# Geethanjali College of Pharmacy

Approved by AICTE, PCI New Delhi, Permanently Affiliated to JNTUH & B. Pharmacy Accredited by NBA Recognized Under UGC Section 2F & 12B of UGC Act, 1956, by DSIR-SIRO & HI/BI of MSME, Certified by ISO 9001:2015 Cheeryal (V), Keesara (M), Medchal-Malkajgiri Dist., Telangana State- 501301

# **NAAC CRITERION-1**

## **Curricular Aspects**

### 1.2.2 Number of Add on /Certificate programs offered during the last five

years

S.No.	File No	File Description
4.	1.2.2 (4)	Number of Add on/Certificate programs offered during A.Y 2017-18

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Date: 16/06/2017

### **CIRCULAR**

This is to inform B. Pharmacy III year students that, they will have "Add-on Course on Soft Skills & Communication Skills" training classes from 16<sup>th</sup> July to 20<sup>th</sup> August, 2017. Hence, all of you are instructed to attend for classes without fail.

> Principal PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

# **ADD-ON COURSE**

# ON

# **"SOFT SKILLS & COMMUNICATION SKILLS"**

# From:16/07/2017 to 20/08/2017



## ORGANIZED

## BY

## **GEETHANJALI COLLEGE OF PHARMACY**

Cheeryal (V), Keesara (M), Medchal Dis

Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

### **PROGRAMME OBJECTIVES**

Soft Skills & Communication skills program is to aid candidates in their preparation for recruitment through campuses or outside campuses. Students in their final step of graduation looking for placements in reputed organizations can make use of this training to get deliver their best in the selection processes of organization

- 1. Train the students to think out of the box
- 2. Mock group discussion sessions
- 3. Resume making and information sessions
- 4. Interactive mythology (audio & video base)
- 5. Grooming' body language, soft skills, attitude etc

#### **RESOURCE PERSON**

#### Mr. B. Kondal, Assistant Professor

### ORGANIZING COMMITTEE

Dr B. Bharath Bhushan

Programme Coordinator, GCPK, Hyderabad

Prof Dr. M. Ravi kumar

Principal, GCPK

#### Shri. G. R. Ravinder Reddy

Secretary, Teja Educational Society, Hyderabad

### STUDENT COORDINATORS

Ms K.Anusha Reddy and Ms G.Mounika

metite PRINCIPAL

Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

Session	Topic name	Approach
1	Self Awareness	<ul> <li>Aptitude and personality assessment,</li> </ul>
	& Psychometric Test	suggestions for improvement
2	Industry Expectations &	Academics and industry –current
	Career Planning	scenario
		➢ Gaps
		A few myths
		Industry expectations on skill base
3	Communication	Recognize the importance of body
	Professional: in an interview	language , and manage body
		language for success in an inertview
4	JAM	Practice session
5	Grooming and etiquette	Identify the importance of appropriate
		dress sense and grooming in an
		interview
6	Group discussions	Know the importance of GD for final
		placements
7	MOCK GD	Practice session
8	Resume Writing	Customization of resume to the
		candidate
9	Interview Concepts	Elaborate on the interview concepts
10	MOCK interview (personal)	Practice session
11	Interview: personal	We discuss introducing self and more
		about self in personal interviews
12	Interview : HR	Different questions asked by HR and
		how to give answers for them
13	Interview :telephonic	Telephonic etiquette
14	Job interview & video	Mock interview can be conducted here
	mirroring	to give practical exposure to students
15	Personality assessment	Conducting SWOT analysis and make
	round	studets to realize how to bring the
		interviewer to students comfortable
		zone

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## **Curriculum for Soft Skills & Communication Skills**

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### List of Students Enrolled for Add-on Course on Soft Skills and Communication Skills for Academic Year 2017-18

S.No	Hall Ticket Number	Name
1	15Z51R0001	A. Deborah
2	15Z51R0002	Adapa Akhila
3	15Z51R0003	Alladurgam Bhargavi
4	15Z51R0004	Annapurna Deshpande
5	15Z51R0005	B. Archana
6	15Z51R0007	Borigam Tejasree
7	15Z51R0008	Budidha Ravali
8	15Z51R0009	Ch Chaithanya
9	15Z51R0010	Chada. Vinitha
10	15Z51R0012	Chiningani Rani
11	15Z51R0013	Chowhan Manisha
12	15Z51R0014	D Haritha
13	15Z51R0015	Dudam Pavan Kumar
14	15Z51R0016	Elasani Roja
15	15Z51R0018	Gouni Mounika
16	15Z51R0019	Jerepothula Lahari
17	15Z51R0020	K Komala Sai
18	15Z51R0021	K. Anusha Reddy
19	15Z51R0022	Kalakuntla Swetha
20	15Z51R0023	Kashyap Vishwa Priya
21	15Z51R0024	Katukojwala Sahithi
22	15Z51R0025	Konda Gadapa Jahnavi
23	15Z51R0026	Lingam Anusha
24	15Z51R0027	Mandala Niharika
25	15Z51R0028	Mantri Harika
26	15Z51R0029	Mohammed Sameer
27	15Z51R0030	Muddhasani Apoorva
28	15Z51R0031	N Chinna Pandu Yadav
29	15Z51R0032	Nazari Sai Bhavana
30	15Z51R0033	N. Sai Charan Goud
31	15Z51R0034	P. Mohitha Durga
32	15Z51R0035	Priyanka Reddy.K
33	15Z51R0036	R. Achyutha

