

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

Ethirmedi, 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: 8.12.2023

DEPARTMENT OF PHARMACEUTICS REPORT

SEMINAR ON REGULATORY FRAMEWORKS AND LEGAL CONSIDERATIONS FOR PHARMACEUTICAL START-UPS RESOURCE PERSONS

1. Mr. K. JAGANATHAN. M. PHARM.,

ASSOCIATE PROFESSOR,

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
KOMARAPALAYAM

2. Mrs S. KAVI BHARATHI., M.Pharm.,

ASSISTANT PROFESSOR,

DEPARTMENT OF PHARMACEUTICS,

JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY,
KOMARAPALAYAM.

No. of students enrolled: 46

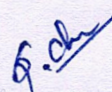
No. of students certified: 44

Objective:

The healthcare imperatives and the resultant laws and regulations around health in India are unique. In the absence of any significant reimbursement or insurance system in place, the focus of successive Indian governments has been on achieving significant reductions in out-of-pocket expenditure on healthcare and drugs. Drug prices and affordable healthcare have been an integral part of campaign rhetoric in general and state elections since 2014. The issue of affordable healthcare and the disproportionate focus on prices of drugs and devices have been occupying a progressively larger space in the political and media area

Learning outcomes:

Pharmaceutical regulations across the world play an important role in ensuring the safety and efficacy of the approved drugs. They not only regulate the pricing of drugs but the quality as well. The regulations are required both for new innovations and already existing products, in order to improve health status. Both products which are produced domestically and those imported from other countries require regulation. Every country has its own regulations which apply to innovation, manufacturing, drug testing, marketing, and post marketing studies. The aim is to maintain the standards of the drug at every step to cater for the patient population of each country. This chapter focuses on the pharmaceutical regulations of India.


Head of the Department


Co-Ordinator


Principal

Dr. N. Senthilkumar,
Principal,

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ETHIRMEDU, KOMARAPALAYAM - 638 183,
NAMAKKAL DISTRICT, TAMILNADU.



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

REF.NO: JKKM/PHARM/CEU/REQ/2023/001

Date: 6.12.2023

From

Department of Pharmaceutics,
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 one day seminar regarding: -

Respected Sir,

We Are writing this letter to request permission to conduct a **ONE-DAY** seminar in the **SEMINAR HALL** on **8.12.2023** We wish to conduct seminar regarding "**REGULATORY FRAMEWORKS AND LEGAL CONSIDERATIONS FOR PHARMACEUTICAL START-UPS**". 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.

Thank you

Yours sincerely,

Dr.S. CHANDRA.,

Head of the Department
Department of pharmaceutics



Dr. N.SENTHILKUMAR,
PRINCIPAL,

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Principal

DATE: 6.12.2023

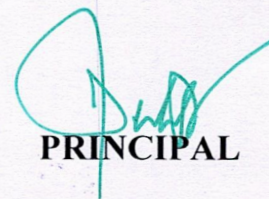
CIRCULAR

This is informed to the **M. Pharm (Pharmaceutics & Regulatory Affairs)** Students that the following SEMINAR can be conducted by the Department of Pharmaceutics, JKKMMRF'S ANNAI JKK SAMPOORANI AMMAL COLLEGE OF PHARMACY, KOMARAPALAYAM. and it will be commenced as per the schedule:

SEMINAR NAME	SCHEDULE	DURATION	VENUE	RESOURCE PERSON
"REGULATORY FRAMEWORKS AND LEGAL CONSIDERATIONS FOR PHARMACEUTICAL START-UPS".	8.12.2023	FN (10AM - 12PM)	SEMINAR HALL	Mr. K. JAGANATHAN
		& AN (2.30-4.30 PM)		Mrs S. KAVI BHARATHI

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 course and examination.


PRINCIPAL

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JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
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SYLLABUS

DATE	HOURS	SEMINAR TOPIC	SUB TOPICS	RESOURCE PERSON
08.12.2023	FN (10AM - 12PM) & AN (2.30-4.30 PM)	Regulatory frameworks and legal considerations for pharmaceutical start-ups	Regulatory frameworks and legal considerations in industries	Mr. K. JAGANATHAN
			Managing High Costs Associated with Regulatory Processes	Mrs S. KAVI BHARATHI

TOTAL HOURS – 4 HOURS


HEAD OF THE DEPARTMENT


CO-ORDINATOR


PRINCIPAL

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DEPARTMENT OF PHARMACEUTICS

ONE DAY SEMINAR ON: "REGULATORY FRAMEWORKS AND LEGAL CONSIDERATIONS
FOR PHARMACEUTICAL START-UPS".

