GANPAT UNIVERSITY

FACULTY OF ENGINEERING & TECHNOLOGY

Programme	Bachelor of Technology	Branch/Spec.	Biomedical Engineering
Semester	VII	Version	2.0.0.0
Effective from Academic Year	2017-18	Effective for the batch Admitted in	July 2017
Subject code	2BM706	Subject Name	Medical Devices Standards & Regulations

Teaching scheme						Examination scheme (Marks)			
(Per week)	Lecture(DT)		Practical(Lab.)		Total		CE	SEE	Total
	L	TU	P	TW					
Credit	3	-	-	-	3	Theory	40	60	100
Hours	3	-	-	-	3	Practical	-	-	-

Pre-requisites: Basic Principle of Medical Equipment, Hospital Management, Fundamental Physics

Learning Outcome: The educational objectives of the course are to educate students to attain the following:

- To provide foundational information related to the global regulation of medical devices with emphasis placed on US, EU and Asia-Pacific countries.
- The role of the global regulatory professional will be examined in the context of these regulatory frameworks to design medical devices.
- Medical device regulation in the US, EU & Asia- Pacific with an emphasis on the product lifecycle and an extended examination of the submissions process.

Theory syllabus

Unit	Content	Hrs.
1	**INTRODUCTION TO MEDICAL DEVICES AND NEED OF REGULATORY AFFAIRS** Classification of medical devices , Steps to be considered while carrying out classification of medical devices , Purpose and principle for regulations, Development of regulations and safety standards for medical devices	6
2	**QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES MANUFACTURING** History of ISO 13485, General requirements of ISO 13485:2012, Document required by ISO 13485:2012, Process of getting ISO 13485:2012, ISO 13485 applications in EU, Canada and Japan	5
3	**THE PROCESS OF GAINING APPROVAL FOR NEW MEDICAL DEVICE** USA: Classification of device, Premarket submission, Documentation for necessary submission to FDA, Premarket review, Final registration and listing EU: Determination of device class as per Annex IX, Registration process for II(a) & II(b) device, Registration process for III device, Necessary documentation required for registering CE mark on medical device	7
4	**REGULATIONS AND STANDARDS IN MEDICAL DEVICES FOR USA** The classification of medical devices by level of risk and the regulatory controls in different countries **United States Medical Device Regulatory Framework** Legislation and Device Laws, Total Product Life Cycle Approach, The Regulatory Environment for Bringing a Medical Device to Market, Regulatory Considerations to Market and Keep Devices in Distribution, Registration, Medical device listing, Special controls and pre-market notifications, Premarket approval, Labelling practices, Good manufacturing practice & Quality services, Medical device reporting, Two common pathways for pre-market approval of medical devices in USA	8
5	**REGULATIONS AND STANDARDS IN MEDICAL DEVICES FOR EU EUROPEAN UNION MEDICAL DEVICE REGULATORY FRAMEWORK** New Approach concept for European directives, Harmonized standards and various bodies in European Union, Overview of medical devices directives in EU, Risk based classification of medical devices as per EU standards, CE mark and procedure to obtain CE mark, Essential requirements for obtaining CE mark for medical devices, Labelling process, Technical documentation and Risk management system, Overview of pre-market to post-market scenario of CE marked medical device	8
6	**REGULATIONS AND STANDARDS IN MEDICAL DEVICES FOR INDIA UNITED STATES MEDICAL DEVICE REGULATORY FRAMEWORK** Market overview of medical devices in India, Overview of laws governing medical devices and governing bodies, Classification of medical devices as per risks, Role of distributors and subsidiaries body, Product registration process and Quality system regulations, Manufacturing regulations , Labelling and technical requirement, Clinical trials, Commercials aspects and regulations on price, Upcoming regulations on medical devices in India	8

Learning Assignments: **Assignments & Case studies shall be based on the above syllabus.**

Text Books:

1	Handbook of Medical Device Regulatory affairs in Asia – Jack Wong, Raymond K. Y. Tong, Pan Stanford Publishing

2	Medical Devices: Regulations, Standards and Practices – Seeram Ramakrishna, Lingling Tian, Charelene Wang, Susan Liao and Wee Eong Teo, Woodhead publishing house
Reference Books	
1	Medical Products and Regulatory Affairs – Pharmaceuticals, Diagnostics, Medical Device John J. Tobin and Gary Walsh, Wiley- VCH