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15Z51R0037	R. Nisha
15Z51R0038	Rajapudi Divya Sri
15Z51R0039	Safina Khan
15Z51R0040	Sandra Neelima
15Z51R0042	Srigiri Srineet
15Z51R0043	Thumma Tejaswini
15Z51R0044	Uppala Sravya
15Z51R0045	Vadipelliwar Sourab
15Z51R0047	Adiba Taha
15Z51R0048	Alle Shravani
15Z51R0049	B Yamini Satya
15Z51R0050	B Vinay Kumar
15Z51R0051	B. Shiva Krishna Goud
15Z51R0052	Borundiya Keerthi
15Z51R0053	C. Madhuri
15Z51R0054	Ch. Praveen Kumar
15Z51R0055	C. Lakshmi Sai Sri Sowmya
15Z51R0056	Chilumula Kaushika
15Z51R0057	Chitta Shravya
15Z51R0058	Danaboiena Alekhya
15Z51R0059	Duvvala Bhargavi
15Z51R0060	G Niharika
15Z51R0061	Gayam Bhavya
15Z51R0062	Jayasree Chandekar
15Z51R0063	K Alekhya
15Z51R0064	K Sindhu
15Z51R0065	Kadannagari Shirisha
15Z51R0067	Katukam Rithika
15Z51R0068	K.Boina Durga Bhavani
15Z51R0070	M.Venkata Sai Niharika
15Z51R0071	Mannem Vyshnavi
15Z51R0072	Meriyalkar Mamatha
10101110071	M. Lakshman Durga Sai
15Z51R0073	Kumar
15Z51R0074	Mudigondla Manikanta
	Nallala Sree Latha
	Nilgonda Sruthi
	Pabbu Mahender Goud
15Z51R0077 15Z51R0079	Pulicharla Priyanka
TOTOTUO012	Funchalla FilyallKd
15Z51R0080	R. Chandra Shekar
	15251R0038 15251R0040 15251R0042 15251R0043 15251R0043 15251R0044 15251R0045 15251R0047 15251R0049 15251R0050 15251R0050 15251R0051 15251R0053 15251R0053 15251R0054 15251R0056 15251R0057 15251R0058 15251R0061 15251R0061 15251R0061 15251R0063 15251R0063 15251R0063 15251R0064 15251R0064 15251R0065 15251R0065 15251R0065 15251R0064 15251R0071 15251R0071 15251R0071 15251R0073

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74	15Z51R0083	Salla Nikitha
75	15Z51R0084	Shaik Kamal Saheb
76	15Z51R0085	Sri Perambudur Santhosh
77	15Z51R0086	Syeda Sana Fatima
78	15Z51R0087	Thummala Abhishiktha
79	15Z51R0088	V Sravyasudha
80	15Z51R0089	Vadyanam Sai Ram
81	15Z51R0090	Shaistha Tabassum
82	15Z51R0091	Shamilla Likitha
83	15Z51R0092	Adarasupally Deepika
84	15Z51R0093	Manda Sukanya
85	14Z51R0039	Punduru Swathi

Bonchagable Programme Coordinator

PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medichal Dist. T.S. -501301.

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Date: 16/09/2017

### REPORT

Name of the programme: Add-on Course on Soft Skills & Communication Skills

Duration: 16/07/2017-20/08/2017

### **Resource Person Details:**

Mr B. Kondal, Assigtant Professor, GCPK

### Number of students attended: 85

Geethanjali College of Pharmacy organized "Add-on Course on Soft Skills & Communication Skills" for B. Pharmacy III year students by the resource person Mr. B Kondal from 16/7/17 to 20/8/17. This training was conducted to train students for upcoming campus recruitment drives. All the students participated energetically and they were able to know the following objectives and learning outcomes.

### **Objectives:**

- Unique short cut techniques for mathematics to improve speed and accuracy.
- Mock Group Discussions.

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- To train students on programme include problem solving and time saving techniques.
- > Preparedness to become suitable to pharma and non-pharma jobs.
- Graduates have to enhance their employability skills before leaving educational institutions.
- > To bridge the gap between industry and university.
- To develop confidence, communication skills, teamwork (how you manage and engage fellow participants) and technical knowledge of the subject.

### Learning Outcomes:

- Organize and write an effective cover letter and resume
- Understand organizational procedures and policies as related to how the employers process for campus recruitment and employer preferences.
- Exercise judgement and logical decision making in selecting from alternative techniques for group discussion & interview.
- Use self assessment to identify strengths, weakness, transferable skills, and prime marketable characteristics.

PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301. This course was very much informative to the students and their feedback was positive about the course. The management and Prof Dr. M. Ravi kumar, Principal-GCPK appreciated the resource person Mr. B Kondal and participants for making the programme successful.

Brangt **Programme Coordinator** 

rounder &

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Date: 16/06/2017

## **CIRCULAR**

This is to inform B.Pharmcy IV year students that, they will have "Add-on Course on Analytical Method Development and Validation" training classes 16<sup>th</sup> July to 20<sup>th</sup> August, 2017. Hence, all of the students are here by informed to attend the classes without fail.

**PRINCIPAL** Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.



ON

ANALYTICAL METHOD DEVELOPMENT



VALIDATION

From: 16/07/17 to 20/08/17



## ORGANIZED

## BY

## **GEETHANJALI COLLEGE OF PHARMACY**

Cheeryal (V), Keesara (M), Medchal Dist

**PRINCIPAL** Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-502 Jun

#### **PROGRAMME OBJECTIVES**

This program introduces the schematics of Methods Development and Validation with a grassroots, conceptual standpoint, based on scientific rationale and method by design approach. The aim is to lead the audience to understanding, basic elements of analytical method with a focus on Quality. At the outset, it implores the analytical chemist to grasp an Analytical Method as a process of measurement.

- 1. To get knowledge about development and optimization of chromatographic methods.
- 2. Study about importance of system suitability parameters in chromatographic methods.
- 3. To get up to date with the ICH and USFDA guidelines for the analytical method validation parameters.

#### **RESOURCE PERSONS**

#### Mr. M. Satish Kumar

Department of Pharmaceutical Chemistry smanthi@gmail.com Mobile: 7416407414

#### Mr. J. Sunil

Department of Pharmaceutical Chemistry sunilpharma49@gmail.com Mobile: 9908145789

#### Dr. N. Anjaneyulu

Department of Pharmaceutical Chemistry anjipharmcy@gmail.com Mobile: 9959967431

#### Prof. Dr. R. Siva Kumar

Department of Pharmaceutical Chemistry rsiva.chemist@gmail.com Mobile: 8008241577

PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S. 501301.

## **Organizing Committee**

Prof. Dr. M. Srinivas Department of Pharmaceutical Chemistry drmsr9@gmail.com, Mobile: 9908606829

Programme Coordinator

Prof. Dr. M. Ravi kumar

Principal, GCPK

Shri. G. R. Ravinder Reddy

Secretary, Teja Educational Society, Hyderabad

#### STUDENT COORDINATORS

Ms. G. Shalini

Ms. G. Mamatha

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Name of the Programme: Add-on Course on Analytical Method Development and Validation Schedule: From 16/07/2017 to 20/08/2017

S.No	Faculty Name	Designation	Signature
1	Prof. Dr. M. Srinivas	Professor	- AF
2	Prof. Dr. R. Siva Kumar	Professor	OSSA
3	Dr. N. Anjaneyulu	Assoc Professor	M. Awer
4	Mr. J. Sunil	Assoc. Professor	A
5	Mr. M. Satish Kumar	Asst. Professor	M.Schidr

#### Curriculum Designed and Developed by:

PRIN( Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S. 501301.

