**ANNEXURE-A(I)**

**COURSE DETAILS**

**POLICIES ON BIOMEDICAL DEVICES**

This programme will be focusing on various aspects of Biomedical Devices Policies.

The topics on which the programme will focus on are as follows:

1. Introduction to Policy Development process: Developing policies, Drafting the policy, Testing draft policy (inviting feedback from stakeholders), Implementing policy, Post implementation changes
2. Classification of Medical Devices
3. Medical Device Prioritization, needs assessment
4. Procurement and Supply Chain: (From framing Technical Specifications to installation process to condemnation of Biomedical Devices)
5. Assessment of Medical Devices
6. Pre-Dispatch Inspection
7. Understanding Biomedical Device Requirements
8. Pricing of Medical Devices, price fixing mechanism for devices, Trade Margin Rationalization (TMR)
9. Managing Biomedical Devices in Hospitals
10. Regulation of Medical Devices
11. Post market surveillance: WHO guidance on procurement and post-market surveillance for IVDs
12. Adverse Event Reporting System
13. Policies on Medical Devices in India: The Medical Device Rules 2017
14. National biomedical equipment maintenance program of India
15. Specific Criteria for Calibration of Medical Devices to accredit the laboratories performing testing and calibration of medical devices