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.

Accredited by NAAC "A" Grade and ISO Certified

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: 12.03.2024

DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS

SEMINAR TITLE: REGULATORY AFFAIRS PROFESSIONALS LEARN ABOUT THE REGULATORY REQUIREMENTS AND APPROVAL PROCEDURE FOR DRUGS.

REPORT

Date: 10.03.2024 **VENUE: SEMINAR HALL**

RESOURCE PERSONS

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

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

No. of students enrolled: 47 **No. of students certified: 47**

OBJECTIVE:

Regulatory Affairs (RA) professionals learning about **regulatory requirements and approval procedures for drugs** is to ensure that pharmaceutical products are developed, manufactured, and distributed in compliance with the regulations and guidelines of health authorities, **Understanding Regulatory Frameworks, Facilitating Drug Development, Efficient Approval Process, Compliance with Good Practices, Mitigation of Risks, Post-Market Surveillance, Global Market Access, Promoting Ethical Standards.**

Learning outcomes:

- **Proficiency in Drug Development and Approval Processes**: Demonstrate knowledge of the regulatory approval pathways for different types of drugs (e.g., NDAs, ANDAs, biologics, generics).
- **Regulatory Compliance** Identify and apply Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP) to ensure quality and safety.
- **Global Regulatory Strategies** Develop strategies to meet regulatory requirements in multiple jurisdictions for global market access.
- **Document Preparation and Submission** Gain expertise in preparing and compiling regulatory documents, including Investigational New Drug (IND) applications, Common Technical Documents (CTDs), and Marketing Authorization Applications (MAAs).
- **Post-Market Surveillance**: Understand requirements for post-market surveillance, including pharmacovigilance, product recalls, and updates to labeling or packaging. Ensure compliance with ongoing reporting obligations to regulatory agencies.

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

Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.

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

REF.NO: JKKM/PHARM RA/REG/REQ/2024/002 **Date: 04.03.2024**

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 **10.03.2024**. We wish to conduct seminar regarding the **Regulatory affairs professionals learn about the Regulatory requirements and approval procedure for drugs.**

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: 10.3.2024

CIRCULAR

This is informed to the M.PHARM STUDENTS OF PHARMACEUTICS AND PHARMACEUTICAL REGULATORY AFFAIRS 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 Regulatory requirements and approval procedure for drugs.	08.03.2024	SEMINAR HALL	FN (2 HOURS) 10.30 Am to 12.30 Pm	❖ Introduction to Intellectual Property Rights (IPR). ❖ Types of IPR Relevant to Pharmaceuticals ❖ Regulatory-Driven IP Considerations	Mr. K. JAGANATHAN M. PHARM,
			AN (2 HOURS) 2.00 Pm to 4 Pm	❖ Compulsory Licensing and Patent Limitations ❖ Generic Drugs and Patent Challenges ❖ Collaboration Between IPR and Regulatory Affairs	Mrs. S. SANGEETHA 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 the all session.

PROGRAM COORDINATOR **HOD** **PRINCIPAL**

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

Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
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: 10.03.2024

RESOURCE PERSONS

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

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

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

ONE DAY SEMINAR

ORGANIZED BY

DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS AND INTERNAL QUALITY ASSURANCE CELL

TOPIC: REGULATORY AFFAIRS PROFESSIONALS LEARN ABOUT THE REGULATORY REQUIREMENTS AND APPROVAL PROCEDURE FOR DRUGS

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638 183

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Principal

DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS

ABOUT THE SEMINAR

ONE-DAY SEMINAR ON: REGULATORY AFFAIRS PROFESSIONALS LEARN ABOUT THE REGULATORY REQUIREMENTS AND APPROVAL PROCEDURE FOR DRUGS.

