ANNEXURE – I

TRAINING SCHEDULE

POLICIES ON BIOMEDICAL DEVICES

This programme will be focusing on various aspects of Biomedical Devices Policies. The schedule of programme will be as follows:

Day 1:

1. Inaugural Function & Activities of CSIO
2. Introduction to Policy Development process: Developing policies, Drafting the policy, Testing draft policy (inviting feedback from stakeholders), Implementing policy, Post implementation changes

Day 2:

3. Classification of Medical Devices (GHTC, EU, FDA)
4. Medical Device Prioritization, needs assessment

Day 3:

5. Procurement and Supply Chain: (Framing Technical Specifications, Pricing, Price Fixing Mechanism, Trade Margin Rationalization of Biomedical Devices)
6. Procurement and Supply Chain: (Pre-Dispatch Inspection, Installation and Condemnation process of Biomedical Devices)

Day 4:

7. Assessment of Medical Devices
8. Understanding Biomedical Device Requirements

Day 5:

9. Management of Medical Devices in Hospitals
10. Adverse Event Reporting System
11. Policies on Radiation Safety

Day 6:

12. Policies on Bio-waste
13. Calibration of Medical Devices

Day 7:

14. National biomedical equipment maintenance program of India
15. Post market surveillance: WHO guidance on procurement and post-market surveillance for IVDs

Day 8:

16. Additive Manufacturing in Orthopaedic Implants & Related Regulatory Policies
17. Regulation of Medical Devices in India: The Medical Device Rules 2017

Day 9:

18. Specific Criteria to accredit the laboratories performing Calibration & Testing of medical devices
19. Presentation by Participants (Policy in their respective countries)

Day 10:

20. Presentation by Participants (Policy in their respective countries)
21. Feedback & Valedictory Session