

Indian Biomedical Skill Council

IBSC Modules & Certificate Programs

Module No	Module Name	Certificate Number	Name of the Program
M01	Anatomy and Physiology	Certificate Program - 1	Certificate in Biomedical Engineering
M02	Fundamentals of Electricity and Electronics		
M03	Healthcare Technology Function and Operation		
M10	Medical Terminology for Engineers		
M16	Hospital Engineering & Management		
M04	Healthcare Technology Problem Solving and Troubleshooting	Certificate Program - 2	Certificate in Biomedical Maintenance
M07	Healthcare Safety & Standards		
M08	NABH & NABL Accreditation		
M12	Radiation Safety		
M14	Facilities / General Management		
M09	Product Development, Testing, Evaluation & Modification	Certificate Program - 3	Certificate in Biomedical Manufacturing
M15	Service Delivery Management		
M17	Operations Management Functions and Strategies		
M18	Manufacture & Assembly (Design and Process)		
M19	Materials Handling and Inventory Management		
M11	Risk Management	Certificate Program - 4	Certificate in Biomedical Quality Assurance
M13	Medical Device Regulation		
M20	Medical Technology Quality Systems		
M21	Design Control & Product Development		
M22	Design Verification, Validation, Clinical evaluation and CAPA		
M23	Basic concepts & Application of Project Management	Certificate Program - 5	Certificate in Biomedical Project Management
M24	Project Modelling and Management with Applications in MS – Project		
M25	People Management in Projects		
M26	Scope Management		
M27	Applying Project Management Principles to Biomedical Industry		
M05	Healthcare Information Technology	Other Module	
M06	Healthcare Technology Management	Other Module	

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Modules and Thematic Areas

Detail Course Content	
1. Anatomy & Physiology	2. Fundamentals of Electricity and Electronics
<ol style="list-style-type: none"> 1. The Human Body: An Orientation 2. Cells and Tissues 3. Skin and Body Membranes 4. Hematological System 5. Eye, Ear and Endocrine System 6. Skeletal and Muscular System 7. Nervous System 8. Cardiovascular System 9. Respiratory System 10. Digestive, Excretory & Reproductive System 	<ol style="list-style-type: none"> 1. Transducers 2. Calculations and Conversions 3. Active & Passive Devices, Solid State Devices, (Analog & Digital) 4. Circuits & Components 5. Oscillators 6. CRTs, X-Ray tubes, Photomultipliers 7. AC Power 8. Display devices. 9. Test Equipment 10. Power Distribution & Storage Systems
3. Healthcare Technology and Function	4. Healthcare Technology Problem Solving & Troubleshooting
<ol style="list-style-type: none"> 1. Understand applicable to healthcare technology (e.g., PEEP sphygmomanometer, manometer, Korotkoff sounds, Einthoven's triangle, 10-20-10 EEG pattern). 2. Understand normal function, use, and underlying technology of test equipment (electrical safety analyzer, defibrillator analyzer, electro surgical analyzer, physiologic simulators, DVM, meters). 3. Understand normal function and underlying technology of monitoring systems (e.g., EtCO₂, ECG, EEG, non-invasive blood pressure, invasive blood pressure, pulse oximetry, fetal monitor, respiration). 4. Understand normal function and underlying technology of laboratory equipment (e.g., centrifuges, water baths, analyzers, cryostats, microtomes). 	<ol style="list-style-type: none"> 1. Identify and resolve fault conditions of modules/subsystems including power supplies. 2. Prioritize repairs of medical devices based on level of risk and/or urgency. 3. Differentiate between a device error and a use error (User Training, Applications) to determine appropriate action. 4. Differentiate between an issue with a localized monitoring device on a network and a system-wide problem. 5. Identify the fault conditions and apply appropriate corrective action for monitoring systems (EtCO₂, ECG, EEG, non-invasive blood pressure, invasive blood pressure, pulse oximetry, fetal monitor, respiration). 6. Identify the fault conditions and apply

