



EXCEL ENGINEERING COLLEGE

(Autonomous)

Approved by AICTE, New Delhi & Affiliated to Anna University, Chennai
Accredited by NBA(AERO,CSE,ECE&MECH), NAAC with "A+" and Recognised by UGC (2f &12B)

KOMARAPALAYAM - 637303

DEPARTMENT OF BIOMEDICAL ENGINEERING

7.1.9 - Sensitization of students and employees of the institution to constitutional obligations: values, rights, duties and responsibilities of citizens:

S.No	Title of the Programe	Date from	Date To	No. of Participants
1	20BM601 Medical Regulatory Affairs and Ethics	19.01.2024	30.04.2024	57
2	Awareness talk on "National Voter's Day"	29.01.2024	29.01.2024	105


Coordinator


HOD



20BM601	Medical Regulatory Affairs and Ethics	L	T	P	C
		3	0	0	3
Nature of course	Professional Core				
Pre requisites	Basics of Biomedical Engineering				

Course Objectives

1. To become Professionals in Regulatory affairs and in ensuring all Medical Devices to comply with regulations governing the Industry.
2. As Regulatory professionals in Industry and get involved with a wide range of medical devices made in various countries.
3. Know Regulatory processes in complexity, scope and globalization within the healthcare domain, matching Industry demand for Medical Devices regulatory affairs.
4. Familiarity with Regulatory Affairs provides with the specialized knowledge required to help biotechnology, medical device, pharmaceutical and food companies manage regulatory processes.
5. Understand Legal Law within medical practice including ethics in patient care.

Course Outcomes

On successful completion of the course, students will be able to

CO. No	Course Outcome	Bloom's Level
CO 1	Understand Medical Devices Regulatory Affairs and MDRA Basics	Understand
CO 2	Apply FDA / CDRH Functioning to Medical Device and In vitro diagnostics	Apply
CO 3	To perform biocompatibility Studies on Medical Devices and Clinical Investigation of Medical Devices	Analyze
CO 4	Understand General controls and Special Controls including Pre-market approval	Understand
CO 5	To know Law within medical practice and its issues in doctor-patient relationship	Understand

Course Contents

Unit – I	Introduction to Regulatory Affairs for Medical Devices	9
	Medical Devices Regulatory Affairs - MDRA Basic concepts - Overview of Regulatory Requirements: Medical Devices - Taxonomy of medical devices and their risk classes - The regulatory process Regulatory Affairs Pre-Clinical Trial-Clinical Trial-Regulatory Bodies in India Central Drug Regulatory System-Drug & Cosmetics Act-Medical Device Registration in India Product Development Protocol-Environmental Protection Act	
Unit – II	Medical Device and In Vitro Diagnostics	9
	IEC 60601-1 Classification of Medical Electrical Equipment- FDA / CDRH Functioning - Medical Device Classification -Types of devices including combination devices and Drug Vs device Vs IVD, Medical Device Rules, 2017: Implications on medical devices, Devices / Device Panels / Regulation Product Codes, 21 CFR Code for Federal Regulations- Parts 800-1299.	
Unit – III	Standards of Medical Device, Quality Assurance, and Testing	9
	Biocompatibility Studies on Medical Devices, Clinical Investigation of Medical Devices - Quality Assurance and Quality Management System: ISO9000 and ISO13485 - Risk management: ISO14971- Distinct Product Code Identification Procedure- Total Product Life Cycle (TPCL) / TPCL Product Code Report - Labeling of medical devices-ISO 13485:2016 complaint handling procedure.	
Unit – IV	Manufacture of Medical Devices and IVDs	9
	General controls and Special Controls-Pre-market approval - PMA-Adulteration-Misbranding-Electronic Establishment Registration-Obtaining a license to manufacture a medical device- Risk Management System for medical devices (ISO 14971) - Inspection of medical device and IVD establishments, Import and export of medical devices and IVDs, Medical device regulation: in India and International practices	


