Table 12: Course of study for M. Pharm (Medical Devices)

Semester I

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
MMD 101T	Basics of Medical Device Technology	4	4	4	100
MMD 102T	Regulatory Affairs of Medical Devices	4	4	4	100
MMD 103T	Medical Device Manufacturing	4	4	4	100
MMD 104T	Medical Device Biocompatibility and Toxicology	4	4	4	100
MMD 105P	Medical Device Technology Lab I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Semester II

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
MMD 201T	Medical Device Innovations and Emerging Technologies	4	4	4	100
MMD 202T	Medical Device Quality Control, Risk Assessment and Safety Management	4	4	4	100
MMD 203T	Clinical Evaluation and Market Access of Medical Devices	4	4	4	100
MMD 204T	Ethics, IPR, and Entrepreneurship in Medical Devices	4	4	4	100
MMD 205P	Medical Device Technology Lab II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

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MMD 101T – BASICS OF MEDICAL DEVICE TECHNOLOGY
THEORY 60 HRS

Scope

This course offers foundational knowledge of medical devices, including in vitro diagnostics (IVDs) and software as medical devices (SaMD), covering their design, classification, applications, regulatory standards, and emerging trends, while emphasizing the integration of engineering with healthcare.

Objectives

Upon completion of this course, students will be able to:

- Explain the concept, scope, regulations, and healthcare role of medical devices and IVDs.
- Classify medical devices and IVDs based on risk and function as per Medical Devices Rules (MDR)- 2017.
- Describe safety principles, performance requirements, risk management, and design lifecycle of medical devices.
- Interpret the role of different national and international standards in medical device development.
- Explain biomaterials, biocompatibility, and key biomedical engineering principles in healthcare devices.

Unit	Contents	Hours
Unit I	Introduction to Medical Devices and in vitro Diagnostics (IVDs) Definition and scope of medical devices and IVDs, Historical evolution and impact on healthcare, Overview of regulatory bodies like Central Drugs Standard Control Organization (CDSCO), US Food and Drug Administration (FDA), European Conformity (CE – Conformité Européenne), Japan, Canada. Ethical and safety considerations in medical devices, Role of medical devices in diagnostics, treatment, and rehabilitation. Veterinary Medical devices, Medical devices from all branches of medicine, including AYUSH. Human tissue-based and Xenografts used in medical devices, excluding pharmaceutical drug applications, radiotracers (other than radiopharmaceuticals), Personalised Medical devices, customized medical devices, Assistive and Rehabilitative Medical Devices	12
Unit II	Classification of Medical Devices - and IVDs Regulatory Classification: Class A, B, C, and D as per Indian MDR-2017 and other classifications such as Class I, II (IIa & IIb), III (Risk-based classification followed in other countries), IVDs Class A, B, C, D, or as Class I, II, and III (As per USA). Functional categorization: Diagnostic, therapeutic, monitoring, surgical instruments. Examples: Imaging Devices, Cardiovascular Devices, Neurological Devices, Orthopaedic Devices, Wearable and Smart Medical Devices. Combination products.	08
Unit III	Principles, General Safety, Performance Requirements, Design and Manufacturing Requirements Introduction to Essential Principles (based on vertical & horizontal standards by Bureau of Indian Standards	16

