J.K.K. MUNIRAJAH MEDICAL RESEARCH FOUNDATION
ANNAI J.K.K. SAMPOORANI AMMAL COLLEGE OF PHARMACY
Ethirmedu, B. Komarapalayam-638 183, Namakkal Dist. Tamilnadu,India.
Approved by : Pharmacy Council of India. New Delhi & Affiliated to The Tamilnadu Dr. M.G.R Medical University, Chennai.
Website : www.jkkmmrfpharmacy.edu.in / E-Mail : principal@jkkmmrfpharmacy.edu.in
Contact No : +919789456750, +919943066944, +919943069944.

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

DATE: 24/12/2022

REPORT

ADD-ON COURSE TITLE - Regulatory Requirements for Pharmaceutical Product Development and Approval

VENUE-SEMINAR HALL

RESOURCE PERSONS

Dr.N.SENTHILKUMAR., M. PHARM, Ph.D.,
Professor, JKKMMRF'S Annai JKK sampooraniammal College of pharmacy, komarapalayam.

Dr.S. CHANDRA., M. PHARM, Ph.D.,
Professor, JKKMMRF'S Annai JKK sampooraniammal College of pharmacy, komarapalayam.

Dr. V. SURESH., M. PHARM, Ph.D.,
Professor, JKKMMRF'S Annai JKK sampooraniammal College of pharmacy, komarapalayam.

Mr. R. SURESH., M. PHARM.,
Professor, JKKMMRF'S Annai JKK sampooraniammal College of pharmacy, komarapalayam.

No. of students Enrolled: 62 No. of students certified: 60 No. of Absentees:02

OBJECTIVE OF THE COURSE

This topic focuses on ensuring drugs meet safety and quality standards throughout their lifecycle, from pre-clinical testing to post-market surveillance. It covers submitting NDAs for approval, adhering to GMP regulations, and understanding specific requirements for different drug types.

Note:Certificate will be issued only for the students attending more than Three days

LEARNING OUTCOMES FROM THE COURSE

1. Demonstrate an understanding of regulatory compliance in drug discovery and development.
2. Develop the ability to create and implement documented procedures for each stage of pharmaceutical product development, including preclinical studies, clinical trials, manufacturing, and post-approval surveillance.
3. Apply knowledge and skills to prepare and submit a New Drug Application (NDA) to the FDA, ensuring compliance with the regulatory requirements for review and approval prior to marketing a new drug.

HOD

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

PRINCIPAL

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

Principal

REF.NO: JKKM/PHARM/CEU/REQ/2022/017 **Date: 09/12/2022**

From

Department of Pharmaceutics,
JKKMMRF'S Annai JKK SampooraniAmmal College of Pharmacy.
Komarapalayam, Namakkal [Dist]
Tamil Nadu, PIN:638183.

To

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

Subject: **Letter for requesting Permission to Conduct an ADD ON COURSE regarding: -**

Respected Sir,

We are writing this letter to request permission to conduct a add on course in the **seminar hall** on **12/12/2022 to 24/12/2022**.we wish to conduct a add on course regarding the add on course on **Regulatory Requirements for Pharmaceutical Product Development and Approval**. We request you to kindly permit to conduct **ADD ON COURSE** program as this would be a great opportunity for students to and that would help a great deal to shape the students.

Looking forward to hearing from you.

Thank you,

Yours sincerely

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

Dr. N.SENTHILKUMAR,
PRINCIPAL
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Principal

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

DATE: 09.12.2022

CIRCULAR

This is informed to the **B.Pharm,M. Pharm &Pharm.D** Students that the following value-added course can be conducted by the Department of Pharmaceutics, JKKMMRF'S ANNAI JKK SAMPOORANIAMMAL COLLEGE OF PHARMACY, KOMARAPALAYAM and it will be commenced as per the schedule:

COURSE NAME	SCHEDULE	DURATION	VENUE	RESOURCE PERSON
Regulatory Requirements for Pharmaceutical Product Development and Approval.	**12/12/2022 to 24/12/2022**	**30 HOURS**	**SEMINAR HALL**	**Dr.N.SENTHILKUMAR Dr.S.CHANDRA Mr.R.SURESH Dr.V.SURESH**

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.

