

ANNEXURE - III
Model Curriculum - Job Code 4

Job Code: IBSC / BME / 04

Qualification Title: “Certificate in Biomedical Quality Assurance”

Occupation(s) to which the qualification give access: Quality Manger

Course Curriculum:

- QM01: Medical Device Quality and Regulatory Fundamentals
- QM02: Risk Management & Risk Analysis
- QM03: Medical Technology Quality Systems
- QM04: Design Control & Product Development
- QM05: Design verification, Validation, clinical evaluation and CAPA

Module overview

QM01 Medical Device Quality, Regulatory Fundamentals and Standards

- Medical device and quality regulatory requirement for both India and International regulations and standards.
- Quality standards including ISO 13485 and their relationship to the FDA’s QRS and EU directives.

QM02 Risk Management & Risk Analysis

- Risk Management (ISO 14971) in the development and use of medical devices. Standards, regulations methods, and tools for identifying, analyzing, and controlling risks.
- Risks and hazards associated with the system and its use so that we can reduce the probability of its harm to people and environment by using Risk analysis methods like FTA and FEMA.

QM03 Medical Technology Quality Systems

- Application, Management, responsibilities and planning concepts of quality management systems.

- India and international standard requirements, and current document control processes in the development, manufacture and distribution of medical devices.

QM04 Design Control & Product Development

- 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

QM05 Design Review, Verification, Validation, clinical evaluation and CAPA

- 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.

Certificate in Biomedical Quality Assurance - Career Graph