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	(BIS), International Organization for Standardization (ISO), American Society for Testing and Materials (ASTM), and other regulatory bodies. Checklist Documentation and Regulatory Importance; Medical Device Safety, Risk–Benefit Acceptability, Risk Management, Clinical Performance, Protection against Biological Risks, Infection and Microbial Contamination Control, Chemical, Physical, and Biological Properties, Electrical and Mechanical Safety, Software Validation, Protection against Radiation; Product Design and Development Lifecycle, Manufacturing Quality Control and Management, Risk Assessment (Usability and Human Factors), Stability, Shelf Life and Regulatory Compliance, Disposals, Post-Market Surveillance.	
Unit IV	Standards for Medical Devices Standard as per Bureau of Indian Standards (BIS), International Organization for Standardization (ISO), International Electro Technical Commission (IEC), or by any other pharmacopeia standards, or in the absence of all above, manufacturer's own validated in-house standards.	06
Unit V	Biomaterials and Biocompatibility Introduction to Biomaterials, Types of biomaterials, Biocompatibility considerations- Surface modifications and coatings, Host response to biomaterials (immune response, toxicity), Mechanical and chemical properties of biomaterials, Applications of biomaterials in Medical Devices. Antibodies, Antigens, Plastics & biochemicals and chemicals in IVDs.	06
Unit VI	Biomedical Engineering and Instrumentation Introduction to Biomedical Engineering, Principles of Medical Imaging X-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), and Ultrasound Technologies, Image Processing and Analysis, Diagnostic Instrumentation, Biosensors and Biomechanics, Medical Robotics and Rehabilitation Engineering	12

REFERENCES:

1	Bronzino, J. D., & Peterson, D. R. (Eds.). (2015). The Biomedical Engineering Handbook: Four Volume Set (4th ed.). CRC Press.
2	Ratner, B. D., Hoffman, A. S., Schoen, F. J., & Lemons, J. E. (2013). Biomaterials Science: An Introduction to Materials in Medicine (3rd ed.). Academic Press.
3	FDA. (2024). Overview of Device Regulation. U.S. Food and Drug Administration.
4	World Health Organization (WHO). (2017). Medical Devices: Managing the Mismatch: An Outcome of the Priority Medical Devices Project.
5	Mak, W., & Rachlin, J. (2010). Medical Device Design: Innovation from Concept to Market (2nd ed.). Academic Press.
6	Medical Devices Rules 2017 and Amendments, Guidance Documents, Circulars by CDSCO

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MMD 102T – REGULATORY AFFAIRS OF MEDICAL DEVICES
THEORY 60 HRS

Scope

This course provides an understanding of the global regulatory frameworks, clinical evaluation and investigation, and risk management for medical devices, including IVDs and Software as a Medical Device (SaMD), with emphasis on Medical Device Quality Management System (MDQMS) (ISO 13485), risk management (ISO 14971), customer feedback, post-market surveillance, and regulatory reporting.

Objectives

Upon completion of this course, students will be able to:

- Learn Indian Medical Device Regulation, along with USFDA, EU-CE, for medical devices;
- Understand requirements for Clinical Evaluation, clinical investigation/clinical performance evaluation in compliance with 7th Schedule of MDR-2017, ISO (14155, 20916), and others
- Apply ISO standards (14971, 13485) in risk management and quality systems;
- Learn requirements for post-market surveillance and vigilance processes;
- Prepare regulatory documentation for device approval and compliance.

Unit	Contents	Hours
Unit I	Global Regulatory Framework [(CDSCO, USFDA, EU-CE (MDR 745/IVDR746), WHO]) Introduction to Global Regulatory Framework: Definition and Importance of Regulatory Framework, Role of Regulatory Bodies in Healthcare and Drug Development, Overview of Global Regulatory Authorities (like CDSCO), US-FDA, EU-CE, WHO, etc.) and their medical device approval pathway. Submission formats, CTD, and dossier structure.	10
Unit II	Clinical Investigation, Clinical Performance Evaluation and Good Clinical Practices (GCP) Introduction and role of Clinical Investigation, clinical performance evaluation for Medical Devices, Preclinical and Clinical Evaluation, Materiovigilance, Key differences between medical device clinical investigations, clinical performance evaluations and drug clinical trials, Good Clinical Practice (GCP) Guidelines, Detailed review of international GCP standards (e.g., GCP, ISO 14155), Clinical Evaluation Requirements. Clinical Evaluation reports (CER).	10
Unit III	Quality Management Systems (QMS) (ISO 13485) Principles of QMS, ISO 13485, Tools in QMS, Regulatory Audits: Overview of regulatory inspections and audits that assess compliance with QMS, including FDA, ISO, and EU audits.	06
Unit IV	Risk Management in Medical Devices (ISO 14971): Principles of Risk Management in Medical Devices, ISO 14971: Medical Device Risk Management Process, and Corrective Actions.	06
Unit V	Life cycle assessment, Testing facility, Post-market Surveillance, Vigilance, and applicable laws on Medical Devices. Total medical device life cycle assessment (LCA): Conceptualization, development (including design, verification, and validation), production, market introduction,	28