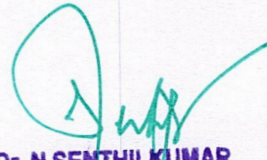
ABOUT THE SEMINAR

Pharmaceutical regulations are crucial in research for product approval and eventual marketing of the product. Hence it has a series of complex laws and guidance documents depending on the regulatory bodies. The product development should comply with most regulatory authorities, like FDA (US), EMA (Europe), PMDA (Japan), to provide global access to the beneficial therapeutic products, safe and maximum returns on the investments. International Conference on Harmonization (ICH) harmonizes the requirements for stability testing in the three areas of Europe, Japan, and the United States. ICH guidance documents are classified as safety, efficacy, and quality. This guidance helps in identifying the critical elements that are involved in product development and found the stipulations that turn into the basis for defining a product Gives an outline of the development of specifications.

Regulatory authorities recognize that modifications are performed during early phases of product development. Regulations are emphasized to provide information for development of a stable formulation which can support a shelf life suitable for the complete duration of the initial clinical studies. During the Phase I and II clinical trials, stability data (1–2 years) is required for the developed product. Appropriate quality data is generated for quality submission to regulatory authorities that supports a Clinical Trials Application (CTA) or Investigational New Drug (IND) submission. It also provides supporting data for a Product Licence Application too. This information will examine the changes in product performance behavior and identify formulation degradation that is observed in actual storage conditions. Adequate stability data will help to develop the final formulation, and also to select the most suitable primary container and closure packaging materials.

Detailed regulatory guidelines are available to assist the pharmaceutical companies in making the regulatory submissions, including the recommendations to design, conduct, and use of stability studies. Examples of such guidelines are FDA guidance on "Stability Testing of Drug Substances and Drug Products" and the Committee for Proprietary Medicinal Products' (CPMP) notes on "Stability Testing: Testing of New Drug Substances and Products". Information is readily available from the Web sites of various national and international regulatory authorities and manufacturers' associations, (FDA guidance), (CPMP guidance), (ICH guidance).




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DEPARTMENT OF PHARMACEUTICS

STUDENT FEEDBACK FORM

NAME OF STUDENT:

COURSE:

SEMINAR TOPIC:

REGISTRATION NO:

YEAR & SEMESTER:

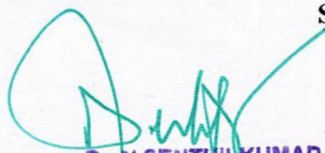
DATE & TIME:

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%
 - ☐ 0%
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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DATE :8.12.2023

STUDENT 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	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

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		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

HEAD OF THE DEPARTMENT

CO-ORDINATOR

PRINCIPAL



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REPORT SUMMARY

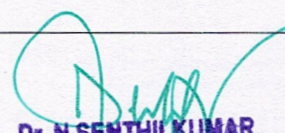
DATE:08.12.2023

Duration of the Course	6 HOURS
Total participants Enrolled	46
Successfully Completed	44
Type of Feedback Assessment	Multiple Choice Questions (MCQ's)
Course Outcome	<ul style="list-style-type: none">✓ The drug regulatory authority is "the agency that develops and implements most of the legislation and regulations on pharmaceuticals. Its main task is to ensure the quality, safety and efficacy of drugs, and the accuracy of product information.✓ The manufacture, procurement, import, export, distribution, supply and sale of drugs, product promotion and advertising, and <u>clinical trials</u> are carried out according to specified standards. Several of these functions also contribute to efforts to promote rational drug use" (WHO, 2001).