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SYLLABUS

DATE	HOURS	TOPIC	SUB TOPICS	RESOURCE PERSON
12/12/2022	6 HOURS	**Regulatory Requirements for Pharmaceutical Product Development and Approval**	Product Regulatory Compliance	Dr.S.Chandra
			The process of drug discovery and development	Dr.N.Senthilkumar
15/12/2022	6 HOURS		Documented procedure	Mr.R.Suresh
			New Drug Application (NDA)	Dr.V.Suresh
19/12/2022	6 HOURS		FDA approval and drug manufacturers	Dr.S.Chandra
			GMP regulations including record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling	Dr.N.Senthilkumar
21/12/2022	6 HOURS		FDA for permission to market a new drug	Dr.S.Chandra
			Abbreviated New Drug Application (ANDA), Over-the-Counter Drug (OTC)	Dr.V.Suresh
24/12/2022	6 HOURS		Biologics License Application (BLA), and Investigational New Drug (IND)	Mr.R.Suresh
			FDA Post-Market Drug Safety Monitoring	Dr.N.Senthilkumar
Total hours = 30				

HOD

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

Principal

JKKMMRF'S ANNAI JKK SAMPOORANIAMMAL COLLEGE OF PHARMACY,KOMARAPALAYAM

DEPARTMENT OF PHARMACEUTICS

COURSE TITLE

Regulatory Requirements for Pharmaceutical Product Development and Approval.

RESOURCE PERSONS

VENUE: SEMINANAR HALL

DATE:12/12/2022

TO 24/12/2022

TIMING:09.30AM-04.30PM

Dr.N.SENTHILKUMAR., M. PHARM, Ph.D.,
Professor, JKKMMRF'S Annai JKK sampoorani ammal College of pharmacy, komarapalayam.

Dr.S. CHANDRA., M. PHARM, Ph.D.,
Professor, JKKMMRF'S Annai JKK sampoorani ammal College of pharmacy, komarapalayam.

Dr. V. SURESH., M. PHARM, Ph.D.,
Professor, JKKMMRF'S Annai JKK sampoorani ammal College of pharmacy, komarapalayam.

Mr. R. SURESH., M. PHARM.,
Professor, JKKMMRF'S Annai JKK sampoorani ammal College of pharmacy, komarapalayam.

TOPICS

- Product Regulatory Compliance
- The process of drug discovery and development
- Documented procedure
- FDA Post-Market Drug Safety Monitoring
- New Drug Application (NDA)
- FDA approval and drug manufacturers
- FDA for permission to market a new drug
- Biologics License Application (BLA), and Investigational New Drug (IND)
- GMP regulations including record keeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling
- Abbreviated New Drug Application (ANDA), Over-the-Counter Drug (OTC)

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ADD-ON COURSE TITLE	**: Regulatory Requirements for Pharmaceutical Product Development and Approval.**
ACADEMIC YEAR	**: 2022-23**
DATE	**: 12/12/2022 to 24/12/2022.**

RESOURCE PERSON PROFILE

Name	:Dr.N.Senthilkumar
Designation	:Professor & Principal
Department	: Pharmaceutical Chemistry
Organization	: JKK Munirajah Medical Research Foundation - Annai JKK Sampoorani Ammal College Of Pharmacy, Komarapalayam
Phone Number	:+91 - 9789456737
Email Id	: senthilkumarjkkm@gmail.com
Qualification	: M.Pharm., Ph.D
Experience	:28 Years.

Dr. N. SENTHILKUMAR,
PRINCIPAL,
JKK MUNIRAJAH MEDICAL RESEARCH FOUNDATION
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ACADEMIC YEAR	**: 2022-23**
DATE	**: 12/12/2022 to 24/12/2022.**

RESOURCE PERSON PROFILE

Name	: Dr.V.Suresh
Designation	: Professor & HOD
Department	: Pharmacology
Organisation	: JKK Munirajah Medical Research Foundation - Annai JKK Sampoorani Ammal College Of Pharmacy, Komarapalayam
Phone Number	: +91 - 9865610568
Email Id	: velayuthamsuresh79@gmail.com
Qualification	: M.Pharm., Ph.D.,
Experience	: 18 Years

JKK Munirajah Medical Research Foundation, TN, India. Annai J.K.K. Sampoorani Ammal College of Pharmacy. Komarapalayam 638 183.

Dr. N. SENTHILKUMAR,
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ACADEMIC YEAR	**: 2022-23**
DATE	**: 12/12/2022 to 24/12/2022.**

RESOURCE PERSON PROFILE

Name	: Dr.S.Chandra
Designation	: Professor & HOD
Department	: Pharmaceutics
Organization	: JKK Munirajah Medical Research Foundation - Annai JKK Sampoorani Ammal College Of Pharmacy, Komarapalayam.
Phone Number	: +91-9655 95281
Email Id	: chandrajkkm@gmail.com
Qualification	: M.Pharm., Ph.D
Experience	:18 Years

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ADD-ON COURSE TITLE	**: Regulatory Requirements for Pharmaceutical Product Development and Approval.**
ACADEMIC YEAR	**: 2022-23**
DATE	**: 12/12/2022 to 24/12/2022.**

RESOURCE PERSON PROFILE

R. Suresh

Name	: Mr.R.Suresh.
Designation	: Associate Professor.
Department	: Pharmaceutics.
Organization	: JKK Munirajah Medical Research Foundation - Annai Jkk Sampoorani Ammal College Of Pharmacy, Komarapalayam.
Phone Number	: +91- 98650 84226.
Email ID	: suresh.krs20011@gmail.com.
Qualification	: M.Pharm.,Ph.D.,
Experience	:21 Years.

