microbial Infections	1
	Choose any core courses of other department (BT/MC/NP/PA/PC/PE)	
	Total	**16**
Semester II		
CORE SUBJECTS (ALL COMPULSORY)		
MD-610	Bioelectricity and Instrumentation	3
MD-620	Tissue Engineering and Regenerative Medicine: Basics and Applications	2
MD-630	Nanomaterials and Bionanotechnology	2
MD-640	Medical Devices: Production innovation & development	1
PA-650	Testing and Analysis of Medical Devices	1
LS-610	General laboratory experience	2.5
GE-611	Seminar	0.5
	Total	**12**
ELECTIVE SUBJECTS (4 CREDITS)		
EL-601	Biomechanics	2
EL-602	Mathematical Methods in Biomedical Engineering	1
EL-603	Logistics & distribution	1
EL-604	Total quality control	1
EL-605	Lean system, Six sigma	1

EL-606	Introduction to Ayurveda and Polyherbal Formulations	1
EL-607	Chemotherapy and Immunopharmacology	2
EL-608	Pharmacovigilance and Medical Writing	2
	Choose any core courses of other department (BT/MC/MD/NP/PA/PC/PE)	
	Total	**16**
Semester III Project (22 weeks)		
TH- 598	Synopsis	
TH- 599	Presentation	
	Total Credits	**9**
Semester IV		
TH-698	Thesis	
TH-699	Thesis Defense	
	Total Credits	**9**
	TOTAL CREDITS (I TO IV SEMESTERS)	**50**

TABLE OF CONTENTS

MEDICAL DEVICES
M.S. (Pharm.)

SEMESTER I

Core Subjects

MD-510 (2 Credits)

Medical Imaging and Instrumentation	hrs
Physical Principles of Imaging: Fundamentals of Physics and Radiation; Concepts of Radiation science; Electromagnetic Radiation: Photons, Electromagnetic Spectrum, Wave Particle Duality; Fundamentals of acoustic propagation; Interaction between sonic beams and matter; concepts of ultrasonic diagnostics. Antigen-Antibody based Imaging.	4
Imaging with X-Rays: X-ray tube: The generation: Electron-Target Interactions, X-ray emission spectrum: Characteristic x-ray spectrum, Bremsstrahlung spectrum, Factors affecting X-ray Emission Spectrum: Effect of mA, kVp, added filtration; X-ray unit: generators, filters and grids; Image intensifiers; X-ray detectors: Screen film detector, Image Intensifier; quality and exposure.	4
X-ray Diagnostic Methods: Fluoroscopy: Fluoroscopy and Visual Physiology, Image intensifier tube and Multifield intensification; Angiography: Arterial access, Catheters, Contrast media; Mammography: Soft tissue radiography, Equipments: Target composition, Filtration grids, Photo timers, Image receptors; Xeroradiography; Digital radiography; 3-D construction of images.	5
Computed Tomography: System components: Gantry, Collimation; High Voltage generators; Operational modes: First generation scanners, Second, Third, Fourth, Fifth generation scanners; Image characteristics: Image matrix, CT numbers; Image reconstruction; Image Quality: Spatial resolution, Contrast resolution, System noise, Linearity, Spatial Uniformity.	5
Imaging with Ultrasonography: Piezoelectric effect; Ultrasonic transducers: Mechanical and Electrical matching, the characteristics of transducer beam: Huygens principle, Beam profiles, Pulsed ultrasonic filed, Visualization and mapping of the Ultrasonic field; Doppler effect-Doppler methods; Pulse echo systems [Amplitude mode, Brightness mode, Motion mode & Constant depth mode]; Tissue characterization: velocity, Attenuation or absorption, Scattering.	5
Developments in Ultrasound technique: Clinical applications; Intracavity imaging: Design of the Phased array probe, Trans oesophageal, Tannsvaginal or Transrectal scanning; Ultrasound contrast media: Utilization of micro air bubbles, galactose microparticles and albumin encapsulated microairbubbles; 3-D image reconstruction; 2-D echo cardiography.	6
Biological effects of Radiation and Ultrasound and its protection: Modes of Biological effects: Composition of the body and Human response to Ionizing radiation; Physical and Biological factors affecting Radiosensitivity, Radiation Dose-response relationships; Time variance of radiation exposure; Thermal / Nonthermal effects due to cavitation in ultrasound fields; Designing of	6

radiation protections and its procedures.	
Advances in Imaging: Introduction to Magnetic Resonance Imaging, Radionuclide Imaging, and Longitudinal section Tomography, Single Photon Emission Computed Tomography, Positron Emission Tomography.	5

READING MATERIAL

1. Principles of Medical Imaging, K. Kirk Shung, Michael B. Smith, Benjamin Tsui Academic Press
2. Radiologic Science for Technologists, Stewart C. Bushong Mosby: A Harcourt Health Sciences Company
3. Quality Management: In the Imaging Sciences, Jeffery Papp Mosby: A Harcourt Health Sciences Company

Outcomes:

On completion of the course, the student should be able to:

- Analyze fundamental concepts of electromagnetic radiation and acoustic waves for medical imaging.
- Determine the critical parameters of electromagnetic radiation and acoustic waves for safe practice for diagnostic imaging.
- Identify the principle factors to modulate the generation of X-rays and design parameters of X-ray systems for different clinical applications.
- Analyze the advanced X-ray modalities for imaging of static and dynamic anatomical structures of human.
- Determine the materials and design parameters for the production of Ultrasound waves for clinical applications.
- Analyze the key interventions of Ultrasonography with advanced tools for clinical diagnosis.
- Identify the major limitations of various X-ray and Ultrasound based tools to develop systems for better clinical information.

