NITTE | NGSM INSTITUTE OF PHARMACEUTICAL SCIENCES

DST Technology Enabling Centre

NITTE | K S HEGDE MEDICAL ACADEMY

You are cordially invited to the inaugural function of a Seminar on

GOOD LABORATORY PRACTICES (GLP)
&
GOOD CLINICAL PRACTICES (GCP)

Date: 26th February 2024

Time: 9.30 am

Venue: Seminar Hall, NGSM Institute of Pharmaceutical Sciences

Chief Guest

Dr. Sanjeev Rai B

Chief of Research, Father Muller Research Centre, Mangaluru

Presiding Officer

Dr. Iddya Karunasagar

Advisor-Research & Patents, Nitte (DU)

Dr. Indrani Karunasagar
Director-Projects & DST TEC, Nitte (DU)

Dr. C. S. Shastry
Principal, NGSMIPS, Nitte (DU)

Dr. P. S. Prakash
Dean, KSHEMA, Nitte (DU)

Resource Persons

Dr. Bikash Medhi
Professor,
Dept. of Pharmacology,
PGIMER, Chandigarh

Dr. Ekta Kapoor
Scientist 'F' & Head
National GLP Compliance
Monitoring Authority, DST,
New Delhi

Dr. Parasuraman Jaisankar
Chief Scientist & Head,
CSIR-Indian Institute of Chemical Biology, Kolkata

Dr. Ajay Prakash
Associate Professor,
Dept. of Pharmacology,
PGIMER, Chandigarh

Dr. Shoban Babu Varthya
Associate Professor
Dept. of Pharmacology,
AIIMS Jodhpur, Rajasthan

GOOD LABORATORY PRACTICES (GLP)

Date: 26th February 2024

Timings: 09:00 AM to 05:00 PM

Time	Topic	Speaker
09:00-09:30 AM	Registration	
09:30-10:00 AM	Inauguration Lamp lighting Saraswati Vandana Welcome Address	
10:00-10:45 AM	Introduction to Good Laboratory Practices (GLP)	Dr. Ekta Kapoor *NGCMA, New Delhi*
10:45-11:45 AM	History and development of GLP: OECD, MAD, its current perspective	Prof. Bikash Medhi *PGIMER, Chandigarh*
11:45-12:45 PM	Role of Test facility Management in GLP facility	Industry Speaker
12:45-01:30 PM	Role of Quality Assurance in Review of Standard Operating Procedure (SOPs)	Prof. Bikash Medhi *PGIMER, Chandigarh*
01:30-02:00 PM	Lunch	
02:00-02:45 PM	Role of quality assurance in GLP facility	Dr. P J Shankar *CSIR, ICCB, Kolkata*
02:45-03:45 PM	Pre-Clinical/Non-Clinical Toxicity studies: Investigator New Drug Applications (IND)	Prof. Bikash Medhi *PGIMER, Chandigarh*
03:45-04:15 PM	Panel Discussion Q & A	
04:15-04:30 PM	High Tea	
04:30-05:00 PM	Valedictory Function	

- **Please Scan & Register before 23.02.2024.**
- **The number of participants is limited to 100.**

GOOD CLINICAL PRACTICES (GCP)

Date: 27th February 2024

Timings: 08:30 AM to 06:00 PM		
Time	**Topic**	**Speaker**
08:30-09:00 AM	Registration	
09:00-09:45 AM	Overview of Good Clinical Practice (GCP)	Prof. Bikash Medhi *PGIMER, Chandigarh*
09:45-10:30 AM	Role of Sponsor in Clinical Trial	Industry Speaker
10:30-11:15 AM	ICMR Guidelines for Biomedical Research	Dr. Ajay Prakash, *PGIMER Chandigarh*
11:15-12:00 PM	Statistical Significance Vs Clinical Significance Basic Statistics	Dr. Ajay Prakash, *PGIMER Chandigarh*
12:00-12:45 PM	How to Write a Clinical Protocol/Scientific Paper	Prof. Bikash Medhi *PGIMER, Chandigarh*
12:45-01:30 PM	Randomization-IVRS, eCRF, Sample size calculation, Data entry & result representation	Dr. Ajay Prakash, *PGIMER Chandigarh*
01:30-02:00 PM	Lunch	
02:00-02:45 PM	New Drugs and Clinical Trials Rules, 2019 (India)	Prof. Bikash Medhi *PGIMER, Chandigarh*
02:45-03:30 PM	Informed consent process in Clinical Research	Dr. Shoban Babu, *AIIMS Jodhpur*
03:30-04:00 PM	SAE reporting in Clinical trials and Compensation in clinical trials	Prof. Bikash Medhi *PGIMER, Chandigarh*
04:00-04:30 PM	Clinical trial Data management	Industry Speaker
04:30-05:50 PM	Clinical Trial Registry of India (CTRI) clinicaltrialgov.com Registration & Case Discussion	Dr. Shoban Babu, *AIIMS Jodhpur*
05:50-06:00 PM	Valedictory Function	

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