अखिल भारतीय आयुर्विज्ञान संस्थान जोधपुर
ALL INDIA INSTITUTE OF MEDICAL SCIENCES JODHPUR

National Workshop on GOOD CLINICAL PRACTICE

Current regulatory and ethical requirements for conducting clinical trials/research in India

August 04-05, 2018

All India Institute of Medical Sciences (AIIMS) Jodhpur is one of the SIX NEW AIIMS established by the Ministry of Health & Family Welfare, Government of India under the Pradhan Mantri Swasthya Suraksha Yojna (PMSSY) with the aim of correcting regional imbalances in quality tertiary level healthcare in the country and attaining self-sufficiency in graduate and postgraduate medical education. The institution is established by an Act of Parliament on the lines of the original All India Institute of Medical Sciences in New Delhi which imparts both undergraduate and postgraduate medical education in all its branches and related fields, along with nursing and paramedical training to bring together in one place educational facilities of the highest order for the training of personnel in all branches of health care activity. ***www.aiimsjodhpur.edu.in***

Clinical Development Service Agency (CDSA) is an extramural unit of Translational Health Science and Technology Institute, an autonomous institute of Department of Biotechnology, Ministry of Science & Technology, Government of India. CDSA is the Knowledge Partner in this workshop. CDSA works on a national mandate to build capacity and capability in the area of clinical development and translational research in India. It continually strives to bring in interactive learning opportunities for clinical researchers, ethics committee members, scientists, biomedical researchers and all other personnel involved in clinical trials/research. ***www.cdsaindia.in***

AIIMS Jodhpur and CDSA have a common mandate of capacity and capability building and have come together to conduct GCP Workshop at AIIMS Jodhpur.

Good Clinical Practice (GCP) *is an international ethical and quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials, that provides assurance that the*

- *Rights, safety and well-being of human research participants are well protected*
- *Data and reported results are credible and accurate*

Learning Objectives:

- *To seek cognizance towards principles of GCP, roles and responsibilities of various stakeholder involved in a clinical research/trial*
- *To understand current ethical and regulatory requirements for conducting clinical research/trial in India*
- *To be aware of the national ethical guidelines for biomedical and health research involving human participants by ICMR and national ethical guidelines for biomedical research involving children by ICMR*
- *To understand various requirements for seeking accreditation/registration of ethics committees*
- *To enable the participants to understand that by seeking compliance to GCP they can give public an assurance that the rights, safety and well-being of human participants are well protected and the data from the study results are credible and accurate*

Who can attend?

- *Practicing clinicians, Faculty members, Senior Residents and PG from Medical/ Dental Institution*
- *Research scholars in Biomedical Sciences, Pharmaceutical Sciences and Pharmacy Practice*
- *Hospital/Health care administrators*
- *Faculty from Indigenous system of medicine, personnel like CRCs, Monitors, Auditors, etc.*
- *Industry/Institution/Academia*

Number of participants: *Three Hundred [300]*

Fees:

Registration	***Till 10th July 18***	***After 10th July 18/On Spot***
Students & Residents (JR & SR), PhD	***1500 INR***	***1800 INR***
Faculty & Others	***2000 INR***	***2500 INR***

NEFT/RTGS details *for online transaction:*

Bank :	*Bank Of Baroda*
Branch :	*I E Marudhar Branch*
City :	*Jodhpur (Rajasthan)*
IFSC Code :	***BARB0INDJOD (Fifth Character is Zero)***
MICR Code :	*342012004*
Account Name :	***GCP AIIMSJ 2018***
Account Number :	***18720100023447***

How to register?

Kindly send scanned copies of NEFT receipt & duly filled registration form to email: ***gcp.aiimsj@gmail.com****; and for demand draft (DD)/cheque payment, it should be made in favour of* ***"GCP AIIMSJ 2018" payable at Jodhpur,*** *and the payment with duly filled registration form should be sent to* ***Dr. Pradeep Dwivedi, Dept. of Pharmacology, AIIMS, Basni Phase-2, Jodhpur (Rajasthan)-342005****.*

Course Type: *Non-residential*

CME credit hours*: All medical professionals (MBBS and above) will be granted 04 CME credit hours from Rajasthan Medical Council.*

How to reach us?

Workshop Secretariat*: HOD Pharmacology Office, Department of Pharmacology, 2nd Floor, Medical College Block, AIIMS, Basni Phase-2, Jodhpur (Rajasthan)-342005 Mobile: 8003996952*

gcp.aiimsj@gmail.com (Do write to us for workshop related queries.)

