

Dr. Babasaheb Ambedkar Technological University, Lonere

Dr. Babasaheb Ambedkar Technological University
(Established as a University of Technology in the State of Maharashtra)
(Under Maharashtra Act No. XXIX of 2014)
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Course Structure and Detailed Syllabus

of

B. Tech Programme

for

Minor in Healthcare Technology

from

Second to Final Year Engineering

In line with National Education Policy 2020

Effective from Academic year 2025-26 for affiliated colleges

List of Courses for Minor in Healthcare Technology

Multidisciplinary Minor (MDM) Bucket in Healthcare Technology

Semester	Course Code	Course	Credit
3	25AF1HCTMD306	Fundamentals of Healthcare Systems	2
4	25AF1HCTMD406	Medical Statistics & Health Analytics	2
5	25AF1HCTMD506	Medical Devices & Regulatory Standards	3
6	25AF1HCTMD606	Clinical Engineering & Hospital Technology	3
7	25AF1HCTMD706	Assistive & Rehabilitation Technologies	2
8	25AF1HCTMD806	Healthcare Entrepreneurship & Innovation	2

Student can complete the online courses for minor in Healthcare Technology through online platform NPTEL / SWAYAM/ Sector Skill council of India and other online platforms identified by the University time to time. At least 80% contents (including applications of Biomedical Engineering) of the NPTEL / SWAYAM/ Sector Skill council of India course should match with syllabus contents of the subject prescribed by the university.

SECOND YEAR

SEMESTER III

25AF1HCTMD306	MDM Bucket	02 Credits
25AF1HCTMD306	Fundamentals of Healthcare Systems	02 Credits

Course Objectives

1. To introduce the structure and functioning of healthcare systems
2. To understand levels of healthcare delivery and stakeholders
3. To study healthcare organization and administration
4. To familiarize students with public and private healthcare models
5. To create awareness of healthcare challenges in India and globally

Course Outcomes

After successful completion of this course, the student will be able to:

CO1: Understand components of healthcare systems

CO2: Explain roles of healthcare stakeholders

CO3: Compare public and private healthcare models

CO4: Analyze healthcare delivery mechanisms

CO5: Appreciate healthcare system challenges and reforms

Unit I: Introduction to Healthcare Systems

Evolution of healthcare systems, Classification of Diseases, Theories of Disease Causation, Level of Prevention, Measuring the level of health in population, healthcare delivery models, primary, secondary and tertiary care

Unit II: Quantitative Sciences in Healthcare - Epidemiology

Introduction, Definition and Uses of Epidemiology, Fundamental Principles of Data Management, Populations and Samples, Measure of Disease Frequency, Measure of Association and effect, errors of measurement, confounding and bias, Architecture of Epidemiological Designs, Ethics in Epidemiology.

Unit III: Management Process in Healthcare

General Concepts in Management Sciences, Personal Management and Human Resource Development, Financial management in healthcare, logistic management in healthcare, Modern Management techniques in in healthcare.

Unit IV: Healthcare Systems and Policies

Planning and evaluation of Health services and programmes, Assessing Health Status and Health Needs, Assessing the Health Impact, Health and Human Rights, Making Public Health Policies, Aspect of Disaster Management, Accreditation of Healthcare Facilities.

Unit V: Healthcare in India

International Organization, Organization of Healthcare in India, Healthcare planning process in India, National Rural Health Mission (NRHM), National Leprosy Eradication programme, Tuberculosis programme, Immunization / Vaccination programme, Health Legislations in India. AYUSH

Textbooks

1. Ku B. Rajvir, V. Rajesh, T.Rina, G. Rajul, K.Renuka, - *Textbook of Public Health and Community Medicine*

Reference Books

1. Park, K. – *Preventive and Social Medicine*, Banarsidas Bhanot

SEMESTER IV

25AF1HCTMD406	MDM Bucket	02 Credits
25AF1HCTMD406	Medical Statistics & Health Analytics	02 Credits

Course Objectives (COB)

The course enables students to:

1. Understand fundamental concepts of medical statistics and biostatistics.
2. Apply statistical methods for healthcare data analysis.
3. Interpret biomedical datasets using statistical software and visualization.
4. Introduce healthcare analytics and clinical decision-making.
5. Understand applications of AI and data analytics in modern healthcare.

