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 201T – MEDICAL DEVICE INNOVATIONS AND EMERGING TECHNOLOGIES
THEORY 60 HRS

Scope

This course covers the integration of advanced technologies such as 3D printing, nanotechnology, Artificial Intelligence (AI), SaMD, and Internet of Things (IoT) into medical device design, including applications in wearables, implants, smart sensors, and personalized healthcare, as well as the associated regulatory and ethical challenges.

Objectives

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

- Demonstrate the applications of 3D printing in medical device prototyping
- Analyze the role of nanotechnology in diagnostics and drug delivery
- Evaluate the use of AI/ML and IoT in smart medical devices
- Identify challenges in wearable and implantable technologies
- Explore ethical and regulatory concerns in emerging medtech

Unit	Contents	Hours
Unit I	3D Printing and Additive Manufacturing Introduction to 3D Printing and Additive Manufacturing, Applications of 3D Printing in Medical Devices, Materials Used in 3D Printing for Medical Devices, Regulatory frameworks: FDA, CE, and ISO guidelines for 3D-printed medical devices, Ethical considerations in bioprinting and the production of personalized medical devices.	12
Unit II	Nanotechnology in Medical Devices: Fundamentals and principles of nanotechnology, Types of nanomaterials, Characterization of nanomaterials, Applications of Nanotechnology in Diagnostic devices, Drug delivery systems, Implantable devices and theranostic devices, Challenges in the approval of nano-based medical devices. Nano and micro-electronic medical devices are advanced, miniaturized technologies [Micro-Electro-Mechanical Systems (MEMS), bio-MEMS, Nanosensors] designed for in vivo monitoring, diagnostics, and therapeutics.	15
Unit III	AI & Machine Learning in Medical Devices: Overview of artificial intelligence (AI) and machine learning (ML) technologies, Applications of AI and ML in Medical Devices, AI in Wearable and Implantable Devices, Regulatory and Ethical Considerations.	12
Unit IV	Wearable and Implantable Medical Devices; Smart Sensors and IoT in Healthcare: Introduction to Wearable Medical Devices, Applications of Wearable Medical Devices, Introduction to Implantable Medical Devices, Challenges in Wearable and Implantable Devices. Smart Sensors and IoT in Healthcare: Definition and types of smart sensors, Integrated smart sensors, Applications of Smart Sensors in Medical Devices, Definition of Internet of Things (IoT), IoT in patient care, Role of IoT in hospital settings, Challenges and Future Directions.	15

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Unit V	Robotics-based medical devices: Surgical Robots, Rehabilitation & Assistive Robots, Diagnostic & Therapeutic Robots, Hospital Support & Logistics, and Prosthetics & Artificial Organs.	06

References:

1	Murphy, S. V., & Atala, A. (2014). 3D bioprinting of tissues and organs. Nature Biotechnology, 32, 773–785.
2	Geertsma, R.E. et al., (2015). Nanotechnology in medical devices. RIVM Report 2015-0149 by National Institute for Public Health and the Environment, The Netherlands.
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4	Heikenfeld, J. et al. (2018). Wearable sensors: modalities, challenges, and prospects. Lab on a Chip, 18, 217–248.
5	Islam, S. M. R., Kwak, D., Kabir, M. H., Hossain, M., & Kwak, K. S. (2015). The Internet of Things for health care: A comprehensive survey. IEEE Access, 3, 678–708.

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MMD 202T – MEDICAL DEVICE QUALITY ASSURANCE, RISK ASSESSMENT AND SAFETY MANAGEMENT
THEORY 60 HRS

Scope

This course covers quality assurance and control in medical device manufacturing, including risk management, human factors, Failure Modes and Effects Analysis (FMEA), and cybersecurity, along with regulatory compliance and methods to ensure safety, usability, and reliability throughout the lifecycle.