Curriculum for Add on course on Analytical Method Development and Validation

SESSION	TITLE	DURATION
1	ICH Guidelines:	3hrs
	Overview of ICH Guidelines	
	Stability Guidelines	
	GMP Guidelines for Pharmaceuticals	
	Nitrosamme impurities Guidelines	
2	System suitability parameters for HPLC Method	3hrs
	System suitability test	
	Resolution	к
	Retention Time	
	Pressure	
	Column Efficiency	
	Repeatability	
	Plate Number	
	Tailing Factor	
3	Analytical Method Validation Parameters:	3hrs
	ICH Q2B Validation Guidelines	
	The Validation Characterstics	
	Specificity	
	Linearity	
	Quantitation Limit	
	Detection Limit	
	Range	
	Accuracy	
	Precision	
	Repeatability	
	Robustness	

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	System suitability Testing	
4	Trouble shooting of HPLC	3hrs
	Peak Shape	
	Retention Variation	
	Ghost Peaks	
	Column Back Pressure	
	Column Care	
5	Impurity Profiling	3hrs
	Introduction	
	<ul> <li>Classification of Impurities in API</li> </ul>	
	<ul> <li>Impurities present in formulation</li> </ul>	
	Identification of Impurities	
6	Stability Indicating Methods	3hrs
	Introduction	
	Role of QA in SIM	
	General Principle	
	<ul> <li>Photo stability testing of new drug substances</li> </ul>	
	<ul> <li>Photostability studies</li> </ul>	
	Force Degradation studies	
7	Bioanalytical Method Development and Validation	3hrs
	Sample Preparation	
	Extraction Techniques	
	Analytical Method Procedures	
	Validation	
8	Cleaning and Process validation	3hrs
	<ul> <li>Introduction</li> </ul>	
	Back Ground	
	General Requirements	
	<ul> <li>Evaluation of cleaning validation</li> </ul>	

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	Establishment of limits	
9	<ul> <li>Assay Testing of Pharmaceutical substances</li> <li>Introduction</li> <li>Guidelines of specifications</li> <li>General concepts</li> </ul>	3hrs
10	<ul> <li>Stability testing of residual solvents</li> <li>Introduction</li> <li>Types of solvents</li> <li>Testing of solvents</li> </ul>	3hrs

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## <u>List of Students Enrolled for Add-on Course on</u> <u>Analytical Method Development and Validation for A.Y 2017-18</u>

S.No	Hall Ticket Number	Name
1	14Z51R0001	Akula Manusha
2	14Z51R0002	Anuroop
3	14Z51R0003	B Karuna Sree
4	14Z51R0004	B V N Shivani
5	14Z51R0005	Baki Ratnakar
6	14Z51R0006	Bakki Vani Swetha
7	14Z51R0007	Bandla Niharika
8	14Z51R0008	B. Ravindar Reddy
9	14Z51R0009	B.Bhargavi
10	14Z51R0010	B. Emmy Lydia
11	14Z51R0011	Ch. Varsha Sree
12	14Z51R0012	Ch. Chaithanya
13	14Z51R0013	Dammu Ramya
14	14Z51R0014	Dindigala Suresh
15	14Z51R0015	G Shalini
16	14Z51R0016	G Mamatha
17	14Z51R0017	G Pavani Reddy
18	14Z51R0018	Gudise Naresh
19	14Z51R0019	Gunaganti Pavani
20	14Z51R0020	Jinuka Adithya
21	14Z51R0021	K M Bhargavi
22	14Z51R0022	K. Pradeep
23	14Z51R0023	K.Lakshmi Narasimha Mounikavya
24	14Z51R0024	K. Varalakshmi
25	14Z51R0025	Kola Vani
26	14Z51R0026	K.Sree Sai Poojitha
27	14Z51R0027	K.Phani Deepthi
28	14Z51R0028	Koti Prathika
29	14Z51R0029	M Shanker Reddy
30	14Z51R0030	Md Azhar Pasha
31	14Z51R0031	Mamidi Bhavani
32	14Z51R0032	Marisetti Vyshnavi

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33	14Z51R0033	Modem Sadhana
34	14Z51R0034	Mukthavaram Sreeja
35	14Z51R0035	N Mounica
36	14Z51R0036	Nalla Aakash
37	14Z51R0037	Panuganti Renu Sree
38	14Z51R0038	Pulakandla Navya
39	14Z51R0040	Raavi Sudeepthi
40	14Z51R0041	S Vanisree
41	14Z51R0042	Sushmitha Gunti
42	14Z51R0043	Syed Asmal Hussain
43	14Z51R0044	Syed Khaja Tabassum
44	14Z51R0045	T Sri Varsha
45	14Z51R0046	Y Shravana Gowri
46	13Z51R0059	Shanigarapu Sirisha

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**Programme Coordinator** 

**PRINCIPAL** Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S. •501301.

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REPORT

Name of the Programme: Add-on Course on Analytical Method Development and Validation

Schedule: From 16/07/2017 to 20/8/2017

Participated Students: 46

**Resource Person Details:** 

### Mr. M. Satish Kumar

Department of Pharmaceutical Chemistry smanthi@gmail.com Mobile: 7416407414

#### Mr. J. Sunil

Department of Pharmaceutical Chemistry sunilpharma49@gmail.com Mobile: 9908145789

### Dr. N. Anjaneyulu

Department of Pharmaceutical Chemistry anjipharmcy@gmail.com Mobile: 9959967431

## Prof. Dr. R. Siva Kumar

Department of Pharmaceutical Chemistry rsiva.chemist@gmail.com Mobile: 8008241577

PRINCIP Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

Department of Ph Chemistry and Ph Analysis of Geethanjali College of Pharmacy organized **"Add-on Course on Analytical Method Development and Validation"** from 16/07/2017 to 20/08/2017. This program covered the following objectives and learning outcomes.

### **Objectives:**

- Study about importance of system suitability parameters in chromatographic methods.
- To get knowledge about development and optimization of chromatographic method.
- To get up date with the ICH and USFDA guidelines for analytical method validation parameters.

#### Learning Outcomes:

- Parameters influencing chromatographic method development and how to optimize the method.
- Reporting of the results of analytical method validation parameters and their significance.
- Development of analytical methods in a systematic view.

Total 46 students participated actively in the training. The program was very much useful to the students and their response about the program was encouraging. Prof Dr. M. Ravi kumar thanked the resource persons and participants for making the program successful.