Course Outcomes (COs)

After successful completion of the course, students will be able to:

CO1: Explain statistical concepts and biomedical data types.

CO2: Apply descriptive and inferential statistical techniques to healthcare data.

CO3: Analyze biomedical datasets using statistical tools.

CO4: Interpret healthcare analytics for evidence-based clinical decision-making.

CO5: Demonstrate awareness of AI, machine learning, and ethical issues in healthcare analytics.

UNIT I: Introduction to Medical Statistics

Introduction to Biostatistics, Types of biomedical data, Population and sample, Variables and scales of measurement, Data collection methods, Data presentation, Frequency distribution, Tables and graphical representation.

UNIT II: Descriptive Statistics

Measures of central tendency: Mean, Median, Mode. **Measures of dispersion:** Range, Variance, Standard deviation, Coefficient of variation. Skewness and kurtosis, Data visualization using charts and histograms.

UNIT III: Probability and Statistical Inference

Basics of probability, Probability distributions, Normal distribution, Sampling methods, Confidence intervals, Hypothesis testing, t-test, Chi-square test, ANOVA (Introduction)

UNIT IV: Health Analytics

Introduction to Healthcare Analytics, Electronic Health Records (EHR), Clinical databases, Data cleaning and preprocessing, Healthcare data visualization, Disease surveillance, Public health analytics, Predictive analytics in healthcare.

UNIT V: AI in Healthcare Analytics

Introduction to Machine Learning, Regression analysis, Correlation, Classification techniques, Healthcare dashboards, Clinical decision support systems, Ethical issues, Privacy and security of healthcare data, Future trends in digital health .

Text Books

1. Daniel, W. W. & Cross, C. L., **Biostatistics: A Foundation for Analysis in the Health Sciences**, Wiley.
2. Wayne W. Daniel, **Biostatistics**, Wiley.
3. Pagano, M. & Gauvreau, K., **Principles of Biostatistics**, CRC Press.
4. Julie Pallant, **SPSS Survival Manual**.
5. Rangayyan, R. M., **Biomedical Signal Analysis**, IEEE Press.

Reference Books

1. Motulsky H., **Intuitive Biostatistics**.
2. Hastie, Tibshirani & Friedman, **The Elements of Statistical Learning**.
3. Han, Kamber & Pei, **Data Mining: Concepts and Techniques**.
4. Provost & Fawcett, **Data Science for Business**.
5. Healthcare Data Analytics – Chandan K. Reddy & Charu Aggarwal.

THIRD YEAR SEMESTER V

25AF1HCTMD506	MDM Bucket	03 Credits
25AF1HCTMD506	Medical Devices & Regulatory Standards	03 Credits

Course Objectives

1. To introduce classification of medical devices
2. To understand regulatory frameworks and standards
3. To study quality and safety requirements
4. To familiarize students with device approval process
5. To address post-market surveillance

Course Outcomes

CO1: Classify medical devices and technologies
CO2: Understand regulatory pathways
CO3: Apply quality and safety standards
CO4: Explain approval and compliance procedures
CO5: Understand post-market monitoring

Unit I: Medical Device Overview

Introduction to medical devices, ethics in trials, risk classification, and the device life cycle (design, validation, launch, postmarket).

Unit II: Regulatory Frameworks

Overview of Regulatory Authorities and agencies in India, India, United States, Australia, Japan and Canada, Organization structure and types of application of these all authorities.

Unit III: Standards and Quality Systems

ISO 13485 Quality Management, ISO 14971 Risk Management, IEC standards, ISO 10993 (Biocompatibility). REACH, RoHS, CLP regulations (EU).