 CHAIRMAN - BOARD OF STUDIES

Unit – V Medical Ethics

9

Introduction to ethics - Law within medical practice- Issues in the doctor- patient relationship- Ethico- legal issues by medical specialism- Statutory provisions - Regulation of human tissue- The definition of mental disorder under the Mental Health Act

Total: 45 Periods

Text Books

1. Jack Wong, Raymond Tong "Medical Regulatory Affairs: An International Handbook for Medical Devices and Healthcare Products" Jenny Stanford Publishing, 2022
2. Anna Smajdor, Jonathan Herring, Robert Wheeler "Oxford Handbook of Medical Ethics and Law" OUP Oxford, 2022

Reference Books

1. Douglas J. Pisano, David Mantus " FDA Regulatory Affairs- A Guide for Prescription Drugs, Medical Devices, and Biologics" Informa Healthcare, 2003
2. Stephen Amato, Bob Ezzell "Regulatory Affairs for Biomaterials and Medical Devices" Woodhead Publishing, 2014
3. John Harris, "The Value of Life- An Introduction to Medical Ethics" Routledge, 1990

Additional / Web References

1. <https://www.biomedicalviews.com/>
2. <https://www.biomedicalviews.com/search/label/ISO%2013485%3A2016>

Mapping of Course Outcomes (COs) with Programme Outcomes (POs) Programme Specific Outcomes (PSOs)															
COs	POs												PSOs		
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3
CO1	3	2	2	2										2	
CO2	3	2	2	2										2	
CO3	3	3	2	2										3	
CO4	3	3	2	2										3	
CO5	3	3	2	2										3	
	3	High				2	Medium					1	Low		

Formative assessment			
Bloom's Level	Assessment Component	Marks	Total marks
Analyze	Classroom or Online Quiz	5	15
Understand	Assignment	10	


CHAIRMAN - BOARD OF STUDIES



EXCEL ENGINEERING COLLEGE (Autonomous)

Approved by AICTE, New Delhi & Affiliated to Anna University, Chennai
Accredited by NBA(AERO, CSE, ECE&MECH), NAAC with "A+" and Recognised by UGC (2f & 12B)

KOMARAPALAYAM - 637303

DEPARTMENT OF BIOMEDICAL ENGINEERING

Subject Code : 20BM601

Subject Name : Medical Regulatory Affairs and Ethics

Faculty Name : Santhiya.R

S.No	Register Number	Name	Remarks
1	730921121001	Abinaya K	
2	730921121002	Ajai S V	
3	730921121003	Ajay Kumar M	
4	730921121004	Balaji S	
5	730921121006	Dhanush K	
6	730921121007	Dhanu Sri J	
7	730921121008	Dharunsankar M	
8	730921121010	Dinesh R	
9	730921121011	Divya Bharathi R	
10	730921121012	Duraipandi S	
11	730921121013	Giri R	
12	730921121014	Gnanaselvi R	
13	730921121016	Gopinath P	
14	730921121017	Gowtham S	
15	730921121019	Harinisree M	
16	730921121020	Harishree A	
17	730921121021	Hemapriya S	
18	730921121022	Ibraheem I	
19	730921121023	Ilamathi R	
20	730921121024	Imrana Khatoon F	
21	730921121025	Kalaiselvan S	
22	730921121026	Karthik R	
23	730921121027	Kathiresan R	
24	730921121028	Kayal M	
25	730921121029	Lokesh Kannan S	
26	730921121030	Milan Kumar	
27	730921121031	Mohamed Jaseel Ck	
28	730921121032	Mohamed Nafal	
29	730921121033	Mohtashim Saqib M	
30	730921121034	Navin C	
31	730921121035	Nishanthini S	
32	730921121036	Palanivelu M	
33	730921121037	Pavithra M	
34	730921121038	Poovarasam G	
35	730921121039	Pradum Kumar R	
36	730921121040	Pranav N	
37	730921121042	Praveen Kumar S	

