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|---|---|
| **INSTITUTE** | **FACULTY OF PHARMACY** |
| **PROGRAM** | **MASTER OF PHARMACY (REGULATORY AFFAIRS)** |
| **SEMESTER** | **2** |
| **COURSE TITLE** | **REGULATORY ASPECTS OF MEDICAL DEVICES** |
| **COURSE CODE** | **13MR0203** |
| **COURSE CREDITS** | **4** |

**Objective:**

1 This course is designed to impart fundamental knowledge on medicaldevices and in-vitro diagnostics, the basis of classification and product life cycle ofmedical devices, regulatory requirements for approval of medical devices inregulated countries like the US, EU, and Asian countries along with WHOregulations. It prepares the students to learn in detail about the harmonizationinitiatives, quality and ethical considerations, and regulatory and documentationrequirements for marketing medical devices and IVDs in regulated countries.

**Course Outcomes:** After completion of this course, student will be able to:

1 Basics of medical devices and IVDs, the process of development, ethicaland quality considerations.

2 Harmonization initiatives for approval and marketing of medical devicesand IVDs.

3 Regulatory approval process for medical devices and IVDs in India, the US,Canada, EU, Japan and ASEAN.

4 Clinical evaluation and investigation of medical devices and IVDs.

**Pre-requisite of course:--**

**Teaching and Examination Scheme**

| Theory Hours | Tutorial Hours | Practical Hours | ESE | IA | CSE | Viva | Term Work |
|---|---|---|---|---|---|---|---|
| 4 | 0 | 0 | 75 | 15 | 10 | 0 | 0 |

| Contents : Unit | Topics | Contact Hours |
|---|---|---|
| 1 | **Medical devices**<br>Introduction, Definition, Risk-basedClassification and Essential Principles of Medical Devices andIVDs. Differentiating medical devices IVDs and CombinationProducts from of pharmaceuticals, History of Medical DeviceRegulation, Product Lifecycle of Medical Devices, andClassification of Medical Devices., IMDRF/GHTF: Introduction, Organizational Structure, Purposeand Functions, Regulatory Guidelines, Working Groups,Summary Technical Document (STED), Global Medical DeviceNomenclature (GMDN). | 12 |

DR. MAUSAMI CHANDRAKANTBHAI VAGHELA
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DR. LALJI HAKUBHAI BALDANIYA
**Digitally signed by (Name of Dean/ Principal)**

| Contents : Unit | Topics | Contact Hours |
|---|---|---|
| 2 | **Ethics**<br>Clinical Investigation of Medical Devices, ClinicalInvestigation Plan for Medical Devices, Good Clinical Practice forClinical Investigation of Medical Devices (ISO 14155:2011). Quality: Quality System Regulations of Medical Devices: ISO13485, Quality Risk Management of Medical Devices: ISO14971, Validation and Verification of Medical Devices, AdverseEvent Reporting of Medical Devices. | 12 |
| 3 | **USA**<br>Introduction, Classification, Regulatory approval process forMedical Devices (510k) Premarket Notification, Pre-MarketApproval (PMA), Investigational Device Exemption (IDE) and In-vitro Diagnostics, Quality System Requirements 21 CFR Part 820,Labeling requirements 21 CFR Part 801, Post-marketingsurveillance of MD and Unique Device Identification (UDI). Basicsof In-vitro diagnostics, classification, and approval process. | 12 |
| 4 | **European Union**<br>Introduction, Classification, RegulatoryApproval Process for Medical Devices. (Medical Device Directive, Active Implantable Medical DeviceDirective) and In-vitro Diagnostics (In Vitro Diagnostics Directive),CE certification process.Basics of In-vitro diagnostics, classification, and approval process. | 12 |
| 5 | **ASEAN, China & Japan**<br>Medical Devices and IVDs, Regulatoryregistration procedures, Quality System requirements, and clinicalevaluation and investigation.IMDRF study groups and guidance documents. | 12 |
| **Total Hours** | | **60** |

**Textbook :**

1 Medical Device Development: A Regulatory Overview , by Jonathan S.Kahan, Hogan Lovells US LLP, 2014

**References:**

1 FDA regulatory affairs: a guide for prescription drugs, medical devices, andbiologics , FDA regulatory affairs: a guide for prescription drugs, medical devices, andbiologics , by Douglas J. Pisano, David Mantus, 2008

2 Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, MedicalDevices , Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, MedicalDevices , by John J. Tobin , and Gary Walsh, 2008

3 Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics , Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics , by Carmen, Medina.., 2003

**Suggested Theory Distribution:**

The suggested theory distribution as per Bloom’s taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

| Distribution of Theory for course delivery | | | | | |
|---|---|---|---|---|---|
| **Remember / Knowledge** | **Understand** | **Apply** | **Analyze** | **Evaluate** | **Higher order Thinking / Creative** |
| 10.00 | 20.00 | 25.00 | 25.00 | 10.00 | 10.00 |

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