MD-520 (3 Credits)

Advanced Biomaterials	hrs
Material classes: Metal, ceramics, polymers and composites, Material design, fabrication and synthesis (Electrospinning, 3D printing, hydrogelation/gelation, lithography etc. Microstructures and Properties of materials: Bulk and surface properties of materials, Influence of microstructure and environment on fatigue and fracture of materials. Biomaterials for tissue engineering and drug delivery.	8
Physical and chemical characterization techniques: Thermal, spectroscopic, microscopic and laser-based techniques.	6
Degradation of biomaterials in biological environment: Chemical and biochemical degradation of polymers; Degradative effects of biological environment.	6
Implementation problems- inflammation, rejection, corrosion, structural failure. Surface characterization of biomaterials, biomaterial-blood (bio-fluid) interface, Surface modifications for improved compatibility; conducting polymers; Collagen, hyaluronic acid and other biopolymers; biodegradable block copolymers & their application.	9
Biomaterials in cardiovascular system: Anatomy and physiology of cardiovascular system, Cardiovascular implant biomaterials: artificial heart valves, Mechanical and bio-prosthetic valves, materials used, criteria required for fulfillment of physiological functions, Vessel grafts, Endothelial cell seeding as a surface modification of biomaterials.	8
Orthopaedic implant materials: Anatomy and physiology of bone and cartilage; temporary External fixators, Materials for reconstruction of cartilage. Ligaments and tendons, Bone replacement and bone cement, Artificial joint replacement; Orthosis and Prosthetics Devices.	7
Ophthalmology: Anatomy and physiology of eye; Artificial cornea, contact lenses, intra-ocular, lenses, artificial aqueous and artificial vitreous humour, artificial tears, artificial tympanic membrane.	5
Anatomy and physiology of other organs and development of artificial organs: Properties of skin, Wound dressings, artificial skin, facial implants, dental restorative materials, implanted dental interfaces, denture resins and cements, artificial red blood cells, artificial lung surfactants, artificial 3saliva, artificial synovial fluid, dialysis membranes, artificial liver, artificial pancreas, materials used for neuronal reconstruction and regeneration; Diagnostic kits, infusion pumps, syringes, needles, etc.	8
Materials for surgical tools.	3

READING MATERIAL

1. Joon B. Park & Roderic S. Lakes, Biomaterials: An Introduction, Plenum Press, New York, 2007.
2. Donald L. Wise et al. Encyclopedic Handbook of Biomaterials and Bioengineering (4 vols.), 1995, Marcel Dekker, New York.
3. Fredrick H. Silver, Biomaterials, Medical Devices & Tissue Engineering: An Integrated Approach, Chapman & Hall, 1994
4. L.L. Hench, E. C. Ethridge, Biomaterials: An Interfacial Approach, Academic Press, New York, 1982.
5. S. Frederick, H. Chrstiansen, L. David, Biomaterial Science and Biocompatibility, Springer-

Verlag , New York, 1999.
6. Buddy Ratner, Allan Hoffman Frederick Schoen, Jack Lemons, Biomaterials Science: An Introduction to Materials in Medicine, Academic Press, 2004.

Outcomes:

On completion of the course, the student should be able to:

- Describe basic concepts in biomaterials science and categorization of biomaterials (metals, ceramics and polymers-natural and synthetic) and their properties.
- Explain methods to modify and characterize biomaterial surfaces and choose material for desired biological response.
- Design experiments for synthesis and fabrication of scaffolds for specific biomedical application
- Describe interactions between biomaterials, proteins and cells.
- Evaluate host-biomaterial interaction for short-term and long-term implantations; distinguish between reactions in blood and in tissue.
- Correlate biomaterial properties with pre-clinical and clinical applications in tissue repair and regeneration.