Objectives

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

- Apply principles of MDQMS in medical device design and lifecycle management
- Perform risk management using ISO 14971
- Conduct usability engineering and human factors assessment (IEC 62366)
- Implement selected risk management tool for device design and process control
- Develop cybersecurity strategies for connected medical devices

Unit	Contents	Hours
Unit I	Quality Assurance Introduction to quality assurance/ quality control (QA/QC); Principles of Quality Management Systems (QMS) for medical devices; Documentation practices and regulatory compliance (ISO 13485, QMSR); Process validation and verification; Product lifecycle management and traceability; Internal audits, inspections, and corrective actions; Supplier quality management and risk-based approaches. Release of finished product for sale and distribution with Certificate of Analysis (COA) and/or Declaration of Conformity. In process quality assurance. Role of Management Representative.	12
Unit II	Quality Control and Risk Management: Introduction of quality control of the product from raw materials to the finished product. Out of Trends and Out of Specification declarations, Statistical sampling techniques, assigning AR numbers, and issuance of QC status labels of materials across production and warehousing. Material specifications with acceptance criteria. QC records, such as worksheets and analytical reports. Batch/Lot testing. Serial-wise testing. Packing and packaging material testing. Risk Management: Overview of risk management principles (ISO 14971); Hazard identification methodologies; Risk estimation, evaluation, and control strategies; Risk-benefit analysis; Documentation and risk management file creation; Regulatory perspectives and compliance; Post-market surveillance and risk management.	22
Unit III	Human Factors and Usability Engineering: Introduction to human factors engineering in medical devices; Principles and importance of usability (IEC 62366); User-centered design processes; Task analysis and use scenarios; Usability testing methods and documentation requirements; Regulatory expectations (FDA guidance, MDR); Case studies on usability- driven design improvements.	10

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Unit IV	Cybersecurity in Medical Devices Risk Management: Introduction to cybersecurity risks in medical technology; Regulatory guidance (FDA cybersecurity guidance, EU MDR); Cybersecurity risk assessment and vulnerability management; Secure software development lifecycle (IEC 62304); Incident response planning and mitigation strategies; Best practices for maintaining cybersecurity post- market; Case studies on cybersecurity threats and effective mitigation in medical devices.	07
Unit V	Key aspects of medical device testing Risk Management Biocompatibility Testing; Interaction between the device and biological tissues, adhering to standards like ISO 10993. Radiation testing, Electronic testing, Electrical Safety & EMC; For safety and electromagnetic compatibility for electronic devices, complying with IEC 60601. Biological, Physical & Mechanical Testing; Assessing durability, functional performance, and materials used in devices like implants and tools. Animal testing and Simulation testing of Medical devices.	09

REFERENCES:

1	ISO 13485:2016. (2016). Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes. Geneva, Switzerland.
2	ISO 14971:2019. (2019). Medical Devices—Application of Risk Management to Medical Devices. Geneva, Switzerland.
3	IEC 62366-1:2015. (2015). Medical Devices—Part 1: Application of Usability Engineering to Medical Devices. Geneva, Switzerland.
4	FDA. (2023). Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Guidance for Industry and Food and Drug Administration Staff.
5	Stamatis, D. H. (2019). Risk Management Using Failure Mode and Effect Analysis (FMEA) (2nd ed.). ASQ Quality Press.

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MMD 203T – Clinical Evaluation and Market Access of Medical Devices
THEORY 60 HRS

Scope

This course explores the design and regulatory requirements of clinical studies for medical devices, focusing on CER, Clinical Investigations of Medical Devices and SaMD, and Clinical Performance Evaluation of IVDs, methodologies, data management, and ethical considerations. It also covers the integration of real-world evidence, health technology assessment (done by DHR and has no role in manufacturing license), market access strategies, and reimbursement policies to optimize device adoption and commercialization.

Objectives

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

- Design and manage Clinical Evaluation (MD/SaMD) & Clinical Performance Evaluation (IVD)
- Utilize real-world evidence (RWE) for regulatory submissions
- Perform health technology assessments and cost-effectiveness analyses
- Strategize for global market access and regulatory pathways
- Understand reimbursement and pricing models across different markets

