JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION'S

ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY

Approved by: Pharmacy Council of India, New Delhi &

Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.

Ethirmedu, B. Komarapalayam - 638183, Namakkal Dist. Tamilnadu, India.

Website: www.jkkmmrfpharmacy.edu.in / e.mail : principal@jkkmmrfpharmacy.edu.in

Contact No : +919789456750, +919943066944, +919943069944

Dr. N. SENTHILKUMAR, Ph.D.,
Principal

DATE: 10.07.2023

DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS

SEMINAR ON REGULATORY AFFAIRS PROFESSIONALS LEARN ABOUT THE REGULATION OF MEDICAL DEVICES AND COMBINATION PRODUCTS

REPORT

DATE: 07.07.2023 **VENUE: SEMINAR HALL**

RESOURCE PERSONS

Mr. K. JAGANATHAN M. PHARM,
ASSOCIATE PROFESSOR
DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS
JKKMMRF'S ANNAI JKK SAMPOORANI AMMALCOLLEGE OF PHARMACY, KOMARAPALAYAM.

2. Mrs. S. KAVIBHARATHI M. PHARM,
ASSISTANT PROFESSOR,
DEPARTMENT OF PHARMACEUTICS
JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY, KOMARAPALAYAM.

No. of students enrolled: 58 **No. of students certified: 58**

OBJECTIVE:

Regulatory affairs professionals focused on medical devices and combination products aim to ensure compliance with regulations and standards governing the development, manufacturing, and marketing of these products, **To Understanding Regulations, Ensuring Compliance, Facilitating Approvals, Risk Management, Cross-Functional Collaboration (quality assurance, clinical affairs, marketing teams to align product development with regulatory requirements), Staying Informed (keeping up-to-date with changes in regulations and industry), Advocating for Best Practices (to enhance product safety and efficacy).**

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY Komarapalayam 638 183

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ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

LEARNING OUTCOMES:

- **Regulatory Knowledge**: Understanding key regulations and standards that govern medical devices and combination products, including FDA and EMA requirements.
- **Submission Preparation**: Gaining skills in preparing and submitting regulatory documentation, such as 510(k)s, PMAs, and CE marking applications.
- **Compliance Expertise**: Developing the ability to assess and ensure compliance with applicable regulations throughout the product lifecycle.
- **Risk Assessment Skills**: Learning to identify, evaluate, and manage regulatory risks associated with product development and market entry.
- **Post-Market Surveillance**: Understanding the requirements for post-market monitoring and reporting, including adverse event reporting and vigilance.

PROGRAM CO-ORDINATOR **HEAD OF THE DEPARTMENT** **PRINCIPAL**

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Dr. N. SENTHILKUMAR, Ph.D.,
Principal

REF.NO: JKKM/PHARM RA/REG/REQ/2023/001 **Date: 30.06.2023**

From:

Department of Pharmaceutical regulatory affairs,
JKKMMRF'S Annai JKK Sampoorani Ammal College of Pharmacy.
Komarapalayam, Namakkal [Dist.]
Tamil Nadu, PIN: 638183.

To:

The Principal,
JKKMMRF'S Annai JKK Sampoorani Ammal College of Pharmacy.
Komarapalayam, Namakkal [Dist.]
Tamil Nadu, PIN: 638183.

Subject: Letter for requesting Permission to Conduct on two days seminar regarding: -

Respected Sir,

We are writing this letter to request permission to conduct a ONE-DAY SEMINAR in the **SEMINAR HALL** on **07.07.2023**. We wish to conduct seminar regarding the **REGULATORY AFFAIRS PROFESSIONALS LEARN ABOUT THE REGULATION OF MEDICAL DEVICES AND COMBINATION PRODUCTS.**

We request you to kindly permit to conduct seminar program as this would be a great opportunity for Students to learn and that would help a great deal to shape the students. Looking forward to hearing from you.

Looking forward for your approval.