Unit IV: Clinical Evaluation and Trials of Medical Devices

Developing Clinical Trial Prototype of Medical Devices, Institutional Review Board/ Independent Ethics Committee – Formation and working procedures, informed consent process and procedures, GCP obligations of investigators, sponsors and monitors. Clinical investigations, validation, documentation of Medical Devices

Unit V: Post-Market Surveillance

Introduction to Surveillance, Vigilance, recalls, adverse event reporting – Definition and classification of adverse event, detection and reporting, Management of Adverse Event.

Textbooks

1. Aakash Deep. – *Medical Device Regulations - A Complete Guide*, Academic Press

Reference Books

1. Sankar Veinramuthu, S. Pranav Ragavendra. – *Regulatory Affairs Basic Protocols*, PharmaMed Press / BSP Book
2. Fay A. Rozovsky and Rodney K. Adams *Clinical Trail and Human Research – A practical Guide to Regulatory Compliance*

SEMESTER VI

25AF1HCTMD606	MDM Bucket	03 Credits
25AF1HCTMD606	Clinical Engineering & Hospital Technology	03 Credits

Course Objectives

The course aims to:

1. Understand the role and responsibilities of clinical engineers in healthcare institutions.
2. Learn hospital planning, medical equipment management, and healthcare technology assessment.
3. Understand installation, maintenance, calibration, and quality assurance of medical equipment.
4. Study patient safety, risk management, and regulatory standards in hospitals.
5. Develop knowledge of emerging technologies in smart hospitals and digital healthcare.

Course Outcomes (COs)

After successful completion of the course, students will be able to:

CO1: Explain the principles of clinical engineering and hospital technology management.

CO2: Apply medical equipment planning, procurement, installation, and maintenance procedures.

CO3: Analyze quality assurance, calibration, safety testing, and preventive maintenance of biomedical equipment.

CO4: Evaluate hospital safety systems, healthcare regulations, and risk management practices.

CO5: Assess modern hospital technologies, healthcare automation, and emerging trends in clinical engineering.

UNIT I: Introduction to Clinical Engineering

Introduction to Clinical Engineering, Evolution and scope of Clinical Engineering, Role and responsibilities of Clinical Engineers, Hospital organizational structure, Clinical Engineering Department, Medical Equipment Life Cycle, Healthcare Technology Management (HTM), Technology Assessment, Biomedical Engineering support services

UNIT II: Hospital Planning and Medical Equipment Management

Hospital planning and infrastructure, Hospital departments and workflow, Intensive Care Unit (ICU), Operation Theatre (OT), Emergency and Trauma Care, Procurement of medical equipment, Equipment specifications and tender preparation, Acceptance testing, Installation and commissioning, Equipment inventory management, Asset management.

UNIT III: Medical Equipment Maintenance and Quality Assurance

Preventive maintenance, Corrective maintenance, Breakdown maintenance, Calibration of biomedical equipment, Performance verification, Electrical safety testing, Medical equipment documentation, Quality assurance (QA), Quality control (QC), Maintenance contracts (AMC and CMC).

UNIT IV: Hospital Safety, Standards, and Risk Management

Patient safety, Electrical safety in hospitals, Medical gas pipeline systems, Infection control, Biomedical waste management, Fire safety, Radiation safety, Risk management, NABH accreditation, ISO 13485 (Introduction), IEC 60601 Medical Electrical Equipment Standards. (Overview)

UNIT V: Emerging Trends in Clinical Engineering

Smart hospitals, Internet of Medical Things (IoMT), Artificial Intelligence in healthcare, Clinical Decision Support Systems (CDSS), Telemedicine, Remote equipment monitoring, Predictive maintenance, Healthcare cybersecurity, Green hospitals, Future scope of Clinical Engineering

Text Books

1. **Joseph J. Carr & John M. Brown**, *Introduction to Biomedical Equipment Technology*, 4th Edition, Pearson.
2. **Cramer C. DeVries**, *The Clinical Engineering Handbook*, Academic Press.
3. **Richard C. Fries**, *Reliable Design of Medical Devices*, CRC Press.
4. **Khandpur R.S.**, *Handbook of Biomedical Instrumentation*, McGraw Hill.
5. **Webster J.G.**, *Medical Instrumentation: Application and Design*, Wiley.