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Komarapalayam 638 183

Dr. N. SENTHILKUMAR,
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ADD-ON COURSE ORGANISING FACULTY MEMBERS

DEPARTMENT	PHARMACEUTICS
ADD-ON COURSE NAME	Regulatory Requirements for Pharmaceutical Product Development and Approval
ACADEMIC YEAR	2022-2023
DATE	12/12/2022 To 24/12/2022

LIST OF ADD-ON COURSE ORGANISING FACULTY MEMBERS

S.NO	NAME OF THE FACULTY	DESIGNATION
1.	Mr .R.Suresh	Associate professor
2.	Mrs.S.Sangeetha	Assistant professor
3.	Mrs.P.Dhivyabharathi	Assistant professor

(HOD)

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

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LIST OF STUDENTS ENROLLED FOR THE COURSE **DATE: 12/12/2022**

ADDON COURSE TITLE- Regulatory Requirements for Pharmaceutical Product Development and Approval

S.NO	REG.NO	NAME OF THE STUDENT	COURSE	SIGNATURE
1	380021507516	MOHIT R	II-PHARM D	
2	380021507517	PARTHASARATHY S	II-PHARM D	
3	380021507518	PAVITHRA M	II-PHARM D	
4	380021507519	PRASANTH R	II-PHARM D	
5	380021507520	PUNITHKUMAR V	II-PHARM D	
6	380021507521	SARANYA R	II-PHARM D	
7	380021507522	SARATHY S	II-PHARM D	
8	380021507523	SHYAM S S	II-PHARM D	
9	380021507524	SIVAPRASATH G	II-PHARM D	
10	380021507525	SREESANTHEYA S G	II-PHARM D	
11	380021507526	SUBASH B	II-PHARM D	
12	380021507527	SUHITHA SREE M	II-PHARM D	
13	380021507528	THIRUMALAIVASAN V	II-PHARM D	
14	380021507529	THIRUSELVAM C	II-PHARM D	
15	380021507530	USMAAN A	II-PHARM D	
16	381710414	PUSHPARAJ A	VI-PHARM D	

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17	381710415	RAGHUL G	VI-PHARM D	
18	381710416	SHANGEETHA S	VI-PHARM D	
19	381710417	SUDHARSAN V	VI-PHARM D	
20	381710418	SULIMAN B	VI-PHARM D	
21	381710419	TAMIL SELVAN S	VI-PHARM D	
22	381710420	VEDIYAPPAN V	VI-PHARM D	
23	381710421	YOGAVARSHINI K S	VI-PHARM D	
24	381710422	AHAMMED KABEER	VI-PHARM D	
25	381710423	AMRUTHA M.K	VI-PHARM D	
26	381710424	CHANDNA THERASA MATHEW	VI-PHARM D	
27	381710425	DEBORAH ROSE	VI-PHARM D	
28	381710426	HELENNA M	VI-PHARM D	
29	381710427	MUNEER T	VI-PHARM D	
30	381710428	NISSY ESTHER JOHN	VI-PHARM D	
31	381710429	SAMUEL BABU	VI-PHARM D	
32	381710430	NAIVIN D ALMEDA	VI-PHARM D	
33	BPY/1906/2022	SADAKHATH W	I-B.PHARM	
34	BPY/1907/2022	SANJAY KUMAR S	I-B.PHARM	
35	BPY/1908/2022	SANJAY M	I-B.PHARM	
36	BPY/1909/2022	SARATH P	I-B.PHARM	
37	BPY/1910/2022	SARATHYLINGAM S R	I-B.PHARM	

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Principal

38	BPY/1911/2022	SARAVANAN K	I-B.PHARM	
39	BPY/1912/2022	SARAVANESH M	I-B.PHARM	
40	BPY/1913/2022	SARIGASRI K	I-B.PHARM	
41	BPY/1914/2022	SATHISH A	I-B.PHARM	
42	BPY/1915/2022	SEKAR G	I-B.PHARM	
43	BPY/19162022	SHEIK ABDULLA M	I-B.PHARM	
44	BPY/1917/2022	SHOMESHWARAN P	I-B.PHARM	
45	BPY/1918/2022	SIVANI C	I-B.PHARM	
46	BPY/1919/2022	SRIRAM S	I-B.PHARM	
47	BPY/1920/2022	SUBAN M	I-B.PHARM	
48	BPY/1921/2022	SUBASH K	I-B.PHARM	
49	BPY/1922/2022	SUJITH S	I-B.PHARM	
50	BPY/1923/2022	SUNDARRAJ T	I-B.PHARM	
51	261121507508	MOHAMED YASEEN M	II-M.PHARM (PHARMACEUTICS)	
52	261121507509	NAVANANDHINI J	II-M.PHARM (PHARMACEUTICS)	
53	261121507510	PAVITHRA B	II-M.PHARM (PHARMACEUTICS)	
54	261121507511	SHAFIKA M	II-M.PHARM (PHARMACEUTICS)	