Thank you

Yours sincerely,

HEAD OF THE DEPARTMENT

Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
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Dr. N. SENTHILKUMAR, Ph.D.,
Principal

DATE: **06.07.2023**

CIRCULAR

This is informed to the B. Pharm-IV Students that the following SEMINAR can be conducted by the Department of Pharmaceutical regulatory affairs, JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY, KOMARAPALAYAM and it will be commenced as per the schedule:

SEMINAR TITLE	SCHEDULE	VENUE	DURATION	SUB TOPICS	RESOURCE PERSON
Regulatory affairs professionals learn about the regulation of medical devices and combination products	**07.07.2023**	**SEMINAR HALL**	**FN (2 HOURS) 10.30 Am to 12.30 Pm**	Understanding key regulation from agencies like FDA, EMA and Global authorities.	**Mr. K. JAGANATHAN M. PHARM,**
			AN (2 HOURS) 2.00 Pm to 4 Pm	Familiarizing with risk assessment methodologies specific to medical devices.	**Mrs. S. KAVIBHARATHI M. PHARM**

TOTAL HOURS– 4 HOURS

All the above-mentioned students must enroll and actively participate in the course without fail.

NOTE: Certificates should be issued to all the students after completion of All session

PROGRAM CO-ORDINATOR **HEAD OF THE DEPARTMENT** **PRINCIPAL**

JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY Komarapalayam 638 183

Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATIO
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHAR
ETHIRMEDU, KOMARAPALAYAM - 638 18
NAMAKKAL DISTRICT, TAMILNADU.

ABOUT US

Mr.JKK Munirajah founder Trustee founded Annai JKK Sampoorani Ammal Charitable Trust during 1971. He established many temples of learning to perpetuate the ever lasting memory his beloved mother. Presently the trust is run by Mrs. Vasantha Kumari Munirajah as Managing Trustee and his son Mr. J.K.M. Jayaprakash as Correspondent. Trust runs. Paramedical Institutions offering Diploma, Graduate, Post Graduate & Ph.D. Courses and Research in Pharmacy, Nursing, Physiotherapy, Occupational Therapy & Allied Health Science at Komarapalayam, Namakkal District and also running Agriculture, Engineering, College of Education, Polytechnic, Community Polytechnic and an Industrial Training Centre and one more Pharmacy College at T.N.Palayam, Erode District. Also, the trust runs Matriculation School, Higher Secondary School for differently abled, deaf and dumb & mentally ill, Rehabilitation center for differently able children at Komarapalayam. These educational institutions are temples of learning and have contributed much to facilitate remarkable social changes in our society. The trust has won many national and state awards. These renowned Educational Institutions spared education to promote knowledge, wisdom and service-orientation.

Venue: Seminar Hall
Date: 07.07.2023

RESOURCE PERSONS

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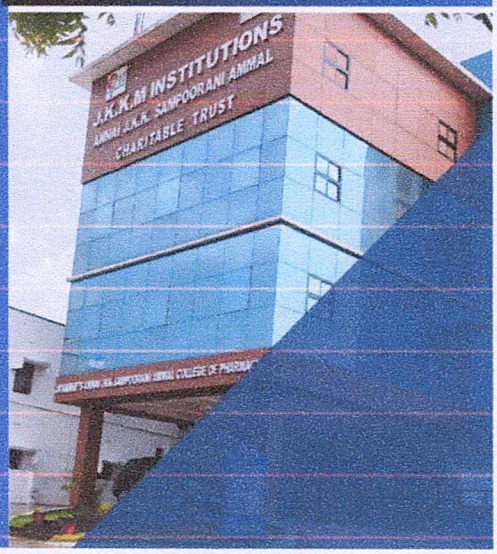
JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY.
KOMARAPALAYAM. 638-183

ONE DAY SEMINAR

TOPIC: Regulatory affairs professionals learn about the regulation of medical devices and combination products

Organized by

DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS AND INTERNAL QUALITY ASSURANCE CELL



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DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS

ABOUT THE SEMINAR

ONE-DAY SEMINAR ON REGULATORY AFFAIRS PROFESSIONALS LEARN ABOUT THE REGULATION OF MEDICAL DEVICES AND COMBINATION PRODUCTS.

As per International Medical Device Regulators Forum (IMDRF) 'Medical Device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes.

A device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals.

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; diagnosis, monitoring, treatment, alleviation or assistance for any injury or disability; investigation, replacement or modification or support of the anatomy or of a physiological process; supporting or sustaining life; disinfection of medical devices; control of conception. Risk management for medical devices helps manufacturers identify potential hazards and assess the associated risks to take steps to reduce those risks.