Date: 16/09/2017

### **Programme Coordinator**

PRINC

Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

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DATE: 16/08/2017

### **CIRCULAR**

This is to inform M.Pharm I year students that, they will have "Add-on Course on Intellectual Property Rights and Patent Filing" training classes from on every Saturday. 4<sup>th</sup> September to 10<sup>th</sup> October 2017. Hence, all of the students are here by informed to attend the classes without fail.

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## ADD-ON COURSE

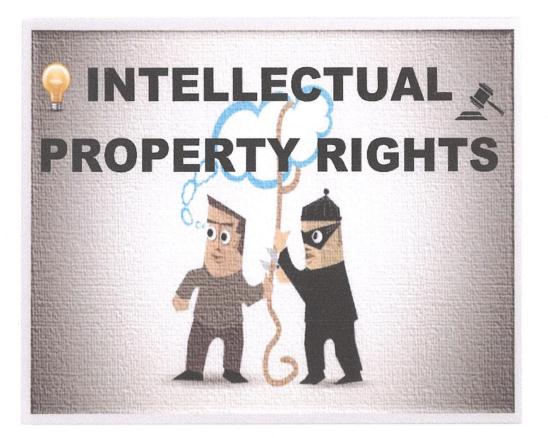
## ON

## **INTELLECTUAL PROPERTY RIGHTS**

## AND

## **PATENT FILING**

## From: 04-09-2017 TO 10-10-2017



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ORGANIZED BY GEETHANJALI COLLEGE OF PHARMACY Cheeryal (V), Keesara (M), Medchal Dist

Geethanjali College of Pharmacy Chearyal(V), Keesara(M), Medchal Dist. T.S.-501301.

#### Introduction to Intellectual Property Rights (IPR):

Intellectual Property Rights (IPR) plays a vital role in enhancing the socio-economic prosperity of the country. Creativity and innovations are new drivers of the world economy. With the increasing relevance of Intellectual Property in this era of globalization, it is important to recognize the role which Intellectual Property systems play in the growth of the Nation. Thus, there is a need to create large public awareness about the pivotal role of IPR in globalized knowledge economy. With the view to create awareness on the significance of IPR to the people from various sectors in the country, Department of Pharmaceutics, Geethanjali College of Pharmacy is organizing 30 hours Certificate course on "Intellectual Property Rights".

#### **Objectives:**

The objective of this certificate program is to impart greater awareness about the issue of Intellectual Property Rights (IPR), which has gained special importance for all the domains of socioeconomic development. It aids to understand of patentability criteria in details and viable aspect of the patent. Also, the patent system and the possible patent routes will be explained in more detail. This program involves invited lectures by distinguished legal experts in the field of drafting of patent specifications, filing of patents, Copyrights and Trademarks etc.

#### Topics to be covered:

- Definition, principles and overview of IPR by leading patent Attorneys.
- Background patent system, Patentability criteria (patentable subject-matter, novelty, inventive step, industrial applicability).
- Sufficiency of disclosure, Content of a patent application, Patent ownership.
- Illustrative case and Confidentiality.
- Information about the patent drafting process by reputed patent attorneys.
- Copyrights and Trademarks etc.
- Various plagiarism software tools.

#### Theme/Scope:

The goal of this short-term training programme is to bring together the faculty members, and students of our college to create awareness about the pivotal role of Intellectual Property Rights which includes drafting of patent specifications, filing of patents, Copyrights and Trademarks etc.

#### **Targeted Participants:**

- ✓ Post-Graduate Science & Engg students
- ✓ Faculty Members
- ✓ Research Scholars

Selection: All branches of M.Pharm students are eligible.

Certificate: It will be provided to the participants with a minimum 80% attendance in the programme.



#### **PROGRAMME OBJECTIVES:**

A patent is a document or legal certificate given for protecting a design, utility or innovation, which comes under the broad umbrella of IPRs. The course will cover the fundamental principles of patent drafting and discuss in detail the concepts in patent law & IPR.

- 1. Vital concepts of Intellectual property.
- 2. Importance of patents in the knowledge economy.
- 3. Tricks & tips to describe an invention in a patent application.

#### **RESOURCE PERSON**

Mrs. Pooja Agarwal, Asst.Professor Department of Pharmaceutics pharmacy.pooja.agarwal@gmail.com, Ph: 9849299548

Mr Y. Shivakumar, Assoc. Professor Department of Pharmaceutics, Shivakumar19842@gmail.com, Ph: 8500214801

#### **ORGANIZING COMMITTEE**

Mr Y. Shiva kumar, Assoc.Professor Department of Pharmaceutics *Programme Coordinator, GCPK* 

> **Prof Dr. M. Ravi kumar** Principal, GCPK

**Shri. G. R. Ravinder Reddy** Secretary, Teja Educational Society, Hyderabad

#### STUDENT COORDINATORS

Mr B.Rajesh Ms K. Suda Rani

PRINCIPA Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

SESSION	TITLE	DURATION		
IN	INTELLECTUAL PROPERTY RIGHTS AND PATENT FILLING			
1	Introduction to Intellectual Property Rights	3		
	History of IPR			
	Rationale for protection of IPR			
	• IPR in India-Genesis and development			
2	International Oreganizations, agencies and treaties.	3		
	• WTO, TRIPS and WIPO			
	Types of IPRs			
3	Introduction to Trademarks	3		
	• Rights and Trade marks			
	• Purpose and Functions of Trade marks.			
4	Introduction to Trademarks	3		
	• Rights and protection covered by Copy rights			
	Importance of Trade Secret			
	• Trade secrets usage in trade and business.			
5	Concepts of Geographical Indications.	3		
	Geographical Indications registration in India.			
	Value of Layout Designs of Integrated circuits.			
6	Protection of Plant varieties.	3		
	Significance of Industrial Designs			
	Registration and protection design in India and abroad.			
7				
/	Patents and its importance	3		
	Patent Act-1970			
	Patent Am, endement act 2005			
8	Patentable and Non-Patentable inventions	3		
	Legal requirements for patents			
	Types of patent applications			
9	Understanding Patent system in India	3		
		5		

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	Filing patents outside of India Patent Application Procress	
10	Searching patents databases for designing research objectoives.	3
11	Drafting of claims Patent filing procedure in India Patent documents, specifications and claims.	3
12	Patent prosecution in India Infringement International treaties fort patent Patent cooperation treaty.	3

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## List of Students Enrolled for Add-on Course on Intellectual Property Rights and Patent Filing for A.Y 2017-18