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55	261121507512	SOUNDARA PANDIYAN G	II-M.PHARM (PHARMACEUTICS)	
56	261121507513	TAMILARASU A	II-M.PHARM (PHARMACEUTICS)	
57	261121507514	VENKATESH S	II-M.PHARM (PHARMACEUTICS)	
58	261121507505	DHIVAGAR R	II-M.PHARM (PHARMACEUTICS)	
59	261121507506	JAFERI SANDOSH A	II-M.PHARM (PHARMACEUTICS)	
60	261121507507	MOHAMED SHIHAB K E	II-M.PHARM (PHARMACEUTICS)	
61	261121507504	DEEPTHI K C	II-M.PHARM (PHARMACEUTICS)	
62	261121507505	DHIVAGAR R	II-M.PHARM (PHARMACEUTICS)	

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STUDENTS ATTENDANCE

ADDON COURSE TITLE- **Regulatory Requirements for Pharmaceutical Product Development and Approval**

S.NO	REG.NO	NAME OF THE STUDENT	COURSE	12/12	15/12	19/12	21/12	24/12
1	380021507516	MOHIT R	II-PHARM D	/	/	/	/	/
2	380021507517	PARTHASARATHY S	II-PHARM D	/	/	/	/	/
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8	380021507523	SHYAM S S	II-PHARM D	/	/	/	/	/
9	380021507524	SIVAPRASATH G	II-PHARM D	/	/	/	/	/
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24	381710422	AHAMMED KABEER	VI-PHARM D	/	/	/	/	/
25	381710423	AMRUTHA M.K	VI-PHARM D	/	/	/	/	/
26	381710424	CHANDNA THERASA MATHEW	VI-PHARM D	/	/	/	/	/
27	381710425	DEBORAH ROSE	VI-PHARM D	/	/	/	/	/
28	381710426	HELENNA M	VI-PHARM D	/	/	/	/	/
29	381710427	MUNEER T	VI-PHARM D	Ab	/	Ab	Ab	Ab

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30	381710428	NISSY ESTHER JOHN	VI-PHARM D	✓	✓	✓	✓	✓
31	381710429	SAMUEL BABU	VI-PHARM D	✓	✓	✓	✓	✓
32	381710430	NAIVIN D ALMEDA	VI-PHARM D	✓	✓	✓	✓	✓
33	BPY/1906/2022	SADAKHATH W	I-B.PHARM	✓	✓	✓	✓	✓
34	BPY/1907/2022	SANJAY KUMAR S	I-B.PHARM	✓	✓	✓	✓	✓
35	BPY/1908/2022	SANJAY M	I-B.PHARM	✓	✓	✓	✓	✓
36	BPY/1909/2022	SARATH P	I-B.PHARM	✓	✓	✓	✓	✓
37	BPY/1910/2022	SARATHYLINGAM S R	I-B.PHARM	✓	✓	✓	✓	✓
38	BPY/1911/2022	SARAVANAN K	I-B.PHARM	✓	✓	✓	✓	✓
39	BPY/1912/2022	SARAVANESH M	I-B.PHARM	✓	✓	✓	✓	✓
40	BPY/1913/2022	SARIGASRI K	I-B.PHARM	✓	✓	✓	✓	✓
41	BPY/1914/2022	SATHISH A	I-B.PHARM	✓	✓	✓	✓	✓
42	BPY/1915/2022	SEKAR G	I-B.PHARM	✓	✓	✓	✓	✓
43	BPY/19162022	SHEIK ABDULLA M	I-B.PHARM	✓	✓	✓	✓	✓
44	BPY/1917/2022	SHOMESHWARAN P	I-B.PHARM	✓	✓	✓	✓	✓
45	BPY/1918/2022	SIVANI C	I-B.PHARM	✓	✓	✓	✓	✓
46	BPY/1919/2022	SRIRAM S	I-B.PHARM	✓	✓	✓	✓	✓
47	BPY/1920/2022	SUBAN M	I-B.PHARM	✓	✓	✓	✓	✓
48	BPY/1921/2022	SUBASH K	I-B.PHARM	✓	✓	✓	✓	✓
49	BPY/1922/2022	SUJITH S	I-B.PHARM	✓	✓	✓	✓	✓
50	BPY/1923/2022	SUNDARRAJ T	I-B.PHARM	Ab	Ab	Ab	Ab	Ab
51	261121507508	MOHAMED YASEEN M	II-M PHARM (PHARMACEUTICS)	✓	✓	✓	✓	✓
52	261121507509	NAVANANDHINI J	II-M PHARM (PHARMACEUTICS)	✓	✓	✓	✓	✓
53	261121507510	PAVITHRA B	II-M PHARM (PHARMACEUTICS)	✓	✓	✓	✓	✓
54	261121507511	SHAFIKA M	II-M PHARM (PHARMACEUTICS)	✓	✓	✓	✓	✓
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60	261121507507	MOHAMED SHIHAB K E	II-M PHARM (PHARMACEUTICS)	✓	✓	✓	✓	✓