MD-530 (2 Credits)

Regulatory Perspectives of Medical Devices	hrs
Definition of Medical Devices; Differences between Medical Device and Drug development, Classification of medical devices, The role of each participant/stakeholder, Shared responsibility for medical device safety and performance.	4
Documentation Management, Good Documentation Practice (GDP), purpose of documentation, The types of cGMP documents, Document and record retention	3
Basics of the different systems for the Medical Device regulations - US FDA, European regulations and other countries, IMDRF.	5
Basics of Drugs and Cosmetics Act (D&C), CDSCO, Existing regulation in India for medical devices.	5
Basics of the Quality Management System for medical devices (ISO 13485, FDA requirements), Quality Systems Regulation.	3
Medical device safety: Medical device safety and risk management, Effectiveness/performance of medical devices, Phases in the life span of a medical device.	3
Standards: need for standards, voluntary and mandatory standards, Standards development process, National and international standard system for medical devices, scenario in India.	5
Material selection and properties: Mechanical strength testing, performance testing of medical devices, Storage considerations for medical devices; implications on material content.	3
Package development: Packaging materials, design, Testing of packages and labeling; scope of improvisation of the packaging materials.	3
Sterilization Procedures: Technology, Equipment and Validation.	2
Preclinical and Clinical Trial Design for Medical Devices; FDA approved devices, Post-market surveillance/vigilance.	4

READING MATERIAL

1. FOOD AND DRUG ADMINISTRATION USA, http://www.fda.gov/medicaldevices/deviceregulationandguidance/default.htm
2. Medical Device Regulations: Global overview and guiding principles, World Health Organisation.

Outcomes:

On completion of the course, the student should be able to:

- Determine regulatory classification of medical devices.
- Explain US-FDA, IMDR and European regulations.
- Decipher the meaning of standard in regulatory perspective.
- Define various testing requirement in a regulatory process.

MEDICAL DEVICES
M.S. (Pharm.)

SEMESTER I

Elective Subjects

EL-505 (1 Credit)

Computer Application in Biomedical Engineering	hrs
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.	3
Digital filters; FIR and IR type and their application to biomedical signal filtering.	3
Data reduction techniques. Spectrum analysis.	2
Intelligent computing systems in medicine; Introduction to Intelligence and Artificial Intelligence. Heuristic search method, knowledge Based system, ANN architecture and learning algorithms.	4
Evolutionary computing and Genetic Algorithm (EC-GA)	2
Fuzzy Logic and its application in decision making.	3
Application of ANN, EC, GA, FL in Medical data analysis and diagnosis.	3

READING MATERIAL

1. Biomedical Informatics: Computer Applications in Health Care and Biomedicine, Editors: Shortliffe, Edward H., Cimino, James J. (Eds.), 2014.

Outcomes:

On completion of the course, the student should be able to:

- Determine the importance of computers intervention for better clinical practice.
- Identify the potential areas for computer engineering mediation for better in healthcare services.
- Identify the various hardware and software modules for healthcare applications.
- Demonstrate different computer programs for clinical data management.
- Demonstrate the advanced tools like AI, ANN and Genetic Algorithms, etc. for future challenges.
- Analyze various computer tools for medical data analysis.

EL-506 (1 Credit)

Biological System Analysis and Control	hrs
Control system: Introduction to linear control system, Mathematical Modeling, Transfer function, signal flow graph, feedback control its characteristics, advantages and state-space models. Time- domain and frequency domain analysis. Stability analysis; Routh Hurwitz criteria, Root locus plots, Bode plots, Nyquist plots and Nichols plots. Introduction to Digital control, Optimal, Adaptive and Non-linear control systems.	7
Physiological control systems: Introduction, mathematical modeling & control. Biological receptors, thermoregulatory system, human limb, semicircular canal, skeletal-muscle, respiratory system, pupil-control systems, neuromuscular reflex motion.	5
Applications of Control theory to physiological systems. Time-domain, frequency domain, stability analysis. Biological performance criteria and adaptive control systems.	4
Simulation implementation.	4

READING MATERIAL

1. Arthur T. Johnson, Biology for Engineers, CRC Press, 2010.
2. John H. Milsum, Biological control systems analysis, McGraw-Hill, 1966.

Outcomes:

On completion of the course, the student should be able to:

- Analyze the relevance of various preceded mathematical models for biological applications.
- Demonstrate the importance control system models to control the artificial systems in clinical applications.
- Analyze the control system performance with different clinical models.
- Derive the control system models by utilizing various domains for better control.
- Develop some simulation modules to analyze certain basic biological models.

EL-507 (1 Credit)

Productivity in Management and Re-Engineering	hrs
Productivity: Productivity Concepts – Macro and Micro factors of productivity – Dynamics of Productivity - Productivity Cycle Productivity Measurement at International, National and Organization level - Productivity measurement models.	4
Systems approach to productivity measurement: Conceptual frame work, Management by Objectives (MBO), Performance Objectivated Productivity (POP) – Methodology and application to manufacturing and service sector.	4
Organizational transformation: Elements of Organizational Transformation and Reengineering- Principles of organizational transformation and re-engineering, fundamentals of process reengineering, preparing the workforce for transformation and re-engineering, methodology, guidelines, LMI CIP Model – DSMC Q & PMP model.	5
Re-engineering process improvement models: PMI models, PASIM Model, Moen and Nolan Strategy for process improvement, LMICIP Model, NPRDC Model.	3
Re-engineering tools and implementation: Analytical and process tools and techniques – Information and Communication Technology – Implementation of Reengineering Projects – Success Factors and common implementation Problem – Cases.	4

READING MATERIAL

1. Sumanth, D.J., Productivity Engineering and Management, TMH, New Delhi, 1990.
2. Edosomwan, J.A., Organisational Transformation and Process Re-engineering, Library Cataloging in Pub. Data, 1996.
3. Rastogi, P.N., Re-engineering and Re-inventing the Enterprise, Wheeler Pub. New Delhi, 1995.
4. Premvrat, Sardana, G.D. and Sahay, B.S., Productivity Management – A, Systems Approach, Narosa Publishing House. New Delhi, 1998.