38	730921121041	Praveen S	
39	730921121045	Roshnipriya S	
40	730921121046	Sakthi Palanivel S	
41	730921121047	Santhosh S	
42	730921121048	Satheesh Kumar A	
43	730921121049	Selva Karthiga T	
44	730921121050	Sibiraj S	
45	730921121051	Sowbarnika S	
46	730921121052	Sowmiya M	
47	730921121053	Sushil Kumar R	
48	730921121054	Umar Kathaf A	
49	730921121055	Umesh U	
50	730921121056	Vanitha P	
51	730921121057	Vedhashini R	
52	730921121058	Venu Krishnan B	
53	730921121059	Vidhyasri M	
54	730921121060	Vignesh K	
55	730921121301	Nithin R	
56	730921121302	Sethu Radhakrishnan	
57	730922121062	Sangishwaran M.V	


SUBJECT INCHARGE


HOD



EXCEL ENGINEERING COLLEGE

(Autonomous)

Approved by AICTE, New Delhi & Affiliated to Anna University, Chennai

Accredited by NBA(AERO, CSE, ECE & MECH), NAAC with "A+" and Recognised by UGC (2f & 12B)

KOMARAPALAYAM - 637303

24.01.2024

DEPARTMENT OF BIOMEDICAL ENGINEERING

Circular

Our department is planned to conduct **Awareness talk on " National Voter's Day"** on 29.01.2024 (Monday) at 09.30 am-12.30 pm at APJ Hall. The resource person will be DR. B. Balasubramanian, HOD/BME, AP/BME at Excel Engineering College. We request all the students for kind co-operation to conduct the event in an effective manner. On behalf of our Department, all the students are invited.

HOD /BME

To

1. Department Notice Board

Copy To,

1. Circulated to all faculty members
2. File

EEC/2024-25/ODD/BME/SD-NT/ACT-04



ENGINEERING COLLEGE - AUTONOMOUS

Approved by AICTE, New Delhi & Affiliated to Anna University, Chennai | Accredited by NBA
(AERO, MECH, CSE & ECE), NAAC (A+Grade - 3.26) and Recognized by UGC (2f & 12B)

Komarapalayam - 637 303, Namakkal District, Tamil Nadu

Date

29.01.2024
Monday

Time

9.30am -12.30pm



DEPARTMENT OF BIOMEDICAL ENGINEERING

Awareness talk on National Voter's Day

Chief Guest



Dr. B. Balasubramanian

HoD / BME
Excel Engineering College
Komarapalayam, Namakkal District.

Venue

Dr. A.P.J Abdul Kalam Hall A/C

PROGRAM CO ORDINATOR

R. Santhiya
Assistant Professor / BME

CONVENOR

Dr. B. Balasubramanian
Head of the Department

Dr. C. Karthikeyini
Director Academics

Dr. S. Anbu Karuppusamy
Director Administration

Dr. K. Bommanna Raja
Principal & Executive Director



EXCEL ENGINEERING COLLEGE

(Autonomous)

Approved by AICTE, New Delhi & Affiliated to Anna University, Chennai
Accredited by NBA (AERO, CSE, ECE & MECH), NAAC with "A+" and Recognised by UGC (2f & 12B)
KOMARAPALAYAM – 637303

DEPARTMENT OF BIOMEDICAL ENGINEERING

Awareness talk on " National Voter's Day"

We the department of Biomedical Engineering, Excel Engineering College have conducted a **Awareness talk on " National Voter's Day"** 29.01.2024 (Monday) at 09.30 am-12.30 pm at APJ Hall. The theme for India's National Voters' Day in 2024 is **"Nothing Like Voting, I Vote For Sure."** This theme reflects the Election Commission's goal to reinforce the significance of each vote and encourage active, responsible participation in the democratic process, particularly among the youth. DR. B. Balasubramanian, HOD/BME, gave awareness talk among students related to importance of voting. BME at Excel Engineering College Students got awareness about voting. Around 105 Biomedical engineering students attended the seminar.