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ADD-ON COURSE-ANSWER KEY

ADD-ON COURSE NAME	Regulatory Requirements for Pharmaceutical Product Development and Approval	
DATE		
NAME OF THE STUDENT		
REGISTER NO		
COURSE/YEAR/SEM		MARKS OBTAINED:
SIGNATURE	STUDENT:	STAFF:

Duration: 01:00 Hour **Maximum Marks:2x25=50**

1.What is full form for the CDSCO ?

A. Central Drugs Standard Control Organization.

B. Centre for Drugs standards control Organization.

C. Central drugs standard complaint Organization.

D. None of the above..

2. What kind of registration process followed by India for pharmaceutical products?

A. One registration process

B. Two registration process

C. Multiple registration process

D. None of the above

3.What is FDA ?

A. Food and drug association.

B. ***Food and drug administration***.

C. Foreign drug administration.

D. None of the above.

4.Who is the license issuing authority for the new drug approval?

A. DCGI

B. CDSO

C. PCI

D. None of the above.

5. Kefauver- Harris Amendment (1962)

A. It was passed after the thalidomide disaster. It requires the manufacturers to prove that drug is safe and effective. All the firms should send adverse effect reports to FDA.

B. It deals with convictions related to ANDA approvals.

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C. It contains some changes in Federal Food, Drug and Cosmetic Act regarding collection and assessment of user fees and accelerated approval processes.
D. It was enacted after sulfanilamide tragedy, to prove the safety of a drug before being marketed.

6.What is DCGI?
A. Drug control and governing of India
B. Drug controller general of India
C. Device controller general of India
D. None of the above

7.Which is one the Stages involved in approval of new drug?
A. Requirement for new drugs approval.
B. Submission of clinical trial application for evaluating safety and efficacy.
C. Post approval changes in biological products: quality, safety, efficacy document.
D. All the above.

8.What is the meaning of CTD?
A. ***Common technical Document***.
B. Communication tech Document.
C. Common teaching Document.
D. None of the Above.

9.IND Means
A. ***Investigational New Drug***.
B. Investigative novel drug.
C. Indian novel drug.
D. All the above.

10.What is the meaning of the ANDA?
A. Abbreviated New Drug Application
B. Aggregated new drug application
C. Abbreviated Novel Drug Application
D. All the above

11.What is Phase IV ?
A. Confirmatory trial - Confirmation of therapeutic benefits
B. Post marketing trial - Studies done after drug approval
C. Exploratory trial - estimation of effectiveness and short term side effects
D. Human pharmacology trial - estimation of safety and tolerability

12.What is the meaning of the ICH?
A. International conference on Harmonization.
B. Interstate conference on harmonization.

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C. International committee for Harmonization.
D. None of the above

13.Approval timeline for new drug in India
A. 12 months
B. 2 - 18 months
C. 1 month
D. None of the above

14.CHMP Means?
A. Common for Human Medicinal Products.
B. ***Committee for Human Medicinal Products***.
C. Committee for Human Medicinal products.
D. None of the above.

15.What is Phase III trial?
A. Confirmatory trial - Confirmation of therapeutic benefits
B. Post marketing trial - Studies done after drug approval
C. Exploratory trial - estimation of effectiveness and short term side effects
D. Human pharmacology trial - estimation of safety and tolerability

16.Which is the meaning of CPMP?
A.***Committee for Proprietary Medicinal Products***
B.Committee for property medicinal products
C.Committee for professional medicinal products
D.None of the above

17.Which is the correct meaning for EPAR?
A. European People Assessment Report
B. European Public Assessment Result
C. European Public Assessment Report
D. All the above

18.Which was the Act passed by India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics?
A. The Drug and Cosmetic Act 1941 and Rules 1945
B. The Drug and Cosmetic Act 1940 and Rules 1945
C. The Drug and Cosmetic Act 1943 and Rules 1945
D. The Drug and Cosmetic Act 1940 and Rules 1948

19.Which is the Phase I trial?
A. Confirmatory trial - Confirmation of therapeutic benefits
B. Post marketing trial - Studies done after drug approval
C. Exploratory trial - estimation of effectiveness and short term side effects

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D. ***Human pharmacology trial - estimation of safety and tolerability***

20.How much fees should pay for the application of new drug approval in India?

A. 50,000 INR
B. 20,000 INR
C. ***70,000 INR***
D. 80,000 INR

21.What kind of registration process followed by EU for pharmaceutical products?