Outcomes:

On completion of the course, the student should be able to:

- Explain basic concepts in productivity measurement and evaluation.
- Define different productivity measurement models and their implementation.
- Determine basics of process re-engineering and re-engineering models for process improvement.
- Implement the re-engineering tools for improving productivity.

MEDICAL DEVICES
M.S. (Pharm.)

SEMESTER II

Core Subjects

MD-610 (3 Credits)

Bioelectricity and Instrumentation	hrs
Action potential of excitable cells: Quantitative description, Hodgkin-Huxley model, significance of parameters in Hodgkin-Huxley equations; Voltage-clamp experiments: design, and analysis of results; Factors determining the initiation, amplitudes, and kinetic properties of action potentials.	5
Passive membrane electrical properties: Cellular resistance, capacitance, time constant and space constant, methods of measurement; Importance in cellular excitation and signaling: Impulse propagation.	4
Electrophysiology of synaptic transmission: Prejunctional and postjunctional electrical events; time courses of transmitter-activated membrane currents and potentials in skeletal and smooth muscle; Electrical models of the skeletal and smooth muscle membranes.	6
Review of biopotentials, Electrodes as bioelectric transducers: The electrode-electrolyte interface; Specification and selection criteria for electrodes; Surface, needle, implanted electrodes; Polarizable and non-polarizable electrodes; Practical considerations.	6
Sensor architecture and Classification; Medically significant measurands, sensing methods for biological signals; Sensor characteristics: linearity, repeatability, hysteresis, drift; Sensor models in the time & frequency domains.	4
Sensors for physical measurands: strain, force, pressure, acceleration, flow, volume, temperature and biopotentials.	3
Sensors for measurement of chemicals: potentiometric sensors, ion selective electrodes, ISFETS; Amperometric sensors, Clark Electrode; Catalytic biosensors, immunosensors; concept of theranostics.	4
Instrumentation for biopotential recording: Practical considerations for optimum performance; Reduction of interference, grounding, safety; Commonly measured biopotentials and their clinical interpretation ENG, ECG, EMG, etc.; Sensory evoked potentials (visual, auditory, somatosensory).	5
Electrical Stimulation: Use in generating evoked potentials, and for therapeutic correction (ECT, pacemakers, defibrillation); Stimulation parameters; Safety limits and precautions.	4
Electromagnetic Blood flow meters; Ultrasonic Blood Flow meters; NMR Blood Flow meters; Laser Doppler Blood Flow Meters.	5
Robotic equipments, procedures and remote sensing devices.	2
Kidney Instrumentation: Kidney Structure, Regulation of Water and Electrolyte Balance, Artificial Kidney, Dialysis System, Lithotripsy Sensory Instrumentation	3

Mechanism of Hearing, Sound Conduction System, Basic Audiometer; Pure tone audiometer; Audiometer system Bekesy; Evoked response Audiometer system, Hearing Aids.	2
Anatomy of Eye, Errors in Vision, ophthalmoscope, Tonometer, Perimeter,	2
Electrical safety, Significance of Electrical Danger, Physiological Effect of Current, Ground Shock Hazards, Methods of Accident Prevention.	3
Diagnostic strips.	2

READING MATERIAL

1. B. Katz: Nerve, Muscle, and Synapse, Mc-Graw Hill, New York, 1966.
2. J.G. Nicholls, A.R. Martin & B. Wallace: From Neuron to Brain, 3rd ed., Sinauer, Sunderland, 1992.
3. J.J.B. Jack, D. Noble & R.W. Tsien: Electric Current Flow in Excitable Cells, Oxford University Press, 1983.
4. R.D. Barr & R.L. Plonsey: Bioelectricity: A Quantitative Approach, Academic Press, N.Y., 1988.
5. E.R. Kandel& J. Shwartz (ed.): Principles of Neural Science, 3rd ed., 1991.
6. M.J. Aminoff: Electrodiagnosis in Clinical Neurology, 3rd edition, Churchill Livingstone, USA, 1992.
7. J.A. Delisa, H.J. Lee, E.M. Baran, K.S. Lai & N. Spielholz : Manual of Nerve Conduction and Clinical Electrophysiology, 3rd Edition, Academic Press, New York, 1993.
8. J. Kimura (Ed.): Peripheral Neuropathy vol. 1, W.B. Saunders & Co., Philadelphia, 1984.
9. John G. Webster (ed.): Medical Instrumentation - Application and Design; Houghton Mifflin Co., Boston, 1992.
10. Richard Aston: Principles of Biomedical Instrumentation and Measurement, Merril Publishing Co., Columbus, 1990.
11. Richard S.C. Cobbold: Transducers for Biomedical Measurements: Principles and Applications, John Wiley & Sons, 1974
12. Ernest O. Doeblin: Measurement Systems, Application and Design, McGraw-Hill, 1985
13. A.P.F. Turner, I. Karube & G.S. Wilson : Biosensors : Fundamentals & Applications, Oxford University Press, Oxford, 1987