A seminar on "Regulatory Requirements and Approval Procedures for Drugs" is an essential learning opportunity for regulatory affairs professionals, equipping them with the knowledge and skills needed to navigate the complex and ever-evolving landscape of drug development and compliance. This seminar focuses on the critical role regulatory affairs play in ensuring that pharmaceutical products meet stringent safety, efficacy, and quality standards while adhering to local and international guidelines. Participants are introduced to the key regulatory frameworks governing drug approval, including the FDA in the United States, EMA in Europe, MHRA in the UK, and agencies in other regions like India, Japan, and China. A significant portion of the seminar is dedicated to understanding the drug development process, starting from preclinical research and clinical trials to the preparation and submission of regulatory dossiers, such as the Common Technical Document (CTD) and its electronic version (eCTD).

Through practical insights and case studies, attendees learn about critical submission milestones, such as Investigational New Drug (IND) applications, New Drug Applications (NDA), and Marketing Authorization Applications (MAA), along with fast-track and priority review pathways for innovative therapies. The seminar emphasizes the importance of region-specific compliance while also addressing global harmonization efforts led by organizations like the International Council for Harmonisation (ICH). Additionally, emerging trends such as the integration of digital tools in regulatory submissions, advancements in personalized medicine, and the regulatory challenges associated with biosimilars and gene therapies are explored. By participating, professionals gain a deeper understanding of regulatory strategies, enabling them to manage submissions efficiently, mitigate risks, and achieve timely drug approvals. This seminar not only enhances theoretical knowledge but also offers actionable insights that empower attendees to drive success in regulatory compliance and ensure patient access to safe and effective drugs worldwide.

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DEPARTMENT OF PHARMACEUTICAL REGULATORY AFFAIRS

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%

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SIGNATURE OF STUDENT

Dr. N.SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
ETHIRMEDU, KOMARAPALAYAM - 638 183,
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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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Principal

DATE: 10.03.2024

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**
		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	

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

Dr. N.SENTHILKUMAR,
PRINCIPAL,
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ANNAI JKK SAMPOORANI AMMALCOLLEGE OF PHARMA
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Principal

10.03.2024

REPORT SUMMARY

Duration of the Course	4 HOURS
Total participants Enrolled	47
Successfully Completed	47
Type of Feedback Assessment	Multiple Choice Questions (MCQ's)
Course Outcome	• **Proficiency in Drug Development and Approval Processes**: Demonstrate knowledge of the regulatory approval pathways for different types of drugs (e.g., NDAs, ANDAs, biologics, generics). • **Regulatory Compliance** Identify and apply Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP) to ensure quality and safety. • **Global Regulatory Strategies** Develop strategies to meet regulatory requirements in multiple jurisdictions for global market access. • **Document Preparation and Submission** Gain expertise in preparing and compiling regulatory documents, including Investigational New Drug (IND) applications, Common Technical Documents (CTDs), and Marketing Authorization Applications (MAAs). • **Post-Market Surveillance**: Understand requirements for post-market surveillance, including pharmacovigilance, product recalls, and updates to labeling or packaging. Ensure compliance with ongoing reporting obligations to regulatory agencies.