A. One registration process
B. ***Two registration process***
C. Multiple registration process
D. None of the above

22.The time between the Application to ethical committee and Clinical trials started is

A. ***Within 12 weeks***
B. Within 18 months
C. Within 12 months
D. Within 18 weeks

23.Which is the correct meaning for CTRI?

A. Clinical Trials Register of India
B. ***Clinical Trials Registry of India***
C. Clinical Trials Registration of India
D. NONE OF THE ABOVE

24.The Drugs and Cosmetics Rules 1945 Rule 122A explains

A. Application for approval to manufacture new drug other than the drugs specified under Schedule C and C (1).
B. ***Application for permission to conduct clinical trials for New Drug/Investigational New Drug.***
C. Application for permission to import new drug.
D. Compensation in the case of injury or death during the clinical trials

25.Food and Drugs Act (1906):

A. ***It requires that the drugs must meet official standards of strength and purity.***
B. It was passed after the thalidomide disaster. It requires the manufacturers to prove that drug is safe and effective. All the firms should send adverse effect reports to FDA
C. It deals with convictions related to ANDA approvals.
D. None of the above

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MARK STATEMENT

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3	380021507518	PAVITHRA M	II-PHARM D	46	92
4	380021507519	PRASANTH R	II-PHARM D	42	84
5	380021507520	PUNITHKUMAR V	II-PHARM D	44	88
6	380021507521	SARANYA R	II-PHARM D	36	72
7	380021507522	SARATHY S	II-PHARM D	41	82
8	380021507523	SHYAM S S	II-PHARM D	42	84
9	380021507524	SIVAPRASATH G	II-PHARM D	36	72
10	380021507525	SREESANTHEYA S G	II-PHARM D	44	88
11	380021507526	SUBASH B	II-PHARM D	37	74
12	380021507527	SUHITHA SREE M	II-PHARM D	45	90
13	380021507528	THIRUMALAIVASAN V	II-PHARM D	41	82
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30	381710428	NISSY ESTHER JOHN	VI-PHARM D	44	88
31	381710429	SAMUEL BABU	VI-PHARM D	42	84
32	381710430	NAIVIN D ALMEDA	VI-PHARM D	43	86
33	BPY/1906/2022	SADAKHATH W	I-B.PHARM	36	72
34	BPY/1907/2022	SANJAY KUMAR S	I-B.PHARM	47	94
35	BPY/1908/2022	SANJAY M	I-B.PHARM	38	76
36	BPY/1909/2022	SARATH P	I-B.PHARM	42	84
37	BPY/1910/2022	SARATHYLINGAM S R	I-B.PHARM	37	74
38	BPY/1911/2022	SARAVANAN K	I-B.PHARM	39	78
39	BPY/1912/2022	SARAVANESH M	I-B.PHARM	34	68
40	BPY/1913/2022	SARIGASRI K	I-B.PHARM	41	82
41	BPY/1914/2022	SATHISH A	I-B.PHARM	37	74
42	BPY/1915/2022	SEKAR G	I-B.PHARM	42	84
43	BPY/19162022	SHEIK ABDULLA M	I-B.PHARM	44	88
44	BPY/1917/2022	SHOMESHWARAN P	I-B.PHARM	33	66
45	BPY/1918/2022	SIVANI C	I-B.PHARM	44	88
46	BPY/1919/2022	SRIRAM S	I-B.PHARM	42	84
47	BPY/1920/2022	SUBAN M	I-B.PHARM	36	72
48	BPY/1921/2022	SUBASH K	I-B.PHARM	42	84
49	BPY/1922/2022	SUJITH S	I-B.PHARM	32	64
50	BPY/1923/2022	SUNDARRAJ T	I-B.PHARM	A	A
51	261121507508	MOHAMED YASEEN M	II-M PHARM (PHARMACEUTICS)	41	82
52	261121507509	NAVANANDHINI J	II-M PHARM (PHARMACEUTICS)	41	82
53	261121507510	PAVITHRA B	II-M PHARM (PHARMACEUTICS)	42	84
54	261121507511	SHAFIKA M	II-M PHARM (PHARMACEUTICS)	43	86
55	261121507512	SOUNDARA PANDIYAN G	II-M PHARM (PHARMACEUTICS)	39	78
56	261121507513	TAMILARASU A	II-M PHARM (PHARMACEUTICS)	38	76
57	261121507514	VENKATESH S	II-M PHARM (PHARMACEUTICS)	46	92
58	261121507505	DHIVAGAR R	II-M PHARM (PHARMACEUTICS)	44	88
59	261121507506	JAFERI SANDOSH A	II-M PHARM (PHARMACEUTICS)	39	78
60	261121507507	MOHAMED SHIHAB K E	II-M PHARM (PHARMACEUTICS)	42	84
61	261121507504	DEEPTHI K C	II-M PHARM (PHARMACEUTICS)	46	92
62	261121507505	DHIVAGAR R	II-M PHARM (PHARMACEUTICS)	48	96

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ADD-ON COURSE- STUDENT ANSWER SHEET

ADD-ON COURSE NAME	Regulatory Requirements for Pharmaceutical Product Development and Approval		
DATE	24.12.2022		
NAME OF THE STUDENT	PAVITHRA.M		
REGISTER NO	380021507518		
COURSE/YEAR/SEM	II. PHARM.D	MARKS OBTAINED:	46
SIGNATURE	STUDENT: M. Pavithra	STAFF:	B.