S.No	Hall Ticket Number	Name
1	17Z51S1001	B. Bhanu Kiranmai
2	17Z51S1002	Bonagari Deepika
3	17Z51S1003	J James
4	17Z51S1004	K.Vijayakanth
5	17Z51S1005	N. Nandini
6	17Z51S1006	Pemmaraju Sowjanya
7	17Z51S1007	P. Venkata Sai Sarvani
8	17Z51S0301	Aangothu Govind
9	17Z51S0302	A. Divya Reddy
10	17Z51S0303	B. Rajesh
11	17Z51S0304	C.Aishwarya
12	17Z51S0305	K. Sudha Rani
13	17Z51S0306	Kasireddy Harika
14	17Z51S0307	Kumar Veenitha
15	17Z51S0308	Molugu Rasagna
16	17Z51S0309	M. Shireesha
17	17Z51S0310	Sonia Chowdhury
18	17Z51S0401	Dheeravath Vanitha Sri
19	17Z51S0402	Gotike Sreenath
20	17Z51S0403	J Divya
21	17Z51S0404	Jogu Sharada
22	17Z51S0405	Jupalli Shirisha
23	17Z51S0406	Katta Madhavi
24	17Z51S0407	M Mamatha Asha
25	17Z51S0408	P Prashanthi
26	17Z51S0410	Rakesh Kumar Sai Vinay
27	17Z51S0411	Shaik Murtuza
28	17Z51S0412	Sk Sattar
29	17Z51S0413	Sumayya Javeed

PROGRAM COORIDNATOR

PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301,

Approved by AICTE, PCI New Delhi, Permanently Affiliated to JNTUH Cheeryal (V), Keesara (M), Medchal-Malkajgiri Dist., Telangana State- 501301

#### **REPORT**

#### **Date:** 06/11/17

**Name of the Program**: Add-on Course on Intellectual Property Rights and Patent Filing

Duration: 04-09-17 TO 10-10-17

#### **Resource Person Details:**

Mrs. Pooja Agarwal	Mr Y. Shiva Kumar
Asst.Professor	Assoc Professor
Department of Pharmaceutics	Department of Pharmaceutics
Geethanjali College of Pharmacy	Geethanjali College of Pharmacy
Email:	Email: Shivakumar19842@gmail.com
pharmacy.pooja.agarwal@gmail.com	Contact: 8500214801

Contact: 9849299548

Geethanjali College Of Pharmacy, Cheeryal, Keesara, Hyderabad organized an add-on course on **"INTELLECTUAL PROPERTY RIGHTS AND PATENT FILING"** for M. Pharmacy I Year students by Mrs. Pooja Agarwal, Asst. Professor, and Mr. Y. Shiva kumar, Assoc. Professor, Department Of Pharmaceutics from 4<sup>th</sup> September to 10<sup>th</sup> October 2017. This program was designed to educate the students about the advanced information of the said topic in addition to regular curriculum. Total 29 students participated in this

> Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.: 501301.

course. Upon completion of the course the students were able to understand and the following objectives and learning outcomes.

#### **Objectives:**

- To understand the vital concepts of intellectual property.
- To know the process of search and filing of patents.
- To obtain knowledge about parents.
- To know the various types of IPRs.
- To acquire the preliminary skills of patents drafting.

#### **Learning Outcomes:**

- Understand the procedures to convert the research outcome into patents.
- Impact greater awareness about the issue of IPRs.
- Understand patent drafting and commercialization of research work.

This program was very useful to the students and feedback was positive about the program. The management and Prof Dr. M. Ravi kumar Principal of GCPK thanked the resource persons Mrs. Pooja Agarwal, Mr. Y. Shivakumar and participants for making the program successful.

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**PROGRAM COORIDNATOR** 

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DATE: 22/08/2017

## **CIRCULAR**

This is to inform M. Pharmacy II year students that, they will have <u>"Add-on Course on Advances in Pharmaceutical Drug</u> <u>Delivery Systems</u>" training classes from 23<sup>rd</sup> September to 4<sup>th</sup> November 2017. Hence, all of the students are here by informed to attend the classes without fail.

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# **Add-on Course**

# On

# **Advances in Pharmaceutical Drug Delivery Systems**

From: 23/09/17 to 04/11/17



## ORGANIZED

 $\bigcirc$ 

## BY

# **GEETHANJALI COLLEGE OF PHARMACY** Cheeryal (V), Keesara (M), Medchal Dist

1-PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S. -501301.

### **PROGRAMME OBJECTIVES**

Advances in Pharmaceutical drug delivery technologies enhance drug efficacy, and patient experience. When combined with absorption, appropriate targeting moieties, drug-coated nanoparticles drugencapsulating liposomes and nanotubes, and tree-like dendrimers enable organ and tissue targeting. This program was designed to improve the knowledge on the area of novel drug delivery systems and technology.

- 1. Principle & approaches for development of various advanced drug delivery systems.
- 2. Criteria for selection of drugs and polymers for the development of novel drug delivery systems, their formulation and evaluation.
- 3. Various new technologies used in Pharmaceutical industries.

### **RESOURCE PERSON:**

Mr Y. Shivakumar Department of Pharmaceutics, shivakumar19842@gmail.com Ph: 8500214801

Mrs. P. Neeraja Department of Pharmaceutics. neeraja.podichety@gmail.com Ph: 9985709316

Dr. T. Mangilal, Professor Department of Pharmaceutics teelavath@gmail.com Ph: 8008241585

PRINCIP Geethanjali College of Pharmacy

Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301

### **ORGANIZING COMMITTEE:**

**Dr. T. Mangilal** Professor Department of Pharmaceutics

Programme Coordinator, GCPK

## Prof Dr. M. Ravi kumar

Principal, GCPK

## Shri. G. R. Ravindher Reddy

Secretary, Teja Educational Society, Hyderabad

### **STUDENT CO-ORDINATORS**

Mr D. Anil Naik

Ms G. Sneha

Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

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**Programme Name:** Add-on course on Advances in Pharmaceutical Drug Delivery Systems

Duration: 23/09/2017 to 04/11/2017

**A.Y:** 2017-2018

#### Curriculum Designed and Developed by:

S.No	Faculty Name	Designation	Signature
1	Dr. T. Mangilal	Professor	llij.
2	Mr. Y. Shiva Kumar	Assoc Professor	Ch
3	Mrs. P. Neeraja	Assoc Professor	eup

