

Course contents for the proposed course

Enabling medical devices Policies in Global South (Medical Devices and Invitro Diagnostics-Design, Development and Regulations)

Introduction to Medical Devices and IVDs

- Definition, scope, and classification of medical devices and IVDs
- Difference between drugs, medical devices, IVDs, and combination products
- Global overview of medical device and IVD markets
- Medical device and IVD product life cycle
- Risk-based classification principles (Class A–D / Class I–III)
- Role of medical devices and IVDs in healthcare delivery and public health

Biodesign Approach to Medical Device Innovation

- Overview of the Biodesign innovation framework
 - (Identify → Invent → Implement)
- Clinical need identification and unmet need assessment
- Stakeholder analysis and clinical immersion
- Translating clinical needs into device concepts
- Design thinking and user-centric design
- Early-stage feasibility, prototyping, and proof-of-concept development
- Intellectual property consideration in device innovation

Tissue Construct and Advanced Medical Devices

- Introduction to tissue-engineered and regenerative medical devices
- Types of tissue construct devices (scaffolds, implants, cell-based products)
- Biomaterials used in tissue constructs
- Design considerations for tissue-based devices
- Regulatory challenges and classification of tissue construct devices
- Preclinical evaluation and safety considerations
- Ethical and translational challenges in tissue engineering

Medical Devices patches and Low-Risk Devices

- Definition and regulatory classification of Class I medical devices

- Examples: wound care patches, transdermal patches, dressings, catheters, and accessories
- Essential principles and general safety and performance requirements
- Materials selection and biocompatibility
- Design and usability considerations
- Manufacturing controls for low-risk devices
- Labelling, packaging, and shelf-life considerations
- Post-market requirements for Class I devices

V. Regulatory Framework and Quality Management Systems

- Overview of global regulatory frameworks for medical devices and IVDs
 - Indian Medical Device Rules (MDR 2017)
 - CDSCO device and IVD regulations
 - EU MDR and IVDR
 - US FDA medical device and IVD regulations
- Quality Management Systems for medical devices
 - ISO 13485 requirements and implementation
- Risk management (ISO 14971)
- Design control and documentation
- Supplier qualification and control
- Regulatory submissions and technical documentation

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