Outcomes:

On completion of the course, the student should be able to:

- Analyze different principle equations and models in relevance with action potentials.
- Compile in detail about Passive membrane electrical properties for Impulse propagation.
- Analyze electrophysiology importance in different biological models.
- Determine the biosensor intervention in healthcare and its design parameters.
- Identify the various transduction technologies for biosensors.
- Identify the physiologically significant biopotentials and their recording strategies.
- Analyze biopotentials in relevance with health condition.
- Analyze advanced Electrical Stimulation and Blood flow systems.
- Compile latest technologies for kidney, ear and eye related medical devices.

MD- 620 (2 Credits)

Tissue Engineering and Regenerative medicine: Basics and Applications	hrs
Introduction to tissue engineering and regenerative medicine	1
Tissue organization, dynamics and morphogenesis with a focus on tissue mechanics and mechanobiology	5
Cell Biomaterial interaction: Cell adhesion, migration, differentiation, immune response	6
Role of Stem cells and Stem cell niches for tissue regeneration, legal and ethical issues associated with use of stem cells	5
Engineering Methods and Designing biomaterials (de-cellularized, synthetic and natural scaffolds) for Musculoskeletal, cardiovascular, ocular, neurological, skin and other soft tissues. Tissue fabrication and organ regeneration techniques.	8
Bioreactors in tissue engineering: Types and applications	3
Immunotherapy in tissue engineering: altered immune reactions, cancer, tissue inflammation etc.	4
In vitro models for drug screening and understanding disease pathophysiology using biomaterial and tissue engineering approaches, Lab-on-chip, tissue organoids etc.	4
Clinical Implementation of Tissue engineering and regenerative medicine approaches and applications (including gene therapy) in various tissues: Brain, bone and joint, eye, gut, heart, kidney, lung, liver, muscle, pancreas, skin, tendon	4

READING MATERIAL

1. Robert Lanza, Robert Langer, Joseph P. Vacanti. Principles of Tissue Engineering. Academic press, 2013.
2. Bernhard O. Palsson and Sangeeta N Bhatia. Tissue Engineering, Pearson Prentice Hall, 2004.
3. Fredrick H. Silver, Biomaterials, Medical Devices & Tissue Engineering: An Integrated Approach, Chapman & Hall, 1994.
4. Joseph P. Vacanti. Tissue Engineering and Regenerative Medicine. A Cold Spring Harbor Perspectives in Medicine Collection, 2017.
5. Selected articles from the current literature

Outcomes:

On completion of the course, the student should be able to:

- Explain the basic concepts, current status and future potential of tissue engineering.
- Describe the complex interaction between biomaterials, cells and signalling pathways involved in various cell fate processes.
- Determine the sources, selection and regulations associated with the use of stem cells with relevance to current literature.
- Select biomaterials/scaffold fabrication process based on the type of tissue repair and regeneration.

- Evaluate the need for bioreactors in tissue engineering.
- Choose the appropriate pre-clinical models in drug testing or understanding disease pathophysiology.
- Explain the challenges (such as scale-up, ethical and regulatory issues) and trajectory associated with clinical implementation of tissue-engineered products.

MD-630 (2 Credits)

Nanomaterials and Bionanotechnology	hrs
Introduction to nano materials and Bio-Nanotechnology, Cellular nanostructures, Forces acting, self-assembly of colloidal nanostructures of biological relevance, Layer by Layer self-assembly, Applications of bio nanotechnology.	10
Bioactive nanoparticles: respiratory surfactants, magnetic nanoparticles, Nanoparticles as antioxidants, metal nanoparticles and quantum dots.	6
Nanoparticles for drug delivery: solid lipid nanoparticles, synthetic and biopolymeric nanoparticles, Nano-emulsions, carbon nanotubes, fullerenes, graphene, polymeric nanofibers, Implications in tissue engineering and diagnosis.	10
Multilayer Thin Film: Polyelectrolyte multilayers, coated colloids, smart capsules.	4
Nanoengineered biosensors, Fiber Optic Nano-sensors in medical care.	4
Environmental and safety aspects of bio-nanotechnology.	4
Peptides and Biosimilar	2

READING MATERIAL

1. Gero Decher, Joseph B. Schlenoff. Multilayer Thin Films, Wiley-VCH Verlag GmbH & Co. KGaA, 2003
2. David S. Goodsell, Bionanotechnology: Lessons from Nature, Wiley-Liss, 2004
3. Kenneth J. Klabunde. Nanoscale Materials in Chemistry, John Wiley & Sons, Inc, 2001.
4. Michael Giersig, Gennady B Khomutov. Nanomaterials for Application in Medicine and Biology, Springer, 2008.
5. Polina Prokopovich, Biological and Pharmaceutical Applications of Nanomaterials CRC Press, 2015.
6. Dong Kee Yi, Georgia C. Papaefthymiou, Nanobiomaterials: Development and Applications, CRC Press, 2013.
7. Gerrard Eddy Jai Poinerm, A laboratory Course in Nanoscience and Nanotechnology, CRC Press, 2014.