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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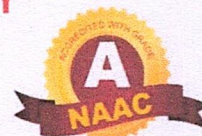
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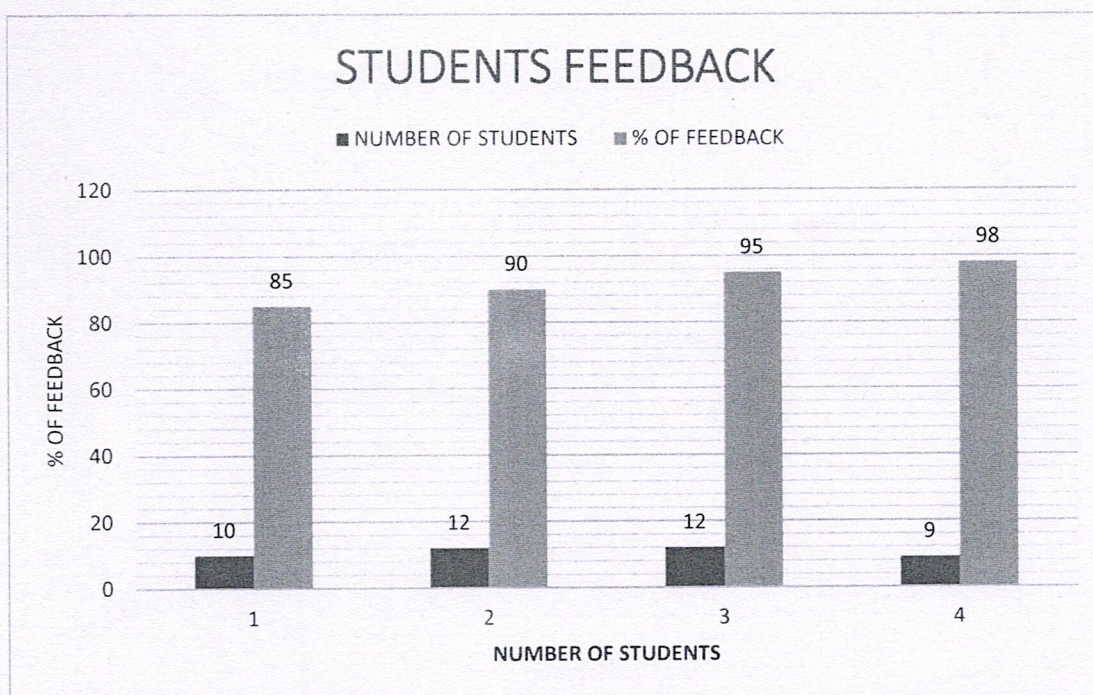
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STUDENTS FEEDBACK ANALYSIS




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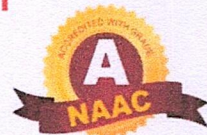
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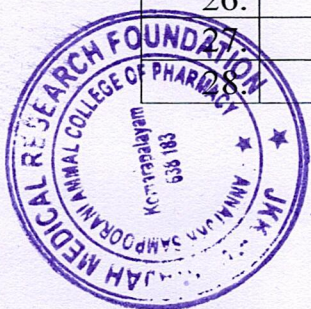
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LIST OF PARTICIPANTS

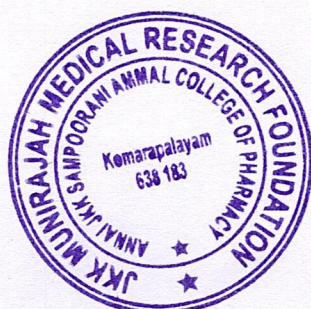
S.NO	NAME OF THE PARTICIPANT	YEAR
1.	CHANDRU D	II M.PHARM
2.	GOWTHAM M	II M.PHARM
3.	KALAIYARASI R	II M.PHARM
4.	KOTHAI S	II M.PHARM
5.	MANI BHARATHI P	II M.PHARM
6.	MOHAMMED AABITH M	II M.PHARM
7.	MOHANA KANNAN M	II M.PHARM
8.	NAVEEN KUMAR M	II M.PHARM
9.	PRASANTH R	II M.PHARM
10.	VATHENDIRAN S	II M.PHARM
11.	ANBUDURAI S	II M.PHARM
12.	DURAI K	II M.PHARM
13.	RAGHU A	II M.PHARM
14.	SILAMBARASAN D	II M.PHARM
15.	SWARNAMBIGAI J	II M.PHARM
16.	VINOTHKUMAR V	II M.PHARM
17.	BHAVATHARANI R	I M.PHARM
18.	CHANDAN KUMAR V	I M.PHARM
19.	DEEPAPRIYA K	I M.PHARM
20.	HARIHARAN M	I M.PHARM
21.	KAVIN V R	I M.PHARM
22.	KIRUTHIKA K	I M.PHARM
23.	MONISHA J	I M.PHARM
24.	NANDHINI J	I M.PHARM
25.	NIVEDHA S	I M.PHARM
26.	PRADEEP S	I M.PHARM
	RASIGA S	I M.PHARM
	RENUGA R	I M.PHARM