Duration: 01:00 Hour **Maximum Marks: 2x25=50**

1.What is full form for the CDSCO ?
A. Central Drugs Standard Control Organization.
B. Centre for Drugs standards control Organization.
C. Central drugs standard complaint Organization.
D. None of the above..

2. What kind of registration process followed by India for pharmaceutical products?
A. One registration process
B. Two registration process
C. Multiple registration process
D. None of the above

3.What is FDA ?
A. Food and drug association.
B. Food and drug administration.
C. Foreign drug administration.
D. None of the above.

4.Who is the license issuing authority for the new drug approval?
A. DCGI
B. CDSO
C. PCI
D. None of the above.

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5. Kefauver- Harris Amendment (1962)

A. It was passed after the thalidomide disaster. It requires the manufacturers to prove that drug is safe and effective. All the firms should send adverse effect reports to FDA.
B. It deals with convictions related to ANDA approvals.
C. It contains some changes in Federal Food, Drug and Cosmetic Act regarding collection and assessment of user fees and accelerated approval processes.
D. It was enacted after sulfanilamide tragedy, to prove the safety of a drug before being marketed.

6.What is DCGI?

A. Drug control and governing of India
B. Drug controller general of India
C. Device controller general of India
D. None of the above

7.Which is one the Stages involved in approval of new drug?

A. Requirement for new drugs approval.
B. Submission of clinical trial application for evaluating safety and efficacy.
C. Post approval changes in biological products: quality, safety, efficacy document.
D. All the above.

8.What is the meaning of CTD?

A. Common technical Document.
B. Communication tech Document.
C. Common teaching Document.
D. None of the Above.

9.IND Means

A. Investigational New Drug.
B. Investigative novel drug.
C. Indian novel drug.
D. All the above.

10.What is the meaning of the ANDA?

A. Abbreviated New Drug Application
B. Aggregated new drug application
C. Abbreviated Novel Drug Application
D. All the above

11.What is Phase IV ?

A. Confirmatory trial - Confirmation of therapeutic benefits
B. Post marketing trial - Studies done after drug approval
C. Exploratory trial - estimation of effectiveness and short term side effects
D. Human pharmacology trial - estimation of safety and tolerability

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12.What is the meaning of the ICH?
- A. International conference on Harmonization.
- B. Interstate conference on harmonization.
- C. International committee for Harmonization.
- D. None of the above

13.Approval timeline for new drug in India
- A. 12 months
- B. 2 - 18 months
- C. 1 month
- D. None of the above

14.CHMP Means?
- A. Common for Human Medicinal Products.
- B. Committee for Human Medicinal Products.
- C. Committee for Human Medicinal products.
- D. None of the above.

15.What is Phase III trial?
- A. Confirmatory trial - Confirmation of therapeutic benefits
- B. Post marketing trial - Studies done after drug approval
- C. Exploratory trial - estimation of effectiveness and short term side effects
- D. Human pharmacology trial - estimation of safety and tolerability

16.Which is the meaning of CPMP?
- Committee for Proprietary Medicinal Products
- A. Committee for property medicinal products
- B. Committee for professional medicinal products
- C. None of the above

17.Which is the correct meaning for EPAR?
- A. European People Assessment Report
- B. European Public Assessment Result
- C. European Public Assessment Report
- D. All the above

18.Which was the Act passed by India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics?
- A. The Drug and Cosmetic Act 1941 and Rules 1945
- B. The Drug and Cosmetic Act 1940 and Rules 1945
- C. The Drug and Cosmetic Act 1943 and Rules 1945
- D. The Drug and Cosmetic Act 1940 and Rules 1948

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19.Which is the Phase I trial?

A. Confirmatory trial - Confirmation of therapeutic benefits
B. Post marketing trial - Studies done after drug approval
C. Exploratory trial - estimation of effectiveness and short term side effects
D. Human pharmacology trial - estimation of safety and tolerability

20.How much fees should pay for the application of new drug approval in India?

A. 50,000 INR
B. 20,000 INR
C. 70,000 INR
D. 80,000 INR

21.What kind of registration process followed by EU for pharmaceutical products?