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<ol style="list-style-type: none"> 5. Understand normal function and underlying technology of imaging devices (e.g., Ultrasound, Radiographic / Fluoroscopy). 6. Understand normal function and underlying technology of diagnostic equipment (e.g., otoscope, ophthalmoscope, audiometer, uroflow meter). 7. Understand normal function and underlying technology of infusion equipment (e.g., feeding pumps, infusion devices, syringe pumps, PCA pumps). 8. Understand normal function and underlying technology of life support equipment (e.g., defibrillators, anesthesia machines, ventilators, balloon pumps, external pacemakers). 9. Understand normal function and underlying technology of therapeutic equipment (e.g., infant warmers, ultrasound therapy, hypo/hyperthermia, aspirators, SCD, Bilirubin light). 10. Understand normal function and underlying technology of operating room equipment (e.g., electro surgical generators, video equipment, lasers, tourniquets, sterilizers, warmers). 	<p>appropriate corrective action for laboratory equipment (Centrifuges, Water Baths, Analyzers, cryostats, microtomes).</p> <ol style="list-style-type: none"> 7. Identify the fault conditions and apply appropriate corrective action for diagnostic equipment (otoscope, ophthalmoscope, audiometer, uroflow meter). 8. Identify the fault conditions and apply appropriate corrective action for infusion equipment (feeding pumps, infusion devices, syringe pumps, PCA pumps). 9. Identify the fault conditions and apply appropriate corrective action for therapeutic equipment (infant warmers, ultrasound therapy, hypo/hyperthermia, aspirators, SCD, Bilirubin light, defibrillators, external pacemakers). 10. Identify the fault conditions and apply appropriate corrective action for operating room equipment (electro surgical generators, video equipment, tourniquets, sterilizers, warmers).
5. Healthcare Information Technology	6. Healthcare Technology Management
<p>A. Foundations</p> <ol style="list-style-type: none"> 1. Hardware <ol style="list-style-type: none"> a. Topology b. PCs / Laptops / Servers c. Wiring / Structured Cabling / Connectors d. Switches / Hubs / Routers e. Wireless Communications 2. Software / Middleware / Applications <ol style="list-style-type: none"> a. EMR/EHR 	<ol style="list-style-type: none"> 1. Product Selection / Vendor Selection <ol style="list-style-type: none"> a. Technology Assessment b. Healthcare Strategic Planning 2. Project Management <ol style="list-style-type: none"> a. Capital Planning b. Return on Investment (ROI) Analysis 3. Life Cycle Analysis

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<p>b. Healthcare Information Systems (PACs, LIS, RIS)</p> <p>c. Network Protocols (IP, CCP, UDP)</p> <p>d. Operating Systems</p> <p>B. Function and Operation</p> <p>1. Hardware</p> <p style="margin-left: 20px;">a. PCs, Switches, Patch Panels</p> <p style="margin-left: 20px;">b. Networks, Topology</p> <p style="margin-left: 20px;">c. Peripherals</p> <p>2. Integration</p> <p style="margin-left: 20px;">a. Bedside Medical Device Integration (BMDI)</p> <p style="margin-left: 20px;">b. Medical Device Integration (MDI) (Labs, Printers, etc.)</p> <p style="margin-left: 20px;">c. Mobile Devices (Handhelds, Smart Phones, Tablets, etc.)</p> <p>3. Test Equipment</p> <p style="margin-left: 20px;">a. Cable Test Devices (Copper, Fiber)</p> <p style="margin-left: 20px;">b. Network Test Devices</p> <p>4. Security</p> <p>C. Problem Solving</p> <p>1. Computer Networks</p> <p>2. Integration</p> <p>3. PCs, Switches, Hubs</p>	<p>4. Usability/Compatibility Assessment</p> <p style="margin-left: 20px;">a. Device/System Planning</p> <p style="margin-left: 20px;">b. Clinical Application</p> <p>5. Device Integration Planning</p> <p style="margin-left: 20px;">a. Clinical Systems Networking</p> <p>6. Coordinating Device Interoperability / Interfacing</p> <p>7. EMI/RFI Management</p> <p style="margin-left: 20px;">a. Quality Management</p> <p style="margin-left: 20px;">b. Pre-clinical Procedure Set-up / Testing</p> <p style="margin-left: 20px;">c. Clinical (Non-investigational)</p> <p style="margin-left: 20px;">d. Participation Procedures (e.g., surgery)</p> <p>8. Interpretation Standards</p> <p>9. Other Technology Responsibilities</p>
7. Healthcare Safety & Standards	8. NABH & NABL Accreditation
<p>1. Electrical – Micro / Marco-shock, Electrical Safety Testing</p> <p>2. Chemical - Material Safety Data Sheet</p> <p>3. Biological - Universal Precautions</p> <p>4. Fire (Class, Fire Extinguishers)</p> <p>5. Regulations, Codes and Standards</p> <p style="margin-left: 20px;">a. (CSA Standards, Electromedical,</p> <p style="margin-left: 20px;">b. Laser Safety, Low Pressure</p> <p style="margin-left: 20px;">c. Connecting Assemblies (Medical</p> <p style="margin-left: 20px;">d. Gases), Stability and Transport)</p> <p>6. Biomedical Waste Management</p> <p style="margin-left: 20px;">i) Non-Hazardous</p>	<p>1. Access, Assessment & Continuity of Care (AAC), & Management of Medication (MOM) For NABH</p> <p>2. Care of Patients (COP) For NABH</p> <p>3. Patient Rights (PRE), Responsibilities (ROM), Human Management (HRM) for NABH</p> <p>4. Hospital Infection Continuous Quality (CQI) for NABH</p> <p>5. Facility management (FMS), Information System (IMS) For NABH.</p> <p>6. Documentation Requirements & Implementation Guidelines for NABH &</p>