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## **CURRICULUM**

S. No	Advances in Pharmaceutical Drug Delivery Systems	Duration
1	Nano pharmaceuticals: Generation and significance of Nano- Pharmaceuticals like Nano Suspensions, Nanogels, Nanocarrier systems.	
2	Gastro-Retentive Drug Delivery Systems: Principle, Concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit, Methods of formulations and its evaluations.	
3	Nasal Drug Delivery Systems: Introduction, physiological aspects, mechanism and pathways, drug delivery systems.	3hrs
4	Sub-Micron Cosmeceuticals: Biology, formulation, science and evaluation of various cosmetics for skin, hair, nail, eye etc and its regulatory aspects.	3hrs
5	<ul> <li>Drug carrier systems targeted to widely dispersed cells</li> <li>Delivery to Macrophages</li> <li>Delivery to Lymphoid cells of immune systems</li> <li>Delivery to lysosomal storage disorders</li> </ul>	3hrs
6	Regulatory consideration in controlled release: Modification requirements to demonstrate safety efficiency& controlled release nature. Bioavailability assurance, WHO & Indian condition.	1
7	Basic requirements for design, facility, equipment selection for tablets, capsules, liquid orals, parenteral and semisolid preparations.	
8	Improved capsule manufacturing and filling machine for soft	3hrs

PRINCIPAL Office of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301,

	and hard capsules.	
9	Improved Tablet Production: Tablet production process, unit operation improvements granulation and pellitization equipment.	3hrs
10	Importance, Technology transfer from R&D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parenteral, NDDS.	3hrs
11	Industrial sterilization: Large scale sterilization processes, process selection, specifications, development and validation or process and equipment.	3hrs
12	Packaging Technology: Types of packing materials, machinery, labelling, and package printing for different dosage forms.	3hrs

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#### List of Students Enrolled for Add-on Course on

### Advances in Pharmaceutical Drug Delivery Systems for A.Y 2017-18

S.No	Hall Ticket Number	Name
1	16Z51S0301	B. Ramya Bhanu
2	16Z51S0302	Ch Sravya
3	16Z51S0303	Egoni Beaula Rani
4	16Z51S0304	Geetha
5	16Z51S0306	Jollu Annapoorna
6	16Z51S0307	K. Uday Kumar
7	16Z51S0308	M Naga Prashanthi
8	16Z51S0309	Madhavi Basani
9	16Z51S0310	N V Sai Priyanka
10	16Z51S0311	Thaduri Mahesh
11	16Z51S0403	D.Anil Naik
12	16Z51S0404	Gomari Sneha
13	16Z51S0405	Guduru Megha
14	16Z51S0407	K.Sai Prabha
15	16Z51S0408	Kota Anusha
16	16Z51S0409	M. Sri Laxmi
17	16Z51S0410	R Rajkiran Reddy
18	16Z51S0411	Shaganti. M. Priyanka
19	16Z51S0412	Soma Venkatesh
20	16Z51S0413	Sridhar. Rachcha
21	16Z51S0414	T Anand Kumar
22	16Z51S0415	T.Mamatha
23	16Z51S0416	Vasupathi Jyothi
24	16Z51S0417	B. Dinesh Kumar

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**Programme Coordinator** 

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#### **REPORT**

#### Date: 22/11/17

**Name of the Program**: Add-on Course on Advances in Pharmaceutical Drug Delivery Systems

**Duration:** 23/09/2017 to 04/11/17

#### **Resource Persons:**

- Mr. Y. Shiva kumar, Assoc Professor Department of Pharmaceutics, shivakumar19842@gmail.com Ph: 8500214801
- Mrs. P. Neeraja, Assoc Professor Department of Pharmaceutics, neeraja.podichety@gmail.com Ph: 9985709316
- Dr. T. Mangilal, Professor Department of Pharmaceutics teelavath@gmail.com Ph: 8008241585

Geethanjali College of Pharmacy, Cheeryal, Keesara, Hyderabad organized "Add-on course on Advances in Pharmaceutical Drug Delivery Systems" for M. Pharmacy II Year students by Mr. Y. Shiva Kumar, Assoc Professor, Mrs. P. Neeraja, Assoc Professor, and Dr. T. Mangilal, Professor. This program enables the students to understand the various

1 mont of PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

novel drug delivery systems and appreciate the influence of new technology on the performance of the drug product. Totally 24 students participated in this training program. All the students actively participated. Upon completion of the program they were able to understand the following objectives and learning outcomes.

### **Objectives:**

- Understand the criteria for selection of drugs and polymers for the development of novel drug delivery systems their formulation and evaluation.
- Understand various approaches for development of novel drug delivery systems.
- Understand various new technologies used in Pharmaceutical Industries.
- Understand the formulation and evaluation of novel drug delivery systems.
- Understand the principle involved in formulation of various advanced drug delivery systems.

#### **Learning Outcomes:**

- 1. Know the formulation aspects of advanced drug delivery systems.
- 2. Formulate Gastro retentive drug delivery systems, Floating micro balloons, Magnetic drug delivery systems and evaluate them for their quality.
- 3. Know the pilot plant Scale Up techniques.

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4. Know the various new technologies used in Pharmaceutical industries.

This program was very useful to the students and feedback was positive about the program. The management and Dr. M. Ravi Kumar, Principal of GCPK thanked the resource persons Mr. Y. Shiva Kumar, Assoc Professor, Mrs. P. Neeraja, Assoc Professor, and Dr. T. Mangilal, Professor and participants for making the program successful.

**Programme Coordinator** 

PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S. -501301.

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DATE: 20/06/2017

### CIRCULAR

This is to inform Pharm D IV-year students that, they will have "Add-on Course on Pharmacovigilance" training classes from 26<sup>th</sup> June to 31<sup>st</sup> July 2017. Hence, all of the students are here by informed to attend the classes without fail.

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Principal PRINCIPAL Geethanjali College of Pharmacy

Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

# **ADD-ON COURSE**

# ON

# PHARMACOVIGILANCE



From: 26/06/17 to 31/07/17

## ORGANIZED

## BY

# **GEETHANJALI COLLEGE OF PHARMACY**

Cheeryal (V), Keesara (M), Medchal Dist

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#### **PROGRAMME OBJECTIVES:**

Pharmacovigilance improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions: improve public health and safety in relation to the use of medicines: detect problems related to use of the medicines and communicate the finding in a timely.

- 1. Create a nation-video system for patient safety reporting.
- 2. Identify and analyse the new signal (ADR) from the reported cases.
- 3. Analyse the benefit risk ratio of marketed medicines.
- 4. Support regularly agencies in the decision-making process on use of medications.