A. One registration process
B. Two registration process
C. Multiple registration process
D. None of the above

22.The time between the Application to ethical committee and Clinical trials started is

A. Within 12 weeks
B. Within 18 months
C. Within 12 months
D. Within 18 weeks

23.Which is the correct meaning for CTRI?

A. Clinical Trials Register of India
B. Clinical Trials Registry of India
C. Clinical Trials Registration of India
D. NONE OF THE ABOVE

24.The Drugs and Cosmetics Rules 1945 Rule 122A explains

A. Application for approval to manufacture new drug other than the drugs specified under Schedule C and C (1).
B. Application for permission to conduct clinical trials for New Drug/Investigational New Drug.
C. Application for permission to import new drug.
D. Compensation in the case of injury or death during the clinical trials

25.Food and Drugs Act (1906):

A. It requires that the drugs must meet official standards of strength and purity.
B. It was passed after the thalidomide disaster. It requires the manufacturers to prove that drug is safe and effective. All the firms should send adverse effect reports to FDA
C. It deals with convictions related to ANDA approvals.
D. None of the above

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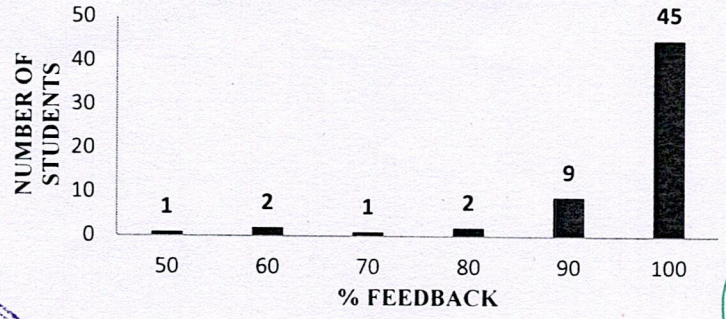
REPORT SUMMARY **Date: 24/12/2022**

Academic year	**2022-2023**
Add on course title	**Regulatory Requirements for Pharmaceutical Product Development and Approval**
Date	12/12/2022 to 24/12/2022
Duration of the Course	30 hours
Total participants Enrolled	62
Successfully Completed	60
No. of Absentees	02
Type of Assessment	Multiple Choice Questions (MCQ's)
Course Outcome	• Understand regulatory compliance • Develop documented procedures for pharmaceutical product development • To know how to Prepare and submit a New Drug Application (NDA) to the FDA
Outcome Attainment	42 Students scored more than 80% of marks - Attainment level 3 Achieved

Student Feedback Analysis

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

STUDENT FEEDBACK ANALYSIS



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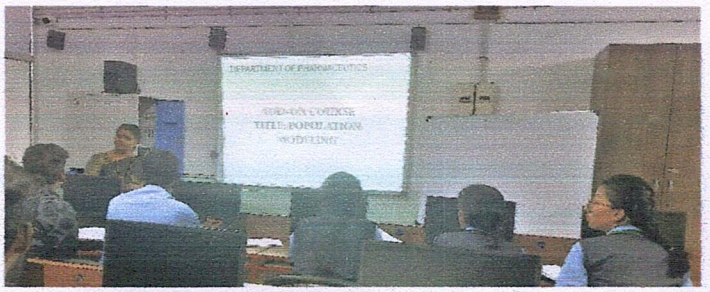
PHOTOGRAPHS

ADD-ON COURSE TITLE	**: Regulatory Requirements for Pharmaceutical Product Development and Approval**
ACADEMIC YEAR	**:2022-23**
DATE	**:12/12/2022 to 24/12/2022**



ADD-ON course regarding the topic Product Regulatory Compliance speech delivered by Dr.S.Chandra.,M.Pharm.,PhD., students able to understand the concepts and it was an interactive session,this would be helpful to update knowledge

ADD-ON course regarding the topic Documented procedure speech delivered by Mr.R.Suresh.,M.Pharm.,students able to understand the concepts and it was an interactive session,this would be helpful to update knowledge

ADD-ON course regarding the topic New Drug Application (NDA) speech delivered by Dr.V.Suresh., M.Pharm.,PhD., students able to understand the concepts and it was an interactive session, this would be helpful to update knowledge.

ADD-ON course regarding the topic The process of drug discovery and development speech delivered by Dr.N.Senthilkumar.,M.Pharm.,PhD., students able to understand the concepts and it was an interactive session, this would be helpful to update knowledge.

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VALUE ADDED COURSE

ORGANIZED BY

DEPARTMENT OF PHARMACEUTICS

CERTIFICATE OF PARTICIPANT

Rahul.G

HAS APPRECIATED FOR HIS/HER PARTICIPATION IN VALUE ADDED COURSE ON

REGULATORY REQUIREMENTS FOR PHARMACEUTICAL PRODUCT DEVELOPMENT AND APPROVAL 12/12/2022 TO 24/12/2022

COORDINATOR

H.O.D

PRINCIPAL

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