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<p>ii) Hazardous (Radioactive waste,</p> <ul style="list-style-type: none"> a. Discarded Glass, pressurized b. Containers, Chemical Waste, c. Cytotoxic Waste, Plastic Disposables, Liquid Wastes) 	<p>NABL</p> <ul style="list-style-type: none"> 7. Accreditation Process of NABH & NABL 8. Accreditation criteria interpretations for NABH 9. Accreditation and perspective of NABL 10. Final Assessment of NABL & NABH
9. Product Development, Testing, Evaluation, & Regulatory Compliance	10. Medical Terminology for Engineers
<ul style="list-style-type: none"> 1. Regulatory Compliance Activities 2. New Product Testing & Evaluation 3. Documentation Development Management. 4. Human Factors Engineering 5. Product / Systems Quality Management 6. Device Modifications 7. Medical Device Design 8. Product Research and Development 9. Medical Device Concept Development / Invention 10. Other Product Development Responsibilities 11. Product Sales / Sales Support 	<ul style="list-style-type: none"> 1. Disease and Treatment 2. Circulation, Blood and Immunity 3. Respiration and Digestion 4. Urinary and Male Reproductive System 5. Female Reproductive System, Pregnancy and Birth 6. Endocrine and Nervous Systems, Behavioral Disorders 7. The Senses 8. The Skeleton and Muscular Systems 9. The Skin
11. Risk Management / Safety	12. Radiation Safety
<ul style="list-style-type: none"> 1. Patient Safety 2. Product Safety / Hazard Alerts / Recalls 3. Incident / Untoward Event Investigation 4. Engineering Assessment of Medical Device Failures 5. Root Cause Analysis 6. Medical Device Incident Reporting 7. Infection Control 8. Failure Mode and Effect Analysis 9. Hazardous Materials 	<ul style="list-style-type: none"> 1. X-Ray Equipment and Production 2. Radiation Units for Measurement of Radioisotopes 3. Radiation Units for Measurement of Ionizing Radiation 4. Personal Maximum Permissible Doses 5. Proposed I.C.R.P. New Maximum Permissible Doses 6. Radiation Detection and Monitoring 7. Basic Principles of Radiation Protection

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<p>10. Other Risk Management / Safety Responsibilities</p>	<p>8. Leak Test and Storage of Radiographic Exposure Devices 9. Biological Effects of Ionizing Radiation 10. Nuclear Regulatory Commission Regulations 11. Documentation and Record Keeping 12. Transportation of Radioactive Material</p>
13. Medical Device Regulation	14. Facilities / General Management
<p>1. Medical Devices, In –vitro devices, Biologics & Combination Products: Introductory Module 2. FDA Regulations and Guidelines on Medical Devices 3. European Union Guidelines on Medical Devices 4. Medical Device Regulations from Indian perspective 5. Management of the risks associated with Medical devices 6. Biocompatibility Studies and Medical Devices 7. Clinical Trials: Medical Devices 8. Overview of <i>In – Vitro</i> Device Regulation 9. Overview of Combination Products Regulation 10. Dossier preparation in CTD format, eCTD submissions</p>	<p>1. Hospital Building plan Review and Hospital building design 2. Emergency Electrical Power and Medical Gas system testing 3. Facility emergency preparedness activities 4. Supervise Manage / Direct Facilities Management and facility / Utility Remediation planning, other facility Management Responsibilities. 5. Budget develop / Execution, Business, / Operation, Plan development / management, Performance Improvement. 6. Personal Management / Supervision, Staffing, Staff skills, Competency assessment, Policy, / Procedure management / Development.</p>
15. Service Delivery Management	16. Hospital Engineering and Management
<p>1. Technician / Service Supervision 2. Equipment Repair and Maintenance 3. Equipment Acceptance 4. Service Contract Management 5. Equipment Performance Testing 6. Maintenance Software Administration 7. Develop Test/Calibration/Maintenance Procedures 8. Parts/Supplies Purchase and/or Inventory Management 9. Other Service Delivery Responsibilities. 10. Technical Library / Service Manuals</p>	<ul style="list-style-type: none"> • Hospital various departmental Planning & Design (Radiology Dept, Nuclear Medicine, ICU, Central Sterilisation and OTs). BME services in hospitals - Role & responsibilities. Setting up of BME dept in a Hospital (Requirements & facilities). • Hospital electrical supply & power systems - Hospital electrical systems, general power & lighting systems, Hospital wiring systems. Electrical safety, isolated