Unit	Contents	Hours
Unit I	Clinical Investigation, Performance Evaluation and Study Designs Introduction to clinical research methods for medical devices; Regulatory framework (MDR-2017, USFDA, EU-CE [(Medical Device Regulation (MDR)/ In Vitro Diagnostic Regulation (IVDR), Good Clinical Practice (GCP)] and clinical trial requirements; Types of study designs (pilot, pivotal, observational, randomized controlled trials); Protocol development, endpoints selection, Biostatistics (Statistical methods, data analysis, sample size calculation, and interpretation of clinical data Patient recruitment strategies and site management; Ethical issues in clinical research, informed consent, and patient rights; data monitoring Clinical data management, analysis, reporting, and post-market clinical follow-up. Medical Writing, stakeholder Communication; Quality assurance in clinical studies. Introduction, role, and principles of Institutional Review Boards (IRB) or Ethics Committees.	12
Unit II	Real-World Evidence (RWE) in Medical Devices: Definition and importance of real-world evidence; Sources of Real-World Evidence (RWE) like registries, electronic health records, claims databases; Regulatory acceptance and guidance [FDA, European Medicines Agency (EMA) guidelines]; RWE study design and data analytics methods; Advantages and limitations of RWE; Case studies illustrating RWE utilization; Integrating RWE into medical device lifecycle management.	08
Unit III	Health Technology Assessment (HTA) Overview and scope of HTA in medical devices; HTA processes and methodologies; Systematic Literature Review (SLR): PICO, screening, data extraction, critical	14

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	appraisal, PRISMA guidelines; Meta analysis; Economic evaluation methods (cost-effectiveness, cost-utility, cost-benefit analyses); Clinical effectiveness assessment; Budget Impact Analysis (BIA) for medical devices; Introduction to Multi Criteria Decision Analysis (MCDA) for device value assessment; Device specific evaluation challenges; Quality-of-life, patient-reported outcomes and humanistic/economic burden; Ethical and societal aspects; International HTA agencies and frameworks; Role of HTA in decision-making and policy development; Overview of HTA in (Health Technology Assessment in India), Key considerations for HTA in India, HTA-informed decisions by HTA in: Case studies.	
Unit IV	Market Access Strategies for Medical Devices: Introduction to market access principles; Key components influencing medical device adoption; Stakeholder analysis (patients, providers, payers, regulators); Stakeholder Mapping; Developing value propositions and communication strategies; Regulatory pathways for market approval and commercialization; Strategic partnerships and stakeholder engagement; Challenges and strategies for global market entry; Case studies on successful market access. Competitive intelligence and market access gap assessment; Payer negotiation strategies (public and private); Tender readiness and hospital account management; Scientific and value-based communication (abstracts, posters, manuscripts, value decks).	12
Unit V	Reimbursement and Pricing Policies Principles of medical device reimbursement; Concept of value & Value based healthcare; Pricing models and strategies (value-based pricing, cost-plus pricing); Overview of reimbursement systems (Diagnosis-Related Groups (DRGs), fee-for-service, bundled payments); Reimbursement processes in major markets (U.S., EU, Asia-Pacific); Negotiation and engagement with payers; Health economics and evidence requirements; Reimbursement dossiers and payer communication packs; Impact of reimbursement policies on medical device innovation and commercialization; Introduction to Managed Entry Agreements (MEAs), Integration of evidence into reimbursement negotiations; Current assessment practice & challenges in India, Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (PM-JAY), Health Benefit Packages, state-level variations, role of insurers/Third Party Administrators (TPAs)/National Health Authority (NHA); Procurement and pricing governance: Government e-Marketplace (GeM), General Technical Evaluation (GTE) norms; National Pharmaceutical Pricing Authority (NPPA), Drug Price Control Order (DPCO) applicability and price differentiation challenges.	14

REFERENCES:

1	U.S. Food and Drug Administration (FDA). (2018). Design Considerations for Pivotal Clinical Investigations for Medical Devices. Guidance for Industry, Clinical Investigators, Institutional Review Boards and FDA Staff.
2	IMDRF (International Medical Device Regulators Forum). (2019). Clinical Evaluation. IMDRF MDCE WG/N56FINAL.