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	and post-market surveillance. Reliability testing (e.g., Highly Accelerated Life Testing (HALT), Highly Accelerated Stress Screening (HASS), Patient safety and Monitoring, Commissioning, installation, quality, performance testing, decommissioning, maintenance of medical devices. Testing facility for medical devices: International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC), ISO/IEC 17025:2017 international standard for the competence, impartiality, and consistent operation of testing and calibration laboratories. Post-market Surveillance, Vigilance: Materiovigilance Program of India, Post-Market Surveillance (PMS) Overview, European Union Medical Device Regulation (EU MDR) and Post-Market Surveillance, Medical Device Reporting (MDR) in the US, Vigilance Reporting Systems (US- FDA, EU), Field Safety Corrective Actions (FSCA), Post-market clinical follow-up. Applicable laws on Medical Devices: legal Metrology, Ionizing Radiation laws, Environmental laws on medical devices, Pre-Conception and Pre-Natal Diagnostic Techniques Act (PC PNDT), etc.	

REFERENCES:

1	U.S. Food and Drug Administration (FDA). (2024). Medical Devices Regulatory Framework: Device Advice: Comprehensive Regulatory Assistance.
2	European Commission. (2021). Medical Devices Regulation (EU) 2017/745. The Official Journal of the European Union.
3	International Organization for Standardization (ISO). (2019). ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices. Geneva, Switzerland.
4	International Organization for Standardization (ISO). (2016). ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. Geneva, Switzerland.
5	World Health Organization (WHO). (2022). Global Model Regulatory Framework for Medical Devices including In Vitro Diagnostic Medical Devices. WHO Technical Report Series.
6	Medical Devices Rules 2017 and Amendments, Guidance Documents, Circulars by CDSCO

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MMD 103T – MEDICAL DEVICE MANUFACTURING
THEORY 60 HRS

Scope

This course covers medical device manufacturing processes, infrastructure, cleanrooms, Air Handling Units (AHUs), dehumidifiers, sterilization, quality control, ISO 13485/5th Schedule compliance, and packaging/labeling, ensuring safety, efficacy, and quality of devices (including IVDs and SaMD).

Objectives

Upon completion of this course, students will be able to:

- Explain manufacturing processes for different categories of medical devices, IVD, and SAMD.
- Learn cleanroom requirements and sterilization techniques. Learn quality control testing methods and applicable documentation.
- Interpret Quality Management principles and compliance requirements;
- Design packaging and labeling in accordance with national and international regulations and applicable standards.

Unit	Contents	Hours
Unit I	Manufacturing Processes of Medical Devices: Introduction to Medical Device Manufacturing, Manufacturing Technologies- Injection molding, extrusion, machining, casting, and assembly techniques, Emerging manufacturing technologies, Design for manufacturability (DFM) and design for assembly (DFA) principles, Role of different software in medical device manufacturing, challenges in medical device production. Good Manufacturing Practice (GMP) for medical devices (Schedule V).	12
Unit II	Quality Control in Medical Device Manufacturing and Cleanroom Requirements. Key principles of quality control: Inspection, testing, and auditing. Testing methods for medical devices: Functional testing, stress testing, biocompatibility testing, and failure mode analysis. Role of material traceability and batch control in ensuring product quality. Non-destructive testing methods: X-ray, ultrasonic, and visual inspection. Analytical Performance Testing of IVDs. Verification Testing of Software. Cleanroom requirements: Definition, types, and classifications of cleanrooms (ISO 14644-1: 1999); design considerations for cleanroom facilities: materials, air-handling systems, and contamination control.	16
Unit III	Importance of Medical Device Quality Management System (MDQMS) ISO 13485 in Medical Devices. Importance of Infrastructure Qualification, Requalification, Design Transfer, Control of Production, Management of Nonconforming Products, Incoming and In-process Materials controls. Production Process Statistical Controls, Personnel Training for specific tasks to ensure consistency in product specifications, Medical Device Files, Device History Record, Device Master Records, and production records.	10
Unit IV	Packaging and Labelling Requirements The role of packaging in maintaining product integrity and sterility (if applicable), Types of	10