Outcomes:

On completion of the course, the student should be able to:

- Identify the importance of nanotechnology for biomedical applications.
- Analyze the key properties of nanomaterial in contrast biological relevance.
- Identify the key fabrication/synthesis techniques to develop different nanostructured materials for medical applications.
- Analyze various nanostructured materials for bioactive device/implant development.
- Determine the potential advantages of nanostructure materials as drug carriers.
- Identify the key features of nanomaterials for sensors for medical care.
- Analyze the safety and environmental aspects related nanomaterials.

MD-640 (1 Credit)

Medical Devices: Production Innovation & Development	hrs
Clinical immersion, problem definition and refinement, role of different stakeholders, ideation through various methods of creative thinking, prototyping, testing and validation tools and methods, business plan development and IP management.	4
Process management: Operations strategy, types of processes, outsourcing, make buy decision, process re-engineering	3
Forecasting: Purpose and application of forecasts, types of forecasts, Delphi & Market surveys, Moving average and exponential smoothing methods, Linear Regression, monitoring of forecasts.	3
Production planning: Aggregate planning problem, costs, strategies, graphical and tabular methods, transportation and linear programming methods, MRP, MRPII, CRP, ERP.	4
Production control: Capacity planning and control, production activity control, JIT, flow shop & Job shop scheduling basic models.	3
Inventory management: Inventory classification and analysis, Basic inventory systems, deterministic and probability models.	3

READING MATERIAL

1. Karal .T. Ulrich, Steven D.Eppinger, Product Design and Development, McGRAW-HILL International Editions, 2003.
2. S.Rosenthal, Effective product design and development, Irwin 1992.
3. Charles Gevirtz, Developing New products with TQM, McGraw – Hill, International editions, 1994.

Outcomes:

On completion of the course, the student should be able to:

- Define problems and ideation to product development.
- Determine operation strategies of process management and various forecasting methods.
- Analyze the functioning of production planning basic and its implementation through software modules.
- Classify inventories.

PA-650 (1 credit)

Testing and Analysis of Medical Device (1 credit)	hrs
Brief Introduction to Medical Devices and types of medical devices (Include Hybrid drug-device combinations)	1
Regulatory Requirement: Premarket Approval; Investigational Device Exemption.	1
GLP requirement with respect to Analytical facility in medical device: Equipment installation: DQ, IQ, OQ and PQ; SOP/IOP preparation; Site Master file and QMS	2
Physical and Mechanical Testing of medical device: The regulatory perspectives of physical and mechanical properties of medical devices and implant materials. Physical properties: testing parameters; porosity & surface area (ISO 9277:2010), zeta potential & size (ISO/TR 19997:2018 & ISO 22412:2017); morphology & particle size by image analysis methods (ISO 13322-1:2014); Method for contact angle and surface tension (ISO15989:2004). Mechanical properties: tensile, compressive, shear, wear and fatigue testing of implants (cardiovascular, orthopedic and dental) and different implant materials (ISO 19213:2017, ISO 12106:2017, ISO 5840-1: 2015 and ISO 14801, etc.)	6
Performance Indicators and CQAs: Setting specifications; Example with two medical devices	2
Quality Guidelines: ISO 13485 Quality Management System for Medical Devices	2
Chemical Testing of Medical Device materials: Identification of Extractable and Leachable chemicals; Forced Degradation Studies and Degradation Product Characterization for identification and quantification of potential degradation products from medical devices; Determination of Active Pharmaceutical Ingredient (API) Drug Release Characteristics; Stability studies including Accelerated and Stressed studies; Imaging of the phase distribution of Drug Components	2
Biological Testing of Medical Devices: Introduction to Biological testing, International Standard ISO 10993 and principles for biological evaluation of medical devices, Biological evaluation process (general biocompatibility testing considerations and test-specific considerations), Endpoints of biocompatibility testing (ISO 10993-1: 2018) as per the category of medical device (nature of body contact as well as the time period of contact)	4

READING MATERIAL

1. Indian Regulation: G.S.R. 102(E)_dated 11.02.2020_ Registration of certain medical devices
2. Indian Regulation: S.O. 648(E) dated 11.02.2020_ Medical Device Definition
3. Indian Regulation: 2019.10.18_G.S.R. 797(E)_Registration of Certain Medical Devices_chapter-IIIA
4. WHO regulation: Amendment in Environmental requirements for mfg. of Medical Devices Annexure- A of the Fifth Schedule of MDR, 2017 [https://www.who.int/medical_devices/publications/en/MD_Regulations.pdf]
5. Quality System Information-Guidance document From USFDA

[https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices]
6. 21 CFR 820: [https://www.ecfr.gov/cgi-bin/text-idx?SID=332944a20dfb1ca8fb05033d20caf52e&mc=true&tpl=/ecfrbrowse/Title21/21CIsubchapH.tpl
7. FDA Perspective on Leachable Impurities [https://www.fda.gov/media/84017/download]
8. Book: Leachables and Extractables Handbook: Safety Evaluation, Qualification, and Best Practices Applied to Inhalation Drug Products, Douglas J. Ball, Daniel L. Norwood, Cheryl L. M. Stults and Lee M. Nagao,
9. *International Medical Devices Regulators Forum http://www.imdrf.org/documents/documents.asp*
10. WHO perspective: https://www.who.int/medical_devices
11. Book: Medical Device 1st edition, Seeram Ramakrishna Lingling Tian Charlene Wang Susan Liao Wee Eong Teo, Woodhead Publishing, Hardcover ISBN: 9780081002896
12. eBook ISBN: 9780081002919
13. Book: Biomaterials, Medical Devices and Combination Products: Biocompatibility Testing and Safety Assessment, Shayne Cox Gad, Samanta Gad-McDonald, CRC Press

Outcomes:

On completion of the course, the student should be able to:

- Evaluate the need for medical devices to undergo physical, chemical or biological testing.
- Perform physical, chemical or biological evaluation of a medical device based on the ISO guidelines.

MEDICAL DEVICES
M.S. (Pharm.)

SEMESTER II

Elective Subjects

EL-601 (2 Credits)

Biomechanics	hrs
Scalar and vector quantities. Different operations on vector. Forces and moments, system of forces, resultant of system of forces in 3D and 2D. Equilibrium equations. Applications with example on human body.	4
Work-energy. Equations: Applications to Biomedical System. Stress-strain diagram, Stress concentration	4
Mechanical properties of human bone: cortical bone, cancellous bone. viscoelasticity, elastic model of bone. Mechanical testing of soft tissues.	7
Wolf's law and introduction to orthopedic biomechanics. Human body dynamics and locomotion analysis. Pressure sore biomechanics. Interaction between tissues and support surface. Mechanics of spinal distraction rods.	6
Principle of continuum mechanics. Tensor treatment to explain elastic, viscoelasticity, electric and electromechanical properties of bones, teeth and connective tissues. Wave propagation in extended and partly bound media and its application in analyzing the structural micro textural symmetry in calcified tissues.	10
Biomechanics of human motion and control interfaces with application to limb orthotics and prosthetics. Design of hip prosthesis. Automated driver's training programme, Sports biomechanics.	6
Dental forces, implant-tissue biomechanics, Crack propagation in bones, dynamic models.	3

READING MATERIAL

1. Yuan-cheng Fung, Biomechanics: Circulation, Springer Science & Business Media, 1997.
2. Duane Knudson, Fundamentals of Biomechanics, Springer Science & Business Media, 2013.

Outcomes:

On completion of the course, the student should be able to:

- Demonstrate the mechanical components and properties of bone.
- Analyze body dynamics.
- Define the role of biomechanics in designing implants.
- Evaluate the mechanics of skeletal system.

EL-602 (1 Credit)

Mathematical Methods in Biomedical Engineering	hrs
Mathematical modeling and solution of biomedical problems namely respiratory rate, blood flow, cardiac output and impedance diffusion, ultra filtration etc.	8
Operational research applied to the description of physiological systems and signals processing by interfacing instrumentation, biomedical variability and probabilistic solution to medical decision making, population dynamics perturbation technique in dealing with the problems of thermodynamics. Stochastic process . Finite- Difference method.	12

READING MATERIAL

1. Urszula Ledzewicz, Heinz Schättler, Avner Friedman, Eugene Kashdan, Mathematical Methods and Models in Biomedicine, Springer Science & Business Media, 2012.
2. Stanley Dunn, Alkis Constantinides, Prabhas V. Moghe, Numerical Methods in Biomedical Engineering, Academic Press, 2006.

Outcomes:

On completion of the course, the student should be able to:

- Analyze the mathematical models in different biological systems.
- Determine the abnormality/performance of different organs by mathematical models.
- Compile the data of mathematical models with clinical models for application relevance.
- Development of different mathematical or simulated models for biological systems.
- Analyze the different mathematical models for clinical decision-making.
- Compiling different modeling methods for decision-making.

EL-603 (1 Credit)

Logistics & Distribution	hrs
Introduction to logistics management: Logistics Management: Definition of logistics and the concepts of logistics. Logistics Activities: Functions of the logistics system – transportation, warehousing, order processing, information handling and procurement	3
Distribution management: Distribution Management, Outbound logistics, Facility location, Classical location problems, Strategic planning models for location analysis, location models, multi objective analysis of location models.	3
Transportation management: Transportation alternatives and technologies; transportation performance analysis; total transportation cost analysis; fleet development and management; fleet performance indicators; routing and scheduling; shipment planning; vehicle loading; transportation management and information systems requirements.	5
Logistics modelling: Logistics Customer Service, Modeling logistics systems, Simulation of logistic systems, cost effective distribution strategies, Value of information in logistics, E-logistics, risk pooling effect, International and global issues in logistics, Integrated functional activities in logistics, Role of government in international logistics and Principal characteristics of logistics in various countries and regions	5
Logistics in different industries: Logistics in different industries: Third party, and fourth party logistics, Reverse logistics, Airline Schedule Planning, Railway Networks, Postal services, the maritime industries, health care industry and other service industries	4

READING MATERIAL

1. David Bloomberg, Stephen LeMay, Joe Hanna: Logistics, Prentice Hall, 2002
2. Thomas Teufel, Jurgen Rohricht, Peter Willems: SAP Processes: Logistics, Addison-Wesley, 2002.
3. Julien Bramel, David Simchi-Levi. “The logic of logistics: theory, algorithms, and applications for logistics management", Springer,2006
4. Murphy, G.J. "Transport and Distribution", 2nd Edition, Business Books

Outcomes:

On completion of the course, the student should be able to:

- Demonstrate basic concepts in logistics management and key roles of various activities in the logistics system.
- Describe the importance of logistics and distribution, and correlate their integration with performance of the firm and supply chain.
- Evaluate the importance of distribution and transportation management in an organization.
- Determine the challenges in Logistics in different industries.
- Develop an effective logistics planning for various industries.

EL-604 (1 Credit)

Total Quality Control	hrs
Introduction: Quality Dimensions – Quality definitions – Inspection - Quality control – Quality Assurance – Quality planning - Quality costs – Economics of quality – Quality loss function	3
Control charts: Chance and assignable causes of process variation, statistical basis of the control chart, control charts for variables and attributes- Construction and application.	4
Special control procedures: Warning and modified control limits, control chart for individual measurements, multi-vari chart, X-chart with a linear trend, chart for moving averages and ranges, cumulative-sum and exponentially weighted moving average control charts.	6
Statistical process control: Process stability, process capability analysis using a Histogram or probability plots and control chart. Gauge capability studies, setting specification limits.	3
Acceptance sampling: The acceptance sampling fundamental, OC curve, sampling plans for attributes, simple, double, multiple and sequential, sampling plans for variables, MIL-STD-105D and MIL-STD-414E & IS2500 standards.	4

READING MATERIAL

1. Grant E.L. and Leavensworth, Statistical Quality Control, TMH, 2000.
2. Douglas C Montgomery, Introduction to Statistical Quality Control, John Wiley, 2001.

Outcomes:

On completion of the course, the student should be able to:

- Define principles of total quality control.
- Describe statistical process control (including design and implementation of control charts) in management of total quality control.
- Define fundamentals of acceptance sampling and its implementation in total quality control.

EL-605 (1 Credit)

Lean System, Six Sigma	hrs
Evolution of lean six sigma 5: Introduction to Lean Principles and Six Sigma Concepts-Similarities and differences – Synergy-Evolution of Lean Six Sigma	4
Lean six sigma approach: Lean Six Sigma Methodology- Phases of Lean Six Sigma Method, Managing Lean Six sigma Project, Six sigma Methodologies (DMAIC, DMADV, DFSS)	4
Six sigma tools and techniques: Advanced Statistical Tools - Statistical Process Control-Process Capability Analysis Sigma computation -Hypothesis Testing-ANOVA-Design of Experiments- chi-square test, Regression analysis –Case studies	4
Lean tools: Value Stream Mapping – Poka Yoke-5S-Cycle Time Analysis-Push-Pull Systems-Waste Elimination- Total Productive Maintenance- Failure Mode Effect Analysis-Standard Work Practices-Control Plans, SMED, Kanban, Visual control , Kaizen –Case studies	4
Lean six sigma implementation: Identifying Lean Six Sigma Projects, Define Scope, Planning for Implementation, Selection of tools and techniques for each phase, measuring the Benefits	4

READING MATERIAL

1. Michael L. George, David Rowlands, Bill Kastle, What is Lean Six Sigma, McGraw-Hill, 2003
2. Thomas Pyzdek, The Six Sigma Handbook, McGraw-Hill, 2000
3. James P. Womack, Daniel T. Jones, Lean Thinking, Free press business, 2003.
4. Forrest W. Breyfogle III, Implementing Six Sigma: Smarter Solutions Using Statistical Methods, 1999.

Outcomes:

On completion of the course, the student should be able to:

- Define principles and importance of Lean Six Sigma in an organization.
- Describe and apply Six Sigma tools and Lean tools.
- Analyze the current workflow in an organization and define value adding and non-value adding steps.
- Implement DMAIC/DMADV methodology for business process improvement in an organization.
- Identify Lean Six Sigma projects and describe Lean tools-based methodologies to improve business in an organization such as by reducing cycle time, increasing revenue and collaboration etc.