#### **RESOURCE PERSON:**

Mr. MD Abubaker, Assistant Professor Department of Pharmacy Practice, abukhan253@gmail.com, Ph: 8712247800

Mrs. P. Madhuri, Assistant Professor Department of Pharmacy Practice, madhu.penumadhula@gmail.com Ph: 8712834116

Dr. B. Rambabu, Professor Department of Pharmacy Practice balu019914@gmail.com Ph: 8978378203

PRINC Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

#### **ORGANIZING COMMITTEE**

Dr. B. Rambabu, Professor Department of Pharmacy Practice

**Programme Coordinator, GCPK** 

Prof. Dr. M. Ravi kumar

### Principal, GCPK

Shri. G. R. Ravinder Reddy

### Secretary, Teja Educational Society, Hyderabad

#### **Student Coordinators**

Mr D. Sai Kumar

Mr R. Sai Kiran

PRINCIPAL Geethanjali College of Pharmacy Cheerval(V), Keesara(M), Medchal Dist. T.S.-501301.

S.No	Course Contents	Duration
1	Introduction and History of Pharmacovigilance	3
2	Adverse events in Clinical Trials vs Post Marketing	2
3	Guidelines for Pharmacovigilance	2
4	Basics of Pharmacovigilance	3
5	CSR, Minimum reporting criteria, Sources of ADRs	3
6	ICSR, Minimum reporting criteria	2
7	ICSR seriousness	2
8	ICSR seriousness-Case examples	3
9	Information in reporting forms	3
10	Information in reporting forms-case examples	2
11	ICSR-Expectedness	2
12	ICSR-Case examples	3
13	ICSR-Reporting timelines	3
14	MedDRA	3
15	Assessment-1	3
16	Introduction to Pharmacovigilance Database	2
17	Book-in	2
18	Introduction to case form	2
19	Case entry 1-Spontaneous case	2
20	Case entry 2-Clinical trial case	2
21	Case entry3-Literature case	2
22	Narrative writing 1-Spontaneous and clinical trial cases	2
23	Narrative writing 2-Literature case	2
24	Case processing-Explained with example-1	2
25	Case processing-Explained with example-2	2

### Curriculum Design for Add-on course on Pharmacovigilance

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26	Development safety update reports	
27	Periodic safety update reports	2
28	Signal Detection	2
29	Final Assessment	3
30	Mock Interview	3
31	Resume writing	2
32	Interview questions and job guidelines	2

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### List of Students Enrolled for Add-on Course on Pharmacovigilance for Academic Year 2017-18

S.No	Hall Ticket Number	Name
1	14Z51T0001	A. Agnish Reddy
2	14Z51T0002	D. Shreya
3	14Z51T0003	D. Sai Kumar
4	14Z51T0004	Divya Sree Sattiraju
5	14Z51T0005	K. Rama Devi
6	14Z51T0006	Kommu Sri Sruthi
7	14Z51T0007	M Vaishnavi Sri
		Varsha
8	14Z51T0008	M. Haritha
9	14Z51T0009	Maliha Naaz
10	14Z51T0010	M.Gowri Priya
11	14Z51T0011	Nerusu Soumya
12	14Z51T0012	P Anusha
13	14Z51T0013	R.Sai Kiran
14	14Z51T0014	S. Shireesha
15	14Z51T0015	Vallem Saikumar
16	14Z51T0016	Yashaswini Kamini
17	14Z51T0017	Korlapati Bhavani
18	17Z55T0001	Cherukuri Shailaja
19	17Z55T0002	Nabila Zahoor
20	17Z55T0003	Shaheen Begum
21	17Z55T0004	Uppala Sushma
22	17Z55T0005	Yedla Bhargav

**Programme Coordinator** 

PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-S01301.

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#### **REPORT**

#### Name of the Program:

Add-on course on Pharmacovigilance

**Duration**:

26/06/2017 to 31/07/2017

**Resource person's details:** 

Mr. MD Abubaker, Assistant Professor Department of Pharmacy Practice, abukhan253@gmail.com, Ph: 8712247800 Mrs. P. Madhuri, Assistant Professor Department of Pharmacy Practice, madhu.penumadhula@gmail.com Ph: 8712834116 Dr. B. Rambabu, Professor Department of Pharmacy Practice balu019914@gmail.com Ph: 8978378203

Geethanjali College of Pharmacy, Cheeryal, Keesara organized Add**-on course** on **Pharmacovigilance** for PharmD IV Year students by Dr. B. Rambabu, Professor, Mr Md Abubaker, Assistant Professor and Mrs P. Madhuri, Assistant Professor from 26/06/2017 to 31/07/2017. This programme involves ongoing monitoring of available drugs to ensure their safety for use, especially since previously undetected adverse events can

> PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

occur at any time. Total 22 students participated in this training program. All the students actively participated. Upon completion of the program they were able to understand the following objectives and learning outcomes.

#### **Objectives:**

- Understand regenerate reports and signal detection.
- Processing of individual case safety reports
- Databases used for case processing.
- Understand drug safety, history and evolution of Pharmacovigilance, the role of health authorities and their guidelines.

#### Learning Outcomes:

- **1.** Understand and determine seriousness, expectedness and casualty.
- 2. Classify ICSRs and completing reports.
- 3. Process cases in safety database.

This program was very useful to the students and feedback was positive about the program. The Management and the Principal of GCPK, Prof Dr. M. Ravi Kumar thanked the resource persons and the participants for making the program successful.

e.d.

**Programme Coordinator** 

Date: 07/08/2017

PRINCIPA'L Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

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Date: 22/08/2017

### **CIRCULAR**

This is to inform V year Pharm D and II year P.B students that, they will have "Add-on Course on Clinical Data Management (CDM) & Statistical Analysis System (SAS)" training classes from 23<sup>rd</sup> September to 4<sup>th</sup> November 2017. Hence, all of you are instructed to attend classes without fail.

PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Hedchal Dist. T.S.-501301. ADD-ON COURSE ON CLINICAL DATA MANAGEMENT (CDM) & STATISTICAL ANALYSIS SYSTEM (SAS)

(From 23/09/2017 to 04/11/2017)





ORGANIZED

BY

## **GEETHANJALI COLLEGE OF PHARMACY**

Cheeryal (V), Keesara (M), Medchal Dist



#### **OBJECTIVES OF THE PROGRAMME:**

Clinical data management (CDM) & Statistical Analysis System (SAS) plays an essential role in the data collection and data processing phase of clinical research. The process of collecting and managing research data is done in accordance with regulatory standards to obtain quality information that is complete and error free: the goal is to gather as much of such data for analysis is possible.