July
HOD /BME



EXCEL ENGINEERING COLLEGE

(Autonomous)

Approved by AICTE, New Delhi & Affiliated to Anna University, Chennai
Accredited by NBA (AERO, CSE, ECE & MECH), NAAC with "A+" and Recognised by UGC (2f &12B)
KOMARAPALAYAM – 637303

DEPARTMENT OF BIOMEDICAL ENGINEERING

"NATIONAL VOTER DAY"

Students Participation list

We the department of Biomedical Engineering, Excel Engineering College have conducted a **Awareness talk on " National Voter's Day"** on 29.01.2024 (Monday) at 09.30 am-12.30 pm at APJ Hall.. The entire sessions were handled by **Dr.B.BALASUBRAMANIAN; HOD/BME.** Around 105 students attended the event.

S.No	Students Name	Remarks
1.	Abinaya K	
2.	Ajai S V	
3.	Ajay Kumar M	
4.	Balaji S	
5.	Dhanush K	
6.	Dhanu Sri J	
7.	Dharunsankar M	
8.	Dinesh R	
9.	Divya Bharathi R	
10.	Duraipandi S	
11.	Giri R	
12.	Gnanaselvi R	
13.	Gopinath P	
14.	Gowtham S	
15.	Harinisree M	
16.	Harishree A	
17.	Hemapriya S	
18.	Ibraheem I	
19.	Ilamathi R	
20.	Imrana Khaton F	
21.	Kalaiselvan S	
22.	Karthik R	

23.	Kathiresan R	
24.	Kayal M	
25.	Lokesh Kannan S	
26.	Milan Kumar	
27.	Mohamed Jaseel Ck	
28.	Mohamed Nafal	
29.	Mohtashim Saqib M	
30.	Navin C	
31.	Nishanthini S	
32.	Poovarasam G	
33.	Pradum Kumar R	
34.	Pranav N	
35.	Praveen Kumar S	
36.	Praveen S	
37.	Roshnipriya S	
38.	Sakthi Palanivel S	
39.	Santhosh S	
40.	Satheesh Kumar A	
41.	Selva Karthiga T	
42.	Sibiraj S	
43.	Sowbarnika S	
44.	Sowmiya M	
45.	Umesh U	
46.	Vanitha P	
47.	Vedhashini R	
48.	Venu Krishnan B	
49.	Vidhyasri M	
50.	Vignesh K	
51.	Nithin R	
52.	Sethu Radhakrishnan	
53.	Sangishwaran M.V	
54.	Aarthi K	
55.	Abinisha A	



EXCEL ENGINEERING COLLEGE

(Autonomous)

Approved by AICTE, New Delhi & Affiliated to Anna University, Chennai

Accredited by NBA (AERO, CSE, ECE & MECH), NAAC with "A+" and Recognised by UGC (2f & 12B)

KOMARAPALAYAM – 637303

56.	Abipriya T	
57.	Alen Sebastin	
58.	Aravinth N	
59.	Aswin G	
60.	Bhuvaneswari V	
61.	Deepalakshmi S	
62.	Deepika M	
63.	Devi Meenatchi G	
64.	Dhanush M	
65.	Dharunprakash S	
66.	Dhilipkumar M	
67.	Dinesh G	
68.	Durka M	
69.	Fareen N	
70.	Guna S	
71.	Jananayagan S	
72.	Jansirani S	
73.	Jaya N	
74.	Jeeva P	
75.	Kaviarasu V	
76.	Kavitha P	
77.	Kaviya S	
78.	Kishore A	
79.	Kokila M	
80.	Kumareesan S	
81.	Madheshwaran P	
82.	Mahendhiran S	
83.	Manav Melvin S	
84.	Manikandan S	
85.	Md Muzamil	

86.	Monika M.P	
87.	Mugesh M	
88.	Nilusiya Raai J	
89.	Pandidevi T	
90.	Pavithra M	
91.	Poovarasam N	
92.	Rajavelu V	
93.	Ramesh G	
94.	Ramya Shri S	
95.	Raqeeb Ul Masnaad K M	
96.	Raushani Bharati	
97.	Rubha Sri S	
98.	Sabishek R	
99.	Sasi Prakash S	
100.	Shanmugam M	
101.	Sumit Raj	
102.	Swetha S	
103.	Thamarai Selvan K	
104.	Vanitha M	
105.	Velan K	


HOD /BME