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3	Makady, A., et al. (2017). What Is Real-World Data? A Review of Definitions Based on Literature and Stakeholder Interviews. Value in Health, 20(7), 858–865.
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6	Chandler J, Cumpston M, Li T, Page MJ, Welch VJ. Cochrane handbook for systematic reviews of interventions. Hoboken: Wiley. 2019;4(1002):14651858.
7	Gheorghe A, Mehndiratta A, Baker P, Culyer A, Prinja S, Kar SS, Guzman J. Health technology assessment in India in the next decade: reflections on a vision for its path to maturity and impact. BMJ evidence-based medicine. 2025 Dec 1;30(Suppl 2):s38-40.
8	Keltie K, Bousfield DR, Cole H, Sims AJ. Medical Technologies Evaluation Programme: A review of NICE progression decisions, 2010–2013. Health Policy and Technology. 2016 Sep 1;5(3):243-50.

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MMD 204T – ETHICS, IPR, AND ENTREPRENEURSHIP IN MEDICAL DEVICES
THEORY 60 HRS

Scope

This course covers intellectual property rights in medical devices, including patents, technology transfer, and commercialization. The course also addressed ethics, entrepreneurship, and innovation case studies.

Objectives

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

- Explain IPR concepts relevant to medical devices. Perform patent searches and draft claims for device innovations
- Assess ethical issues in medical device design and development and clinical studies
- Develop business models and funding strategies for medtech startups
- Analyze case studies on commercialization and successful innovation

Unit	Contents	Hours
Unit I	Intellectual Property Rights (IPR) in Medical Devices Introduction to Intellectual Property (IP); Patents, trademarks, copyrights, and trade secrets relevant to medical devices; Criteria and procedures for patentability; Trademark and brand protection; Management of confidential information; Ethical and regulatory considerations; International IP frameworks [Trade-Related Aspects of Intellectual Property Rights ((TRIPS), World Intellectual Property Organization (WIPO), Patent Cooperation Treaty (PCT); IP portfolio management and commercialization strategies.	12
Unit II	Patent Filing and Technology Transfer Overview of patent filing processes (national and international routes, PCT); Patent search and drafting techniques; Prior art analysis; Patent prosecution, examination, grant, and maintenance; Technology transfer agreements; Licensing models; Negotiation of IP rights; Valuation and commercialization strategies; Role of incubators and tech transfer offices.	12
Unit III	Entrepreneurship and Startups in Medical Devices: Introduction to medical device entrepreneurship; Idea validation and market analysis; Developing business plans and models; Startup funding and investment sources (venture capital, grants); Regulatory pathways and product approval (FDA, EMA, CDSCO); Product commercialization strategies; Scaling operations; Challenges and opportunities for medical device startups.	12
Unit IV	Ethical Considerations in Medical Device Development: Ethical principles in medical device innovation; Patient safety and risk-benefit analysis; Clinical trials and informed consent; Ethical issues in animal and human testing; Privacy, data protection, and cybersecurity; Ethical implications of intellectual property; Conflicts of interest; Regulations and guidelines governing ethical compliance (ICH-GCP, FDA, ISO standards).	12
Unit V	Case Studies on Successful Medical Device Innovations: Analysis of landmark medical device innovations (pacemakers, stents, imaging	12

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	devices); Case studies on commercialization strategies; IP management practices of successful innovations; Regulatory navigation and clinical validation successes; Lessons learned from startup successes and failures; Strategic partnerships and collaborations; Best practices in innovation management and entrepreneurship in medical technology.	

REFERENCES:

1	Merges, R. P., Menell, P. S., & Lemley, M. A. (2023). Intellectual Property in the New Technological Age (8th ed.). Aspen Publishing.
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4	Kaplan, A. V., Baim, D. S., Smith, J. J., et al. (2004). Medical device development: from prototype to regulatory approval. Circulation. 109(25):3068-72.
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6	Van Norman, G. A., & Eisenkot, R. (2017). Technology transfer: from the research bench to commercialization: part 2: the commercialization process. Basic to Translational Science, 2(2), 197-208.

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MMD 205P – MEDICAL DEVICE RESEARCH AND DEVELOPMENT LAB-II

1	Design and Prototyping of Medical Devices
2	Material Testing for Medical Devices
3	Biomechanical and Performance Testing
4	Regulatory Compliance Documentation
5	Clinical Data Analysis and Case Studies

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