- 1. Database Validation, Data entry processes.
- 2. Database Lock, Clinical Data Archiving, and Data storage
- 3. FDA Guidance's, Protocol Review, and Data Management.
- 4. Case report Form Design and Edit Check Creation
- Electronic Data Capture: Selecting an Application, Implementing the system
   and study conduct

The SAS® System, originally Statistical Analysis System, is an integrated arrangement of software products that enables a user to perform:

- ✓ Data entry, retrieval, management, and mining |
- ✓ Report writing and graphics
- ✓ Statistical analysis and operations research
- ✓ Forecasting and decision support
- ✓ Data warehousing
- ✓ Systems management and enterprise solutions
- ✓ Big data and business analytics

As a statistical software package, SAS allows the user to manipulate and analyze data in many different ways. Because of its capabilities, SAS is used in many disciplines, including medical sciences, biological sciences and social

> PRINCIPAL Geethanjali College of Pharmacy (heeryal(V), Keesara(M), Medchal Dist. T.S.-501301,

sciences. The SAS system provides a flexible framework for integrating clinical, sample and experimental data. Knowing the SAS programming language will help you not only in your own research, but also in the development of additional research skills.

#### **RESOURCE PERSON**

Mr. P. Siva Ramakrishna **Digital Solutions Lead Consultant** NTT Data Global Delivery Solutions

#### **ORGANIZING COMMITTEE**

Prof Dr M Srinivas **Programme Coordinator, GCPK** 

> Prof Dr. M. Ravi kumar Principal, GCPK

Shri. G. R. Ravinder Reddy Secretary, Teja Educational Society, Hyderabad

#### STUDENTS COORDINATORS

Mr P. Balram Yadav

Ms S. Sai Sree

PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301. Curriculum for Clinical Data Management (CDM) & Statistical Analysis Systems (SAS)

S.No	Topics	
1	Introduction to clinical research, Roles and Responsibilities of key stakeholders	3
2	Preparations, Planning for Clinical Trials and Essential Documentation in Clinical Research Regulatory submissions	3
3	Introduction to data, Databases and Clinical.Data Management	3
4	CRF Design Considerations	3
5	Data Entry, Transcribing Data, CRF data tracking	3
6	Cleaning data, Identifying and Managing Discrepancies	3
7	Data Management Plan	3
8	Electronic Data Capture	3
9	Tracking CRF Data	3
10	Managing Lab Data	3
11	Collecting Adverse Event Data	3
12	Medical Coding	3
13	Creating Reports and Transferring data	3
14	Case studies	3
15	Audit Trial	3
16	Audit Trial	3

PRINCIPAL Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-501301.

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#### List of Students Enrolled for Add-on Course on Clinical Data Management and Statistical Analysis System for Academic Year 2017-18

S.No	Hall ticket number	Name
1	13Z51T0002	Choppari Vennela
2	13Z51T0003	Dasari Vijaysagar
3	13Z51T0004	Gajula Sreeja
4	13Z51T0005	K Bhavya Sri
5	13Z51T0006	K. Aditya Sai Rama Krishna
6	13Z51T0007	Kamaraju Gadda Bhavana
7	13Z51T0008	Kondam Himabindu
8	13Z51T0009	Lavina Matai
9	13Z51T0010	M. Divya Sree
10	13Z51T0011	M. Pralekhya Sarpana
11	13Z51T0012	Madaboina Suhas
12	13Z51T0013	Marapally Vinay Kumar
13	13Z51T0014	M.Shireesha
14	13Z51T0016	M. Sushmitha Reddy
15	13Z51T0017	Neha Fatima
16	13Z51T0018	Nishitha Goud .
17	13Z51T0019	P. Nehal Sanjana
18	13Z51T0020	P. Shruthi
19	13Z51T0021	Pasham Mounika
20	13Z51T0022	P. Balram Yadav
21	13Z51T0023	Polu Shreeparna
22	13Z51T0024	S Sai Sree
23	13Z51T0025	Sabitha Paka
24	13Z51T0026	Sindhuri V S L
25	13Z51T0027	S.Tulasi Sunandana
26	13Z51T0028	Tula Sneha
27	13Z51T0029	V S Vijaya Lakshmi
28	13Z51T0030	Vani Tadakala
29	16Z51T0003	Najumunisa Begum
30	16Z51T0004	Roshina Fatima

Programme Coordinator

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#### REPORT

Name of the Add-on course: Clinical Data Management (CDM) & Statistical Analysis System (SAS)

Duration: 23/09/17 to 04/11/17

**Resource person details:** Mr. P. Siva Ramakrishna, Digital Solutions Lead Consultant, NTT Data Global Delivery Solutions, Hyderabad.

Geethanjali College of Pharmacy, Cheeryal, Keesara, Hyderabad organized "Add-on course on Clinical Data Management (CDM) and Statistical Analysis System (SAS)" for V Pharm D and II year P.B students. The Clinical Data Management is a critical phase in clinical research, which leads to generation of high quality, reliable, and statistically sound data from clinical trials. This helps to produce a drastic reduction in time from drug development to marketing. Based on the industry need currently this program was organized for PharmD. Total 30 students participated in this training program. All the students actively participated. Upon completion of the program they were able to understand the following objectives and learning outcomes.

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#### **Objectives:**

- 1. Define best practices as they apply to CDM processes.
- 2. Describe CDM processes from study start-up to database lock.
- 3. Apply best practice rationale when assessing data collection requirements/instruments.
- 4. Evaluate the benefits of standardization in establishing CDM processes.
- 5. Discuss current technology methods of data collection and associated documentation.

#### Learning Outcomes:

- 1. Data base validation, data entry processes (EDC/Paper-based studies) and data standards (CDISC/CDASH).
- 2. Safety data management and reporting, serious adverse event reconciliation, and medical coding dictionaries.
- 3. FDA guidelines, protocol review, and data management plan creation and content.
- 4. Case report form design (CRF/eCRF), and edit Check creation.
- 5. Electronic data capturing an application, implementing the system, and study conduct.
- 6. Data quality and metrics.
- 7. External Data, Data transfer agreements, patient reported outcomes and laboratory data.
- 8. Database lock, clinical data archiving, and data storage.
- 9. Project Management for the Clinical Data Manager including Vendor selection.

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This program was very useful to the students and feedback was positive about the program. The management and Prof Dr. M. Ravi Kumar, Principal of GCPK thanked the resource person Mr. P. Siva Rama Krishna from NTT Data Global Delivery Solutions, Hyderabad and participants for making the program successful.

Date: 05/12/2017

Programme Coordinator

PRIN Geethanjali College of Pharmacy Cheeryal(V), Keesara(M), Medchal Dist. T.S.-50130: