



# SYLLABUS

## Ph.D. MEDICAL DEVICES

**NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH  
GUWAHATI**

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# Ph.D. Syllabus

## *MEDICAL DEVICES*

Course No.	Course Name	Credits
<b>Semester-I</b>		
MD -710	Nanotechnology enabled Point-of-care devices	2
MD - 720	Seminar / Any core doctoral subject from other departments	2
*CS-701	<b>Research Methodology</b> (Compulsory)	2

Course No.	Course Name	Credits
<b>Semester-II</b>		
MD - 810	QA, QC and GMP of Medical Devices	2
MD - 820	Biofabrication and Biodesign for Artificial Organs	2
*CS- 801	Research and Publication Ethics (Compulsory)	2

**\*Detailed Syllabus is available at Page No. 44-45**

## SEMESTER-I

### MD -710: Nanotechnology enabled Point-of-care devices

(2 Credits)

Unit 1: Definition of Nano, emergence, and challenges of nanoscience and nanotechnology, types of nanostructure materials (0D, 1D, 2D, 3D), and properties.

Biofunctionalization of nanomaterials, beneficial properties of nanomaterials for diagnosis.

Unit 2: Basic transduction system in Point-of-care devices: Electrochemical, Optical, Piezo-resistive/electric, Signal amplification strategies for higher signal-to-background ratios: Redox Cycling amplification methods, electrode surface modification with nanomaterials, Immobilization of bioreceptor.

Unit 3: Point-of-care devices: Introduction and basic concept of point-of-care Diagnosis, Lab-on-a-chip devices for biomedical diagnostics, Paper-based platform, printed bioelectronics, wearable biosensors, smartphone-based platform, Device characterization and challenges.

Unit 4: Student Presentation

#### Books and References:

1. Kulkarni KS. Nanotechnology: principles and practices. Capital publishing company; 2015.
2. Malhotra BD, Ali MA. Nanomaterials in biosensors: Fundamentals and applications. Nanomaterials for biosensors. 2018:1.
3. Gubala V, Harris LF, Ricco AJ, Tan MX, Williams DE. Point of care diagnostics: status and future. Analytical chemistry. 2012 Jan 17;84(2):487-515.
4. Shrivastava S, Trung TQ, Lee NE. Recent progress, challenges, and prospects of fully integrated mobile and wearable point-of-care testing systems for self-testing. Chemical Society Reviews. 2020;49(6):1812-66.
5. Heikenfeld J, Jajack A, Rogers J, Gutruf P, Tian L, Pan T, Li R, Khine M, Kim J, Wang J. Wearable sensors: modalities, challenges, and prospects. Lab on a Chip. 2018;18(2):217-48.

### MD-720: Seminar

(2 Credits)

This course is designed to give training about research-based case studies and their presentations along with practical exposure.

## SEMESTER-II

**MD-810: QA, QC, and GMP of Medical Devices**

**(2 Credits)**

**Unit 1: Introduction to Medical Device Regulations: India and other major countries**

**Unit 2: Standards and Quality Management Systems in Medical Devices**

**Unit 3: Mechanical Testing of Medical Devices:** Universal Testing Machine- Elasticity – Plasticity – tensile – Fatigue - Endurance, Dynamic Mechanical Analyzer- Damping – Creep and standards corresponding to them. Mechanical testing protocols for Hypodermic Syringe, needles, catheter, Bandages etc.

**Unit 4: Basics of Medical Electronics:** Analog and Digital Circuits, Op-Amps, Transducers, Filters, FET, MOSFET, Boolean Algebra and Logic Gates.

**Unit 5: Calibration of Medical Electronic Devices:** ECG; Infusion Pump, cardiac pacemaker and defibrillators. Electrical and patient safety, safety standards, different types of safety circuits for medical equipment and measures to reduce shock hazards, Safety Codes for Electromedical Equipment, Electrical Safety Analyser, and Testing of Biomedical Equipment.

**Books and Reference:**

1. Joseph J. Carr and John M. Brown, Introduction to Biomedical Equipment Technology, Pearson Education, 2004. 2. John G. Webster, Medical Instrumentation Application and Design, John Wiley and sons, 2004. 4. Joseph Bronzino, Biomedical Engineering and Instrumentation, PWS Engg., 2010.
2. Medical Devices Rules, 2017, Related Guidance documents available at CDSCO websites.
3. US-FDA Regulation of Medical Devices
4. European Union Regulation of Medical Devices
5. Medical Device regulations: global overview and guiding principles, World Health Organization.
6. Book: Medical Devices: Regulations, Standards and Practices; 1<sup>st</sup> Edition, Imprint: Woodhead Publishing; Hardcover ISBN: 9780081002896 (Authors: Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo)
7. R.S. Khandpur, “Handbook of Biomedical Instrumentation”, Tata McGraw Hill, 1980.

**MD-820: Biofabrication and Biodesign for artificial organs****(2 Credits)****1. Biofabrication, history and materials for biofabrication**

Biofabrication, Replacement: engineering prosthetics, Replacement: transplanting living tissues, Organic polymers, Synthetic inorganic biomaterials, Calcium phosphates, Bioactive glass, Metal, Inorganic polymers.

**2. Scaffold free biofabrication**

Biofabrication of spheroids, Hanging drop, Liquid overlay technique, Active rotational method, Microcarrier beads, Magnetic levitation, Acoustic aggregation, Emulsion, Applications of spheroids.

**3. Hydrogels, synthetic and natural extracellular matrix**

What are hydrogels? Chemical hydrogels, Gamma irradiation, Protein crosslinking, Photo crosslinking, Physical hydrogels, Protein-based hydrogels.

**4. Surface functionalization, topography, and porosity**

Surfaces for cell culture, Surface plasma treatment, Plasma polymerization surface coating, Photolithography to create shapes on surfaces, Nanopillar and nanoneedles, Organ-on-a chip, Simulated organs, What is porosity? Cell organization on and in porous scaffolds, Porous scaffold and the immune response.

**5. Biodesign approach and strategy**

Design strategies in biofabrication, The design processes, The design approach in biofabrication, Biomimicry, Design theory, The Creation of a 3D Model from Patient Images, Designing Scaffolds and Porous Structures for Medical Applications, Implant Design with Optimal Biological Interaction.

**Recommended Books:****Text Books:**

1. Aurelien Forget, "Biofabrication" De Gruyter (2022).
2. Atala, Anthony\_ Yoo, James J - Essentials of 3D Biofabrication and Translation- Academic Press an imprint of Elsevier (2015)

**Reference Books:**

1. Gabor Forgacs and Wei Sun (Eds.) - Biofabrication. Micro- and Nano-fabrication, Printing, Patterning and Assemblies (2013)
2. Ritu Raman - Biofabrication-MIT Press (2021)

**(Syllabus for Compulsory Courses)****Semester-I****CS- 701 :- Research Methodology****(2 Credits)**

Unit 1: **Objectives and types of research:** Motivation and objectives, research methods vs methodology. Types of research – descriptive vs analytical, applied vs fundamental, quantitative vs qualitative, conceptual vs empirical. Introduction to drug discovery & development research, objectives, flowchart from discovery to post-marketing research, overview of research methodology in various areas of drug discovery and development research.

Unit 2: **Research formulation and Literature review**– Defining and formulating the research problem, selecting the problem, the necessity of defining the problem, the importance of literature review in defining a problem, Literature review - primary and secondary sources, reviews, monographs, patents, research databases, web as a source, searching the web, critical appraisal of literature, identifying gap areas from literature review and research databases, and development of a working hypothesis.

Unit 3: **Research design and methods:** Research design – basic principles, need of research design, features of good design, important concepts relating to research design, observation and facts, laws and theories, prediction and explanation, research databases, development of models, developing a research plan – exploration, description, diagnosis, and experimentation.

Unit 4: **Execution of the research, data collection and analysis:** Aspects of method validation, observation and collection of data, methods of data collection, sampling methods, data processing and analysis strategies and tools, data analysis with statistical packages (GraphPad Prism, SPSS for Student t-test, ANOVA, etc), hypothesis testing, generalization, and interpretation.

Unit 5: **Safety measures in the laboratory: Handling of hazardous chemicals, incompatible chemicals, flammable solvents, toxic chemicals and forms of toxic materials.** Approaches for prevention and management of fire, electrical, chemical, biological, and gaseous hazards, good laboratory practices. General safety rules, waste minimization approaches and safety practices for disposal of chemical waste, biologicals and other laboratory waste.

**(Syllabus for Compulsory Courses)****Semester-II****CS- 801 :- Research and Publication Ethics****(2 Credits)****Unit 1: Research Ethics:**

- a) Ethics – ethical issues, ethical committees (human & animal)
- b) Ethics with respect to science and research
- c) Intellectual honesty and research integrity
- d) Scientific misconducts: Falsification, Fabrication, and Plagiarism
- e) What is plagiarism? Similarity report software like iThenticate/ Turnitin/ Urkund.
- f) Redundant publications: duplicate and overlapping publications, salami-slicing
- g) Selective reporting, and misrepresentation of data

**Unit 2: Publication Ethics:**

- a) Publication ethics: definition, introduction, and importance.
- b) Best practices / standards-setting initiatives and guidelines: COPE, WAME, etc.
- c) Conflicts of interest
- d) Publication and Research misconduct: definition, concept, problems that lead to unethical behavior and vice versa, types
- e) Violation of publication ethics, authorship, and contributorship
- f) Identification of publication misconduct, complaints, and appeals
- g) Predatory publishers and journals.
- h) Journal finder/journal suggestion tools.

**Unit 3: IPR and scholarly publishing:**

Intellectual Property Rights (IPR) and patent law, commercialization, copyright, royalty, trade-related aspects of intellectual property rights (TRIPS)

**Unit 4: Report and thesis writing:**

- a) Structure and components of scientific reports, types of reports, technical reports, and thesis.
- b) Thesis writing – different steps and software tools (Word processing, etc) in the design and preparation of the thesis, layout, structure (chapter plan), and language of typical reports, Illustrations and tables, bibliography, referencing, and footnotes.
- c) Oral presentation – planning, software tools, creating and making an effective presentation, use of visual aids, the importance of effective communication
- d) Writing a research proposal and research grant
- e) Scholarly publishing – IMRaD concept and design of research paper, citation and acknowledgment, reproducibility, and accountability.
- f) Graphical Abstract and Artwork preparation

**Unit 5: Databases and Research Metrics**

- a) Indexing databases: PubMed, Embase, etc.
- b) Citation databases: Web of Science, Scopus, etc.
- c) Impact Factor of the journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score, etc.
- d) Metrics: h index, g index, i10 index, altmetrics