GANPAT UNIVERSITY									
FACULTY OF ENGINEEIRNG AND TECHNOLOGY									
Programme	Master of Technology					Branch/Spec.	Biomedical Engineering		
Semester	II					Version	1.0.0.0		
Effective from Academic Year			2018-19			Effective for the batch Admitted in			July 2018
Subject code	3BM201		Subject Name			Bioethics, Standards and IPR Issues			
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 knowledge of Ethics and moral value.

Learning Outcome:

After learning this course each student would be able to:

- To get familiar of ethical issues in medicine, health care and life science.
- To understand how to take responsibility for morals and mistakes.
- To understand Intellectual Property assets.
- To provide foundational information related to the global regulation of medical devices with emphasis placed on US, EU and Asia-Pacific countries.

Theory Syllabus

Unit	Content	Hrs
1	**HUMAN VALUES AND ENGINEERS** Morals- Values and Ethics – Integrity – Work Ethic – Service Learning –Respect for Others – Living Peacefully ,Caring , Sharing , Honesty , Courage ,Valuing Time , Co-operation – Commitment – Empathy– Self-Confidence – Character –Spirituality, Engineers as responsible experimenters	**9**
2	**BIOETHICS** Human dignity and human rights – Benefit and harm, Autonomy and individual responsibility, Persons without the capacity to consent, Privacy and confidentiality, Equality, justice and equity, Non-discrimination and no stigmatization, Respect for cultural diversity and pluralism, Social responsibility and health, Protection of the environment, the biosphere and biodiversity	**9**
3	**STANDARDS FOR MEDICAL DEVICES** Need for standards, 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, FDA, ASTM, International, CE, and IEC	**6**
4	**Introduction to Intellectual Property Rights (IPR):** Meaning of IPR, Different category of IPR instruments - Patents, Trademarks, Copyrights, Industrial Designs, Plant variety protection, Geographical indications, Transfer of technology etc. **Importance of IPR in Modern Global Economic Environment:** Theories of IPR, Philosophical aspects of IPR laws, Need for IPR, IPR as an instrument of development.	**6**
5	**Emerging Issues in IPR:** Challenges for IP in digital economy, e-commerce, human genome, biodiversity and traditional knowledge etc. **Basics of Patents:** Definition of Patents, Conditions of patentability, Patentable and non-patentable inventions, Types of patent applications (e.g. Patent of addition etc.), Process Patent and Product Patent, Precautions while patenting, Patent specification Patent claims, Disclosures and non-disclosures, Patent rights and infringement, Method of getting a patent	**9**
6	**Procedure for Filing a Patent (National and International):** Legislation and Salient Features, Patent Search, Drafting and Filing Patent Applications, Processing of patent, Patent Litigation, Patent Publication etc., Time frame and cost, Patent Licensing, Patent Infringement	**6**

Reference Books

1.	Govindarajan M- Natarajan S- Senthil Kumar V- S- "Engineering Ethics", Prentice Hall of India- New Delhi- 2004.
2.	R.S Nagarazan -"A textbook on Professional Ethics and Human Values" New Age International Publishers- New Delhi 2006.
3.	Charles D- Fleddermann, "Engineering Ethics", Pearson Education / Prentice Hall, New Jersey- 2004 (Indian Reprint).
4.	Mike Martin and Roland Schinzinger- "Ethics in Engineering"- Tata McGraw-Hill- 996-3 e.
5.	Handbook of Medical Device Regulatory affairs in Asia – Jack Wong, Raymond K. Y. Tong, Pan Stanford Publishing
6.	Medical Devices: Regulations, Standards and Practices – Seeram Ramakrishna, Lingling Tian, Charelene Wang, Susan Liao and Wee Eong Teo, Woodhead publishing house
7.	Rajkumar S. Adukia, 2007, A Handbook on Laws Relating to Intellectual Property Rights in India, The Institute of Chartered Accountants of India
8.	Keayla B K, Patent system and related issues at a glance, Published by National Working Group on Patent Laws

9.	Kompal Bansal and Praishit Bansal, 2012, Fundamentals of IPR for Engineers, 1st Edition, BS Publications
10.	T Sengupta, 2011, Intellectual Property Law in India, Kluwer Law International
11.	Tzen Wong and Graham Dutfield,2010, Intellectual Property and Human Development: Current Trends and Future Scenario, Cambridge University Press