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Management	power supply, line isolation monitor, IPS in patient care areas, concept of Micro and Macro shock, Earthing schemes, Generator sets, UPS & voltage stabilizers. Causes of failures of electrical supply & ways to minimize them.
17. Operations Management Functions and Strategies	18. Manufacture & Assembly (Design and Process)
<ul style="list-style-type: none"> • Operations and Production Management, organizing to produce goods and services, operations in the service sector, new trends and operation and production management. • Goods and services selection, generating new products, product development, issues for product design, time-based competition, defining the product, documents for production. • Process strategies, process analysis and design, service process design, selection of equipment and technology, production technology, technology in service industry, environmentally friendly processes, business process reengineering. • Functions of inventory, inventory management, inventory models. • Project planning, project scheduling, project control, project management techniques. • Quality & Strategy, defining quality, international quality standards, total quality management, tools of total quality management. 	<ul style="list-style-type: none"> • An Introduction to Design for Manufacture and Assembly: Define manufacturing and describe how it is used to solve problems. Research the five general steps of manufacturing (preparation, processing, assembly, finishing and packaging). • Design for assembly techniques: Assembly model, assembly drawing, manufacturing process plan, electromechanical assembly, test and troubleshoot electromechanical systems. • Identify and describe a wide range of materials used in manufacturing: organic, inorganic, engineering (metallic, polymeric, ceramic, composite). And non-engineering (gases and liquids). • Do's and don'ts in manual assembly, assembly time estimation, design for robotic assembly considerations. • Design for Assembly: Boothroyd Dewhurst method, theoretical minimum number of parts, Xerox producibility index (XPI) method.
19. Materials Handling and Inventory Management	20. Medical Technology Quality Systems
<ul style="list-style-type: none"> • Introduction to materials management, operating environment, the supply chain concept. Manufacturing planning and control system, sales and operations planning, manufacturing resource planning, enterprise resource planning, making the production plan. 	<ul style="list-style-type: none"> • Application, Management, responsibilities and planning concepts of quality management systems. • India and international standard requirements, and current document control processes in the development,

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<ul style="list-style-type: none"> • The essential activities of receiving materials, methods to determining the destination and direction of uploaded products, identify and demonstrate selecting the most appropriate and current packing material to package products. • Government regulations related to hazardous materials handling, safe work practices for unloading and loading hazardous materials, safe work practices for transfer and storage of hazardous materials. • Understand that modern practice discourages holding large quantities of inventory, the significance of controlling actual, on-hand inventory as both a physical object and as an intangible object. • Understand the fundamental difference between finished goods inventories in the retail / distribution sectors and raw materials and work-in-process inventories found in the manufacturing environment. 	<p>manufacture and distribution of medical devices.</p>
<p>21. Design Control & Product Development</p>	<p>22. Design Verification, Validation, Clinical Evaluation and CAPA</p>
<ul style="list-style-type: none"> • India and ISO design control requirements for MedTech product development, translation of user needs into product design, risk management in the design process, and how design revises and a phased approach assure designs are safe, robust, and effective. • Process Control and Monitoring 	<ul style="list-style-type: none"> • Design verification, design validation, and clinical studies using Indian Quality System regulation and ISO 13485. Risk management, statistical sampling and technical reporting. • Corrective Action and Preventative Action methodologies to prevent product failures, anticipate potential problems and correct them. Continuous quality improvement.
<p>23. Basic concepts & Application of Project Management</p>	<p>24. Project Modelling and Management with Applications in MS – Project</p>
<ul style="list-style-type: none"> • What is project management • Why is project management Important? • Different phases of project management 	<ul style="list-style-type: none"> • Project Management Simulation Exercise – Scope, Resources & Scheduling • An Introduction to MS-Project

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<ul style="list-style-type: none"> • Unique Challenges in the Project Management Environment • Tools and Steps in Project Planning • Frameworks for Project Management (Agile, PRINCE2, PMBOK) • CPM & PERT 	<ul style="list-style-type: none"> • Interpreting the output of an MS-Project Report • Applications to Technical Scheduling and Resource Scheduling • Resource Levelling • Tracking and Monitoring Project Progress •
25. People Management in Projects	26. Scope Management
<ul style="list-style-type: none"> • Stakeholder Analysis & Management • Manpower Planning & Staffing in Projects • Managing Teams in Projects • Performance Assessment & Evaluation of Project Teams 	<ul style="list-style-type: none"> • How to plan scope • Collect requirements • Define scope, create WBS and work packages
27. Applying Project Management Principles to Biomedical Industry	
<ul style="list-style-type: none"> • Applying the principles of project management in new product development • Stage gate fundamentals • Stage gate process 	