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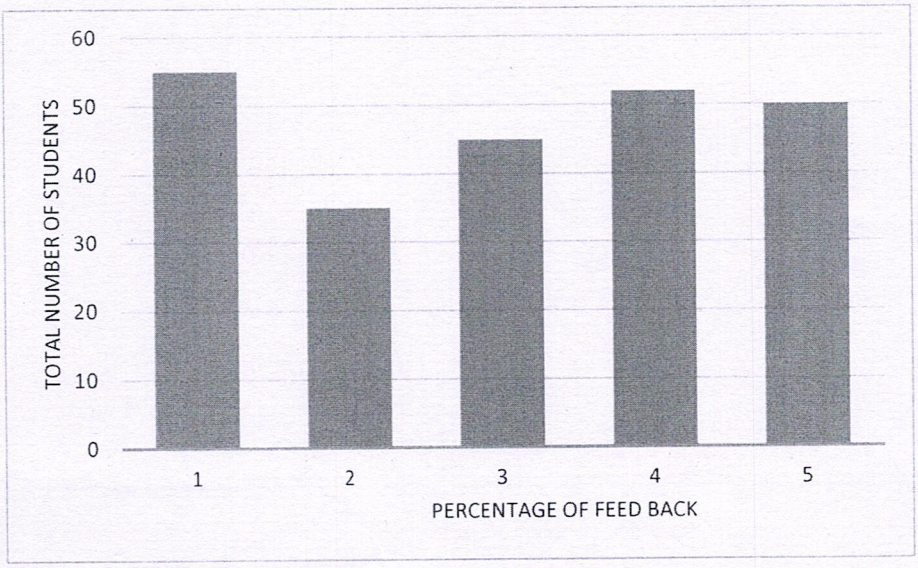
Feedback Question Analysis – Question Asked-Feedback Rating

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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LIST OF PARTICIPANTS

S.NO	NAME	YEAR
1.	CHANDRU D	M.PHARM (III RD SEM PHARMACEUTICS)
2.	GOWTHAM M	M.PHARM (III RD SEM PHARMACEUTICS)
3.	KALAIYARASI R	M.PHARM (III RD SEM PHARMACEUTICS)
4.	KOTHAI S	M.PHARM (III RD SEM PHARMACEUTICS)
5.	MANI BHARATHI P	M.PHARM (III RD SEM PHARMACEUTICS)
6.	MOHAMMED AABITH M	M.PHARM (III RD SEM PHARMACEUTICS)
7.	MOHANA KANNAN M	M.PHARM (III RD SEM PHARMACEUTICS)
8.	NAVEEN KUMAR M	M.PHARM (III RD SEM PHARMACEUTICS)
9.	PRASANTH R	M.PHARM (III RD SEM PHARMACEUTICS)
10.	VATHENDIRAN S	M.PHARM (III RD SEM PHARMACEUTICS)
11.	AVINASH V	M.PHARM (III RD SEM PHARMACEUTICS)
12.	BHAVATHARANI R	M.PHARM (I ST SEM PHARMACEUTICS)
13.	CHANDAN KUMAR V	M.PHARM (I ST SEM PHARMACEUTICS)
14.	DEEPAPRIYA K	M.PHARM (I ST SEM PHARMACEUTICS)
15.	HARIHARAN M	M.PHARM (I ST SEM

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		PHARMACEUTICS)
16.	KAVIN V R	M.PHARM (IST SEM PHARMACEUTICS)
17.	KIRUTHIKA K	M.PHARM (IST SEM PHARMACEUTICS)
18.	MONISHA J	M.PHARM (IST SEM PHARMACEUTICS)
19.	NANDHINI J	M.PHARM (IST SEM PHARMACEUTICS)
20.	NIVEDHA S	M.PHARM (IST SEM PHARMACEUTICS)
21.	PRADEEP S	M.PHARM (IST SEM PHARMACEUTICS)
22.	RASIGA S	M.PHARM (IST SEM PHARMACEUTICS)
23.	RENUGA R	M.PHARM (IST SEM PHARMACEUTICS)
24.	SELVAMANI R	M.PHARM (IST SEM PHARMACEUTICS)
25.	SENTHIL KUMAR S	M.PHARM (IST SEM PHARMACEUTICS)
26.	SESHAGIRIVASAN K	M.PHARM (IST SEM PHARMACEUTICS)
27.	ANBUDURAI S	M.PHARM (III RD SEM REGULATORY AFFAIRS)
28.	DURAI K	M.PHARM (III RD SEM REGULATORY AFFAIRS)
29.	RAGHU A	M.PHARM (III RD SEM REGULATORY AFFAIRS)
30.	SILAMBARASAN D	M.PHARM (III RD SEM REGULATORY AFFAIRS)

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NAMAKKAL DISTRICT, TAMILNADU.