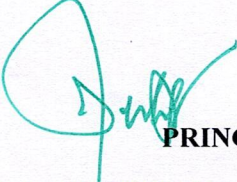


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29.	SELVAMANI R	I M.PHARM
30.	SENTHIL KUMAR S	I M.PHARM
31.	SESHAGIRIVASAN K	I M.PHARM
32.	ARAVINTHRAJ U	I M.PHARM
33.	AYESHA THASNEEM V M	I M.PHARM
34.	BRUNDHA R	I M.PHARM
35.	DINESH S	I M.PHARM
36.	ELAVARASAN P	I M.PHARM
37.	GOPINATH P	I M.PHARM
38.	JAYAPRIYA R	I M.PHARM
39.	JEGANATHAN B	I M.PHARM
40.	JOHN PAUL E	I M.PHARM
41.	KARTHIKEYAN S	I M.PHARM
42.	MAHAVISHNU J	I M.PHARM
43.	RANJITH R	I M.PHARM
44.	ROHIT SUNDHAR S	I M.PHARM
45.	SNEHA A	I M.PHARM
46.	VIJAY A	I M.PHARM




PRINCIPAL

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

DATE:08.12.2023

SEMINAR PHOTOS

Resource person discuss with students

REGULATORY FRAMEWORKS AND LEGAL CONSIDERATIONS IN INDUSTRIES



Resource person speech

MANAGING HIGH COSTS ASSOCIATED WITH REGULATORY PROCESSES



Dr. N.SENTHILKUMAR,
PRINCIPAL,

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



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

**SEMINAR ON
REGULATORY FRAMEWORKS AND LEGAL
CONSIDERATION FOR PHARMACEUTICAL START UPS**

**ORGANIZED BY
DEPARTMENT OF PHARMACEUTICS
CERTIFICATE OF PARTICIPATE**

*This certify that Mr./ Ms./ Mrs./ Dr. _____ has participated in
SEMINAR ON on Regulatory Frameworks And legal Consideration For Pharmaceuticals
Startups held on 8.12.2023*

Organizing Secretary

Convenor



**Dr. N.SENTHILKUMAR,
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ABOUT US

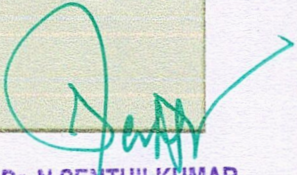
Dr.J.K.K.Munirajah is a reputed industrialist technocrat and educational besides, being a social worker ,a person imbibed in deep spiritual values and philanthropist. At Present Annai J.K.K Sampoorani Ammal Charitable Trust runs Paramedical Institutions offering Diploma, Graduate, Post Graduate & Ph.D., Courses and Research Scholarships in Pharmacy, Nursing, Physiotherapy and Occupational Therapy at Komarapalayam. The Trust has won many national and state awards. These renowned Educational Institutions spared education to promote knowledge, wisdom and service -Orientation.

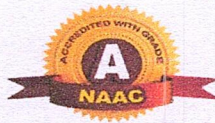
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SAMPOORANI AMMAL COLLEGE
OF PHARMACY**

Komarapalayam, Namakkal Dt-638183

ORGANISED BY

DEPARTMENT OF PHARMACEUTICS

&

INTERNAL QUALITY ASSURANCE CELL


**REGULATORY FRAMEWORKS AND LEGAL CONSIDERATIONS FOR
PHARMACEUTICAL START-UPS**



Venue: SEMINAR HALL

DATE: 8.12.2023




Dr. R. SENTHILKUMAR,
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