ATHEENAPANDIAN'S

INTERNATIONAL CERTIFICATE COURSE

International Certificate Course on Medical Regulatory

COURSE 1

Master global medical regulatory frameworks and compliance.

www.biomedicalinternship.com

CERTIFICATE COURSE ON MEDICAL REGULATORY
Course Name: Medical Regulation
Course Duration: 30 Hours
Course Eligibility:

- This course is eligibility for Students, Faculty, Biomedical Professionals and Other Professional.

Course Fee: Rs 999/11.9 USD

Course Objectives:

- Apply regulatory guidelines from major global regulatory agencies (FDA, EMA, PMDA, Health Canada, TGA, etc.).
- Manage the lifecycle of medical products, from development to market approval and post-market surveillance.
- Ensure compliance with Good Manufacturing Practices (GMP), Good Clinical Practice (GCP), and other regulatory standards.
- Develop strategic plans for regulatory submissions and market entry for healthcare products.
- Address ethical, legal, and risk management issues related to the regulatory approval process.

- **Course Benefits:**
- In-Depth Understanding of Global Regulations
- Knowledge of Regulatory Submissions
- Compliance with Quality and Safety Standards
- Career Advancement Opportunities
- Enhanced Clinical Trial Management Skills
- Expertise in Pre and Post-Market Surveillance
- Strategic Regulatory Planning and Risk Management

Course Coverage:

1. Regulatory systems for medical products

- Introduction
- Good governance of medical products
- Principles of good regulatory practice

2. Design and implementation of national regulatory systems for medical devices

- Why are regulatory controls for medical devices complicated?
- Safety of medical devices

- Typical development phases of national regulatory authorities
- Assessment of a national regulatory authority
- Responsibilities of the medical devices section in a national regulatory authority
- Industry structure and supply chain
- Conformity assessment
- Harmonization of medical devices regulatory practices

3. Medical Regulatory Affairs on global Standards

Global Regulatory Agencies

- FDA, EMA, MHRA, Health Canada, TGA, PMDA, WHO, and ICH

4. Clinical Trial Regulations

Clinical Trials and Ethical Considerations

- Phases of clinical trials (Phase I–IV)
- Institutional Review Boards (IRBs) and ethics committees

Good Clinical Practice (GCP)

- International standards for conducting clinical trialsFDA, EMA, and Global Guidelines for Clinical Trials
- IND, clinical trial applications, and market approval processes

5. Quality Management Systems (QMS)

Overview of QMS in Healthcare

- ISO 13485 standards for medical devices
- Quality by Design (QbD) and risk management

Good Manufacturing Practice (GMP)

- Compliance with global GMP standards (FDA, EMA, WHO)

6. Pre and Post-Market Surveillance and Compliance

Post-Market Obligations

- Adverse event reporting and post-marketing surveillance

Medical Device Reporting (MDR)

- Corrective and preventive actions (CAPA) and field safety corrective actions (FSCA)

Regulatory Strategy Development

- Planning regulatory submissions and strategies for market entry
- Risk Management in Regulatory Affairs
- Risk assessment tools and methods (e.g., ISO 14971 for medical devices)
- Ethics in Regulatory Affairs
- Informed consent, patient safety, data integrity
- Legal Aspects
- Intellectual property, patent law, and market exclusivity

SL.No	Date	Day	Day-wise Plan
1	4.11.2024	Monday	Introduction to Regulatory Systems for Medical Products
			Overview of medical product regulations, governance, and importance
			Assesment on regulatory System for medical product
2	5.11.2024	Tuesday	Principles of Good Regulatory Practice
			Key principles and international practices in medical product regulation
			Assesment on Key principles and international practices in medical product regulation
3	6.11.2024	Wednesday	Regulatory Controls for Medical Devices
			Why are regulatory controls complicated?
			Safety considerations of medical devices
			Assesment on Regulatory Controls for Medical Devices
4	7.11.2024	Thursday	Development Phases and Assessment of National Regulatory Authorities
			Phases of developing regulatory bodies and assessment of their efficacy
			Assesment on Development Phases and Assessment of National Regulatory Authorities
5	8.11.2024	Friday	Responsibilities of Medical Device Regulatory Authorities
			Understanding the roles of regulatory bodies in medical device safety and effectiveness
			Assesment on Responsibilities of Medical Device Regulatory Authorities
6	11.11.2024	Monday	Industry Structure, Supply Chain, and Conformity Assessment
			Overview of industry supply chains and conformity assessment for medical devices
			Assesment on Industry Structure, Supply Chain, and Conformity Assessment
7	12.11.2024	Tuesday	Global Harmonization of Medical Devices Regulatory Practices
			- Efforts and challenges in harmonizing global medical device regulations (IMDRF, GHTF)
			Assesment on Global Harmonization of Medical Devices Regulatory Practices
8	13.11.2024	Wednesday	Global Regulatory Agencies (FDA, EMA, MHRA, TGA, PMDA)
			In-depth overview of global regulatory bodies and their roles in medical device regulation
			Assesment on Global Regulatory Agencies (FDA, EMA, MHRA, TGA, PMDA)
9	14.11.2024	Thursday	Clinical Trials and Ethical Considerations
			Phases of clinical trials and the importance of ethical oversight by Institutional Review Boards (IRBs)
			Assesment on Clinical Trials and Ethical Considerations
10	15.11.2024	Friday	Good Clinical Practice (GCP) and International Standards for Clinical Trials
			Principles of GCP and FDA, EMA guidelines for clinical trials
			Assesment on Good Clinical Practice (GCP) and International Standards for Clinical Trials
11	18.11.2024	Monday	Overview of Quality Management Systems (QMS) for Medical Devices
			ISO 13485 standards and Quality by Design (QbD) for risk management
			Assesment on Overview of Quality Management Systems (QMS) for Medical Devices
12	19.11.2024	Tuesday	Good Manufacturing Practice (GMP) and Global Standards
			Overview of GMP compliance and FDA, EMA, WHO regulations
			Assesment on Good Manufacturing Practice (GMP) and Global Standards
13	20.11.2024	Wednesday	Post-Market Surveillance and Compliance for Medical Devices
			Adverse event reporting and post-market obligations for medical devices
			Assesment on Post-Market Surveillance and Compliance for Medical Devices

14	21.11.2024	Thursday	Medical Device Reporting (MDR) and Corrective Actions (CAPA)
			Procedures for MDR, corrective and preventive actions (CAPA)
			Assesment on Medical Device Reporting (MDR) and Corrective Actions (CAPA)
15	22.11.2024	Friday	Risk Management, Ethics, and Legal Aspects in Regulatory Affairs
			ISO 14971 for risk management, ethics, informed consent, and legal considerations in IP and patents
			Assesment on Risk Management, Ethics, and Legal Aspects in Regulatory Affairs