31.	SWARNAMBIGAI J	M.PHARM (III RD SEM REGULATORY AFFAIRS)
32.	VINOTHKUMAR V	M.PHARM (III RD SEM REGULATORY AFFAIRS)
33.	ARAVINTHRAJ U	M.PHARM (I ST SEM REGULATORY AFFAIRS)
34.	AYESHA THASNEEM V M	M.PHARM (I ST SEM REGULATORY AFFAIRS)
35.	BRUNDHA R	M.PHARM (I ST SEM REGULATORY AFFAIRS)
36.	DINESH S	M.PHARM (I ST SEM REGULATORY AFFAIRS)
37.	ELAVARASAN P	M.PHARM (I ST SEM REGULATORY AFFAIRS)
38.	GOPINATH P	M.PHARM (I ST SEM REGULATORY AFFAIRS)
39.	JAYAPRIYA R	M.PHARM (I ST SEM REGULATORY AFFAIRS)
40.	JEGANATHAN B	M.PHARM (I ST SEM REGULATORY AFFAIRS)
41.	JOHN PAUL E	M.PHARM (I ST SEM REGULATORY AFFAIRS)
42.	KARTHIKEYAN S	M.PHARM (I ST SEM

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		REGULATORY AFFAIRS)
43.	MAHAVISHNU J	M.PHARM (IST SEM REGULATORY AFFAIRS)
44.	RANJITH R	M.PHARM (IST SEM REGULATORY AFFAIRS)
45.	ROHIT SUNDHAR S	M.PHARM (IST SEM REGULATORY AFFAIRS)
46.	SNEHA A	M.PHARM (IST SEM REGULATORY AFFAIRS)
47.	VIJAY A	M.PHARM (IST SEM REGULATORY AFFAIRS)

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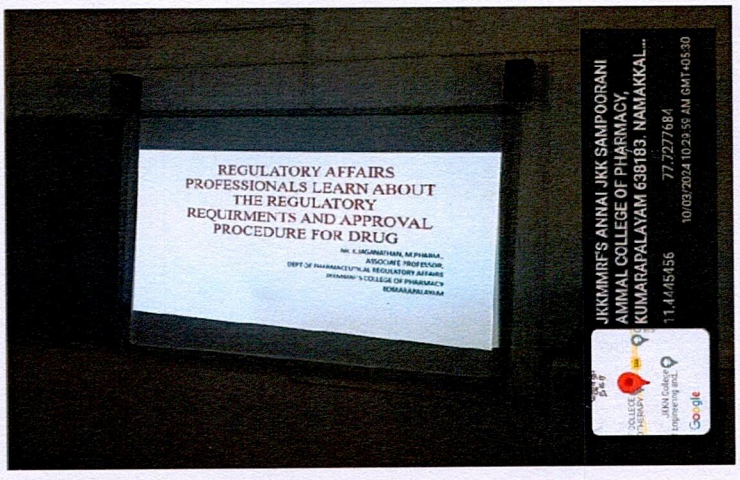
Dr. N. SENTHILKUMAR, Ph.D.,
Principal

Date: 10/3/2024

SEMINAR PHOTOS

Title: Introduction to Intellectual Property Rights (IPR), Types of IPR Relevant to Pharmaceuticals and Regulatory-Driven IP Considerations
Resource Person Speech with Students



Title: Compulsory Licensing and Patent Limitations, Generic Drugs and Patent Challenges and Collaboration between IPR and Regulatory Affairs
Resource Person Speech with Students

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ONE DAY SEMINAR ON

TOPIC: Regulatory affairs professionals learn about the Regulatory requirements and approval procedure for drugs.

ORGANIZED BY

DEPARTMENT OF PHARAMACEUTICAL 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 Regulatory requirements and approval procedure for drugs held on 10.03.2024.

Organizing Secretary

Convenor

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