Reference Books

1. Dyro J.F., *Clinical Engineering Handbook*, Academic Press.
2. Joseph D. Bronzino, *Biomedical Engineering Handbook*, CRC Press.
3. IEC 60601 Standards (Overview).
4. NABH Accreditation Standards for Hospitals.

FINAL YEAR SEMESTER VII

25AF1HCTMD706	MDM Bucket	02 Credits
25AF1HCTMD706	Assistive & Rehabilitation Technologies	02 Credits

Course Objectives

The course aims to:

1. Understand the principles of assistive and rehabilitation technologies used in healthcare.
2. Learn the design, selection, and evaluation of assistive devices for persons with disabilities.
3. Study rehabilitation engineering, prosthetics, orthotics, and mobility aids.
4. Explore smart assistive technologies, wearable devices, and rehabilitation robotics.
5. Understand current trends, standards, and ethical considerations in rehabilitation technology.

Course Outcomes (COs)

After successful completion of the course, students will be able to:

CO1: Explain the principles of assistive and rehabilitation technologies and their role in improving quality of life.

CO2: Analyze the design and applications of prosthetic, orthotic, and mobility assistive devices.

CO3: Evaluate rehabilitation engineering technologies, therapeutic devices, and wearable rehabilitation systems.

CO4: Apply rehabilitation robotics, brain-computer interfaces, and smart assistive technologies in healthcare.

CO5: Assess accessibility standards, ethical issues, and emerging trends in assistive and rehabilitation technologies.

UNIT I: Introduction to Assistive & Rehabilitation Technologies

Introduction to Rehabilitation Engineering, Disability: Types and Classification, International Classification of Functioning (ICF) , Principles of Assistive Technology, Assessment of Patient Needs, Universal Design, Accessibility Standards, Role of Biomedical Engineers in Rehabilitation.

UNIT II: Prosthetics, Orthotics, and Mobility Aids

Introduction to Prosthetics, Upper-Limb Prostheses, Lower-Limb Prostheses , Orthotic Devices Wheelchairs (Manual and Powered), Walking Aids: Canes, Walkers, and Crutches , Seating and Positioning Systems, Smart Prosthetic Technologies.

UNIT III: Therapeutic and Rehabilitation Devices (6 Hours)

Functional Electrical Stimulation (FES), Neuromuscular Electrical Stimulation (NMES), Therapeutic Ultrasound, Rehabilitation Exercise Equipment, Balance and Gait Training

Systems, Wearable Rehabilitation Devices, Sensors in Rehabilitation, Outcome Assessment in Rehabilitation

UNIT IV: Rehabilitation Robotics and Smart Assistive Systems

Rehabilitation Robotics, Robotic Exoskeletons, Robotic Prostheses, Brain–Computer Interface (BCI) for Rehabilitation, Smart Wheelchairs, Wearable Sensors, Internet of Medical Things (IoMT), Artificial Intelligence in Rehabilitation.

UNIT V: Emerging Trends, Standards, and Ethics

Virtual Reality (VR) and Augmented Reality (AR) in Rehabilitation, Tele-rehabilitation, 3D Printing of Prosthetics and Orthotics, Personalized Rehabilitation Technologies, Clinical Evaluation of Assistive Devices, Ethical Issues, Regulatory Standards (ISO and IEC – Overview), Future Trends in Rehabilitation Engineering.

Text Books

1. **Rory A. Cooper**, *Rehabilitation Engineering Applied to Mobility and Manipulation*, CRC Press.
2. **Marcia J. Scherer**, *Assistive Technologies and Other Supports for People with Brain Impairment*, Springer.
3. **Joseph D. Bronzino**, *Biomedical Engineering Handbook*, CRC Press.
4. **John G. Webster**, *Medical Instrumentation: Application and Design*, Wiley.

Reference Books

1. **Albert M. Cook & Jan Miller Polgar**, *Assistive Technologies: Principles and Practice*, Elsevier.
2. **Rory A. Cooper**, *Introduction to Rehabilitation Engineering*, CRC Press.
3. **S. O. Oatis**, *Kinesiology: The Mechanics and Pathomechanics of Human Movement*.
4. WHO, *World Report on Disability*.
5. ISO 9999 – Assistive Products for Persons with Disability (Overview).

SEMESTER VIII

25AF1HCTMD806	MDM Bucket	02 Credits
25AF1HCTMD806	Healthcare Entrepreneurship & Innovation	02 Credits

Course Objectives

The course aims to:

1. Understand the fundamentals of entrepreneurship and innovation in the healthcare sector.
2. Develop skills in identifying healthcare problems and transforming them into innovative business opportunities.

3. Learn business planning, funding mechanisms, and commercialization strategies for healthcare technologies.
4. Understand intellectual property rights, regulatory pathways, and ethical considerations for healthcare innovations.
5. Foster entrepreneurial thinking for developing sustainable healthcare solutions and biomedical start-ups.

Course Outcomes (COs)

After successful completion of the course, students will be able to:

CO1: Explain the principles of healthcare entrepreneurship, innovation, and the healthcare ecosystem.

CO2: Identify unmet clinical needs and apply design thinking to develop innovative healthcare solutions.

CO3: Prepare business models and commercialization strategies for biomedical products and healthcare services.

CO4: Evaluate regulatory requirements, intellectual property, funding opportunities, and ethical issues related to healthcare ventures.

CO5: Develop a viable business proposal or start-up plan for a healthcare innovation.

UNIT I: Fundamentals of Healthcare Entrepreneurship (6 Hours)

Introduction to Entrepreneurship, Characteristics of an Entrepreneur, Healthcare Innovation Ecosystem, Biomedical Industry Overview, Medical Device Industry in India, Healthcare Start-up Landscape, Role of Innovation in Healthcare, Opportunities and Challenges in Biomedical Entrepreneurship.

UNIT II: Innovation and Design Thinking (6 Hours)

Design Thinking Process, Clinical Need Identification, Problem Definition, Ideation Techniques, Concept Development, User-Centered Design, Value Proposition, Lean Start-up Principles, Healthcare Innovation Case Studies.

UNIT III: Business Planning and Commercialization

Business Model Canvas, Market Analysis, Customer Discovery, Product Positioning, Marketing Strategies for Medical Devices, Financial Planning, Cost Estimation, Revenue Models, Commercialization of Healthcare Technologies.

UNIT IV: Regulatory Affairs, Funding, and Intellectual Property

Intellectual Property Rights (IPR), Patents and Copyrights, Technology Transfer, CDSCO Medical Device Regulations (Overview), FDA and CE Certification (Overview), Funding Sources, Venture Capital, Angel Investors, Government Schemes for Healthcare Start-ups, Incubation and Acceleration Centers.

UNIT V: Healthcare Start-up Development and Future Trends

Preparing a Healthcare Business Plan, Pitch Deck Development, Social Entrepreneurship in Healthcare, Digital Health Start-ups, Artificial Intelligence in Healthcare Innovation,

Telemedicine Business Models, Sustainability in Healthcare Enterprises, Ethical and Legal Considerations, Future Trends in Healthcare Entrepreneurship.

Text Books

1. **Peter J. Ogrodnik**, *Medical Device Design: Innovation from Concept to Market*, Academic Press.
2. **Alexander Osterwalder & Yves Pigneur**, *Business Model Generation*, Wiley.
3. **Eric Ries**, *The Lean Startup*, Crown Business.
4. **Joseph D. Bronzino**, *Biomedical Engineering Handbook*, CRC Press.

Reference Books

1. **Steve Blank & Bob Dorf**, *The Startup Owner's Manual*.
2. **Geoffrey A. Moore**, *Crossing the Chasm*.
3. **Vijay Govindarajan & Ravi Ramamurti**, *Reverse Innovation in Health Care*.
4. CDSCO Medical Device Rules (India).
5. Government of India guidelines on Start-up India, Biotechnology Industry Research Assistance Council (BIRAC), and Atal Innovation Mission (AIM).