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	medical device packaging, packaging materials, Design considerations for packaging, Regulatory requirements for medical device labelling as per Medical Device Rules 2017 and other market of interests (US FDA, EU-CE Risk management in labelling, Special labelling considerations, packaging validation, Labelling compliance, Traceability. Unique Device Identification (UDI), Medical Device Symbols, Instruction for Use, and or User Manuals.	
Unit V	Method of sterilization of Medical devices, Validation and Documentation requirement Overview of sterilization techniques: Steam sterilization (autoclaving), ethylene oxide sterilization, radiation (gamma, electron beam), hydrogen peroxide, and ozone sterilization, Advantages and limitations of each sterilization method, Sterilization validation: Sterility assurance level, bioburden testing, and microbial validation, Regulatory compliance for sterilization processes [(FDA, (Ethylene Oxide), ISO 11137 (Radiation), and ISO 17665 (Moist Heat) etc]). Documentation requirements for generating the Plant Master File and the Device master file as per the regulatory norms.	12

REFERENCES:

1	Ratner, B. D., Hoffman, A. S., Schoen, F. J., & Lemons, J. E. (2012). Biomaterials Science: An Introduction to Materials in Medicine (3rd ed.). Academic Press.
2	Guidance Documents (Medical Devices and Radiation-Emitting Products). U.S. Food and Drug Administration (FDA).
3	International Organization for Standardization (ISO). (2016). ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. Geneva, Switzerland.
4	Kucklick, T.R. (2013). The Medical Device R&D Handbook (2nd ed.). CRC Press.
5	Agalloco, J.P., Carleton, F.J. (Ed.) (2008). Validation of Pharmaceutical Processes (3rd ed.). CRC Press.
6	Medical Devices Rules 2017 and Amendments, Guidance Documents, Circulars by CDSCO

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MMD 104T – MEDICAL DEVICE BIOCOMPATIBILITY AND TOXICOLOGY
THEORY 60 HRS

Scope

This course explores the biological evaluation of biomaterials and medical devices, focusing on toxicity assessment, ISO 10993 standards, in vitro/in vivo testing, preclinical studies, and biocompatibility risk management.

Objectives

Upon completion of this course, students will be able to:

- Identify biocompatibility concerns in biomaterials and finished medical devices;
- Identify the requirements for different tests by category and use of the medical device.
- Perform in vitro and in vivo biocompatibility testing as per ISO 10993
- Integrate strategies to mitigate biological toxicity through material selection, production process controls, and packaging controls;
- Understand case studies on biomaterial safety