The formal definition of risk management according to ISO 14971 is The systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk. The definition from ISO 14971 is, of course, technically correct but hard to remember.

A more straightforward way of expressing what risk management is would be to say that it is: "The systematic and continuous work to reduce risk." "Systematic" because if you work systematically, the risk will be reduced, and you will likely reach most of the goals you have set. "Continuous" because risk management does not end when you have developed your product. The process should go on until your product is no longer used. "Reduce risk" because this is what risk management is all about: reducing risk. The goal of risk management is to **create safe products**. Many people define "safe" or "safety" as "free from risk," but no medical device is entirely free from risk.

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Principal

DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS

STUDENT FEEDBACK FORM

NAME OF STUDENT:
COURSE: **YEAR & SEMESTER:**
SEMINAR TOPIC: **DATE & TIME:**

1. **Overall, how satisfied were you with this seminar?**
   - Very satisfied
   - Satisfied
   - Neutral
   - Dissatisfied
   - Very dissatisfied

2. **How clear were the ideas and concepts we presented?**
   - Extremely clear
   - Very clear
   - Moderately clear
   - Not very clear
   - Not at all clear

3. **What percentage of the information was new to you?**
   - 100%
   - 75%
   - 50%
   - 25%

4. **How informative did you find our seminar?**
   - Extremely Informative
   - Very Informative
   - Moderately Informative
   - Not very informative
   - Not informative at all

5. **Were there any technical issues that prevented you from seeing or hearing the seminar?**

- Yes
- No

6. **Would you like to learn more about this topic?**

- Yes
- No

7. **Rate the content of the slides/virtual aid?**

- Extremely clear
- Very clear
- Moderately clear
- Not very clear
- Not at all clear

8. **How accurate was the session description?**

- Extremely clear
- Very clear
- Moderately clear
- Not very clear
- Not at all clear

9. **How did the session compare to your expectations?**

- Excellent
- Good
- Fair
- Poor
- Not at all clear

10. **How would you rate the content of the seminar?**

- 1
- 2
- 3
- 4
- 5

Student Name with Signature

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DEPARTMENT OF PHARMACEUTICAL CHEMISTRY

SEMINAR FEEDBACK FORM

STUDENT NAME: DATE:

YEAR/ COURSE:

NAME OF THE SEMINAR: DURATION:

EVALUATE HONESTLY:

Questions	Excellent	Good	Fair	Poor
The objectives of the training were				
The instructor's contribution to the course was:				
The presentation materials were relevant				
The instructor's effectiveness in teaching the subject matter was:				
Answers to the students questions by the instructor				
The venue was appropriate for the event				
Course organisation was:				
Level of course was				
Course content was:				

Student Participation

1. On average, how many hours a week did you spend on this course (in and out of class)?
   A)0-2 B) 2-5 C)6-10 D)11-14 E)15UP
2. What grade do you expect in this course?
   A)BELOW 50% B) 50-60% C) 60-70% D) 70-80% E) ABOVE 80%

SIGNATURE OF STUDENT

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DATE: 07.07.2023

REPORT SUMMARY

Duration of the Course	4 HOURS
Total participants Enrolled	58
Successfully Completed	58
Type of Feedback Assessment	Multiple Choice Questions (MCQ's)
Course Outcome	• **Regulatory Knowledge**: Understanding key regulations and standards that govern medical devices and combination products, including FDA and EMA requirements. • **Submission Preparation**: Gaining skills in preparing and submitting regulatory documentation, such as 510(k)s, PMAs, and CE marking applications. • **Compliance Expertise**: Developing the ability to assess and ensure compliance with applicable regulations throughout the product lifecycle. • **Risk Assessment Skills**: Learning to identify, evaluate, and manage regulatory risks associated with product development and market entry. • **Post-Market Surveillance**: Understanding the requirements for post-market monitoring and reporting, including adverse event reporting and vigilance.

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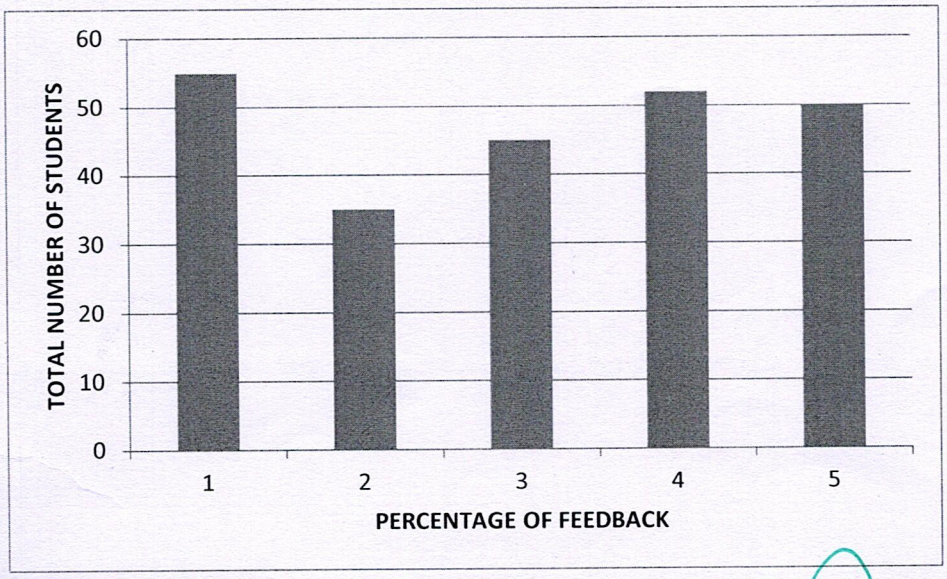
Feedback Question Analysis – Question Asked-Feedback Rating

1. Satisfaction	6. Like to learn more about this topic
2. Clarity	7. Rate the content of the slides/virtual aid
3. Percentage of the information was new	8. Accuracy of the sessions
4. Informative	9. Session expectations
5. Technical issues	10. Rate the content of the seminar



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DATE: 07.07.2023

STUDENTS FEEDBACK ANALYSIS

S.NO	QUESTION DESCRIPTION	ANSWERS	MARKS	TOTAL MARKS
1	Satisfaction	Very satisfied	5	5
		Satisfied	3	
		Neutral	2	
		Dissatisfied	1	
		Very dissatisfied	0	
2	Clarity	Extremely clear	5	5
		Very clear	4	
		Moderately clear	2	
		Not very clear	1	
		Not at all clear	0	
3	The percentage of the information was new	100%	5	5
		75%	4	
		50%	3	
		25%	2	
		0%	1	
4	Informative	Extremely Informative	5	5
		Very Informative	3	
		Moderately Informative	2	
		Not very informative	1	
		Not informative at all	0	
5	Technical issues	Yes	5	5
		No	0	
6	Like to learn more about this topic	Yes	5	5

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		No	0	
7	Rate the content of the slides/virtual aid	Extremely clear	5	5
		Moderately clear	2	
		Not very clear	1	
		Not at all clear	0	
8	Accuracy of the sessions	Extremely clear	5	5
		Very clear	3	
		Moderately clear	2	
		Not very clear	1	
		Not at all clear	0	
9	Session expectations	Excellent	5	5
		Good	3	
		Fair	2	
		Poor	1	
		Not at all clear	0	
10	Rate the content of the seminar	1	1	5
		2	2	
		3	3	
		4	4	
		5	5	

Total marks = 50

PROGRAM CO-ORDINATOR **HEAD OF THE DEPARTMENT** **PRINCIPAL**

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Dr. N. SENTHILKUMAR, Ph.D.,
Principal

LIST OF PARTICIPANTS

S.no	Name	Year
1.	KUPENDRAN S	IV B.PHARM
2.	LINDA DINOLIN B A	IV B.PHARM
3.	LOGESH S	IV B.PHARM
4.	MANOJ K	IV B.PHARM
5.	MARIYA BENIT D	IV B.PHARM
6.	MATHAN RAJ R	IV B.PHARM
7.	MEGAVARSHINI V G	IV B.PHARM
8.	MEIYARASAN K	IV B.PHARM
9.	MOHAN M	IV B.PHARM
10.	MUGILARASU S	IV B.PHARM
11.	NANDHAKUMAR T	IV B.PHARM
12.	NAVEENKUMAR T	IV B.PHARM

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13.	NAWIN S	IV B.PHARM
14.	NIDESHWAR G	IV B.PHARM
15.	PARAMESH K	IV B.PHARM
16.	POORNIMA D	IV B.PHARM
17.	PRABHAKARAN P	IV B.PHARM
18.	PRAKASH S R	IV B.PHARM
19.	PRIYADHARSHINI P	IV B.PHARM
20.	RAJESHKUMAR R	IV B.PHARM
21.	RANJITH R	IV B.PHARM
22.	SABARINATHAN M	IV B.PHARM
23.	SANTHOSH S	IV B.PHARM
24.	SARAN S	IV B.PHARM
25.	SARANYA S	IV B.PHARM
26.	SATHIYANARAYANAN M	IV B.PHARM
27.	SHIVA G	IV B.PHARM

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28.	SHIVAGURU M	IV B.PHARM
29.	SOWMIYA J	IV B.PHARM
30.	SRINITHI N	IV B.PHARM
31.	SURENDHAR J	IV B.PHARM
32.	SURYASUGANTHAN D	IV B.PHARM
33.	SUSIENDRAN CHANDRAN	IV B.PHARM
34.	TAMILAMUTHAN S J	IV B.PHARM
35.	THARAKESH S	IV B.PHARM
36.	THARUN R	IV B.PHARM
37.	THIRUMURUGAN D	IV B.PHARM
38.	UDHAYAKUMAR S	IV B.PHARM
39.	VAISHNAVI V	IV B.PHARM
40.	VARUNKUMAR S	IV B.PHARM
41.	VEERAYUVARAJ P	IV B.PHARM
42.	VENKATESH G	IV B.PHARM
43.	VENKATESH S	IV B.PHARM

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44.	VIGNESH K	IV B.PHARM
45.	VIGNESH R	IV B.PHARM
46.	VIGNESHWARAN R	IV B.PHARM
47.	VIJAY R	IV B.PHARM
48.	VISHWA S	IV B.PHARM
49.	YASAR ARAFATH H	IV B.PHARM
50.	ARULKUMAR G	IV B.PHARM
51.	BALAMURUGAN S	IV B.PHARM
52.	HEMAVARSHINY K	IV B.PHARM
53.	KANNAN M	IV B.PHARM
54.	KARTHIK K	IV B.PHARM
55.	LOKESH R	IV B.PHARM
56.	NAVEENKUMAR M	IV B.PHARM
57.	PONNUVEL M	IV B.PHARM
58.	PRABHU M	IV B.PHARM

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Approved by: Pharmacy Council of India, New Delhi &

Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.

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Dr. N. SENTHILKUMAR, Ph.D.,
Principal

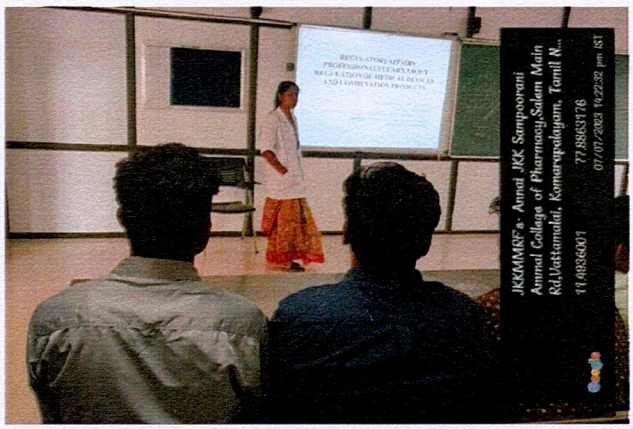
SEMINAR PHOTOS

Title: Understanding key regulation from agencies like FDA, EMA and Global authorities.

Resource person speech with students

Title: Familiarizing with risk assessment methodologies specific to medical devices.

Resource person explaining the topic



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ONE DAY SEMINAR ON

TOPIC: REGULATORY AFFAIRS PROFESSIONALS LEARN ABOUT THE REGULATION OF MEDICAL DEVICES AND COMBINATION PRODUCTS

ORGANIZED BY

DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS AND INTERNAL QUALITY ASSURANCE CELL

CERTIFICATE OF PARTICIPATION

This certify that Mr./ Ms./ Mrs./ Dr. _____ has participated in One Day Seminar on Regulatory affairs professionals learn about the Regulation of Medical Devices and Combination Products held on 07.07.2023.

Organizing Secretary

Convenor

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