Unit	Contents	Hours
Unit I	Biological Toxicity Aspects of Biomaterials: Toxicological principles in biomaterials, Mechanisms of toxicity, Material degradation and its toxicological effects, Types of Toxicity: Cytotoxicity, genotoxicity, hemotoxicity, neurotoxicity, Methods for assessing toxicity risks of biomaterials: In vitro, in vivo, and computational modeling. Strategies for mitigating toxicity: Surface modification, material selection, and biomaterial coatings.	12
Unit II	Biological Evaluation of Medical Devices (ISO 10993) Introduction to ISO 10993 standards: Scope and objectives for the biological evaluation of medical devices. Developing a Biological Evaluation Plan (BEP) for medical devices, Factors influencing the need for testing (e.g., duration of contact, device type, and patient population), Biocompatibility Testing Categories, and additional evaluation tests.	12
Unit III	In Vitro, In Vivo, and Ex vivo Testing Methods Introduction to in vitro testing methods: Cell culture models for biomaterial testing, Toxicity assays, Cytokine release assays, Hemo-compatibility testing in vitro, Introduction to in vivo testing methods: Animal models for biocompatibility testing, Implantation studies, Biodegradation studies, Immunotoxicity and inflammatory response, Integrating in Vitro and in Vivo Testing.	14
Unit IV	Preclinical and Clinical Safety Studies. Key components of preclinical studies: dose selection, animal model selection, exposure duration, and endpoint selection. Overview of clinical trial phases: Preclinical data review. This shall be separated from biological toxicity.	10
Unit V	Case Studies on Biocompatibility Assessment: A practical case study related to the biological safety evaluation of medical devices. Concept and principles of biocompatibility, classification of medical devices based on nature and duration of body contact, and biological evaluation strategy according to ISO 10993. Preparation of Biological Evaluation	12

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	Plan (BEP) and Biological Evaluation Report (BER). Case studies on biocompatibility assessment of different categories of medical devices, including implantable devices (orthopedic implants, cardiovascular stents), blood contacting devices (catheters, vascular grafts, dialysis tubing), and external communicating devices (wound dressings, dental materials, surgical gloves). Regulatory case studies involving biological safety evaluation, device failures, and corrective actions based on guidelines from regulatory authorities such as the U.S. Food and Drug Administration and the Central Drugs Standard Control Organization. Interpretation of test data, preparation of regulatory documentation, and decision-making in biological safety assessment of medical devices.	

REFERENCES:

1	Ratner, B. D., Hoffman, A. S., Schoen, F. J., & Lemons, J. E. (2012). Biomaterials Science: An Introduction to Materials in Medicine (3rd ed.). Academic Press.
2	International Organization for Standardization. ISO 10993 – Biological Evaluation of Medical Devices (Parts 1–23). Geneva, Switzerland.
3	Bowen, P. K., Drelich, J., & Goldman, J. (2013). Zinc Exhibits Ideal Physiological Corrosion Behavior for Bioabsorbable Implants. Advanced Materials, 25(18):2577-82.
4	Williams, D. F. (2008). On the Mechanisms of Biocompatibility. Biomaterials, 29(20):2941- 53.
5	U.S. FDA Guidance Document (2023). Biological Evaluation of Medical Devices – Use of International Standard ISO 10993-1.
6	Biocompatibility Protocols for Medical Devices and Materials – Edited by Prakash Srinivasan Timiri Shanmugam et al.
7	Biomaterials, Medical Devices and Combination Products: Biocompatibility Testing and Safety Assessment – Shayne C. Gad and Samantha Gad-McDonald
8	Biocompatibility and Performance of Medical Devices – Edited by Jean-Pierre Boutrand ISO 10993 Series
9	Medical Device Regulations: Global Overview and Guiding Principles – Susanne Ludgate and Ralf-Michael Jütte
10	Guidance Documents from U.S. Food and Drug Administration and Central Drugs Standard Control Organization

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MMD 105P – MEDICAL DEVICE TECHNOLOGY LAB-I

Sl. No	Experiment
1	Writing Standard Operating Procedures (SOPs) & Designing Formats for SOPs, Writing other important documents like Quality Manual, Quality Policy, Quality Objectives, Quality Plan, Medical Device File
2	Conducting trainings and methods evaluating trainings
3	Fabrication of Simple Medical Devices
4	Performing In Vitro Diagnostic Test (Analysers, ELISA, Rapid Tests, Latex Tests)
5	Mechanical and Electrical Testing of Devices
6	Software Testing
7	Sterilization
8	Biocompatibility Testing
9	Quality Control Techniques for Medical Devices (Different Types)
10	Measurements & Calculations
11	Case Studies on Device Failures

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