Organizing Committee

Chief Patron

Dr. Sanjeev Misra
Director & CEO
AIIMS Jodhpur

Patron

Dr. Kuldeep Singh
Dean (Academic)
AIIMS Jodhpur

Dr. Praveen Sharma
Dean (Research)
AIIMS Jodhpur

Organizing Chairperson

Dr. Sneha Ambwani
Head (Pharmacology)
AIIMS Jodhpur

Organizing Secretary

Dr. Pradeep Dwivedi
Assistant Professor
Department of Pharmacology
AIIMS Jodhpur

Knowledge Partner

Clinical Development Services Agency (CDSA)

Dr. Sucheta Banerjee Kurundkar
Director Training, CDSA, THSTI, DBT

Organizing Co-Secretaries

Dr. Pramod Kumar Sharma
Department of Pharmacology
AIIMS Jodhpur

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AIIMS Jodhpur

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Dr. Govind Mishra, Dr. Ravi Sharma, Dr. Sameer Khasbage

DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology

National Workshop on GOOD CLINICAL PRACTICE

Current regulatory and ethical requirements for conducting clinical trials / research in India including Schedule Y

Department of Pharmacology, AIIMS, Jodhpur

August 04-05, 2018 Venue: AIIMS Auditorium

Program Agenda

August 04, 2018 (Saturday, Day 01)

Time	Title (Learning Objective)	Presenter
08:30 – 09:30	Registration & Ice breaker	Dr. Arup & Team
09:30 – 10:00	Welcome Address Need to know GCP & Indian Regulations Course Introduction & Overview Vote of Thanks	**Prof. Sanjeev Misra** Director & CEO AIIMS Jodhpur **Prof. Y. K. Gupta** Former Dean (Academics), AIIMS, New Delhi **Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA, THSTI, DBT **Prof. Sneha Ambwani** Head, Pharmacology
10:00 – 10:30	**Group Photograph & Networking Tea**	
10:30 – 11:30	Overview of GCP • What is GCP? Why GCP? • Principles of GCP • GCP (CDSCO, ICH GCP R2)	**Prof. Y. K. Gupta** Principal Adviser (Projects), THSTI, DBT, CG Pandit National Chair, ICMR, Former Dean (Academics), AIIMS, New Delhi
11:30 – 12:30	Current regulatory requirements for conducting clinical trials/research in India (including Schedule Y)	**Shri. A. B. Ramteke** Former Joint Drugs Controller (India), CDSCO, HQ, New Delhi; Consultant, Regulatory Affairs, CDSA, New Delhi
12:30 – 13:30	Ethical Considerations • EC Functioning • Informed Consent Process • Confidentiality and Privacy • Vulnerable Population	**Dr. Nandini K. Kumar** Adjunct Faculty, CDSA; Former Deputy Director General (Senior Grade), ICMR, New Delhi
13:30 – 14:15	**Luncheon**	
14:15 – 15:15	Roles and Responsibilities of stakeholders: Sponsor, Institution, Investigator, Monitor	**Dr. Seema Pai** Director–India Cluster, Clinical Development & Operations, Pfizer Limited, Mumbai
15:15 – 15:30	**Tea/Coffee Break**	
15:30 – 16:15	Clinical Trial Documents (essential documents for conduct of a clinical trial) • Protocol • IB, ICF, CRF, CSR • All other essential documents	**Dr. Seema Pai** Director–India Cluster, Clinical Development & Operations, Pfizer Limited, Mumbai
16:15 – 17:00	Safety Reporting in Regulatory/Non-regulatory Trials and Compensation Issues	**Prof. Y. K. Gupta** Principal Adviser (Projects), THSTI, DBT, CG Pandit National Chair, ICMR, Former Dean (Academics), AIIMS, New Delhi
17:00 – 17:45	Exercises, Case studies, Group activities	Participants
17:45– 16:30	**Open Forum for Q & A**	

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Program Agenda

August 05, 2018 (Sunday, Day 02)

Time	Title (Learning Objective)	Presenter
09:00 – 09:45	Recap	Participants
09:45 – 10:30	Record Keeping and Data Handling	**Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA, THSTI, DBT
10:30 – 10:45	**Tea/Coffee Break**	
10:45 – 11:30	Quality Assurance	**Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA, THSTI, DBT
11:30 – 12:30	• National ethical guidelines for biomedical and health research involving human participants by ICMR (2017) • National ethical guidelines for biomedical research involving children by ICMR (2017)	**Dr. Nandini K. Kumar** Adjunct Faculty, CDSA; Former Deputy Director General (Senior Grade), ICMR, New Delhi
12:30 – 13:30	Ethics Committees: Accreditation & Recognition • NABH • SIDCER	**Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA, THSTI, DBT
13:30 – 14:15	**Luncheon**	
14:15 – 15:00	Investigator Initiated Studies/Trials	**Dr. Arpit Jain** Team Lead, Medical Affairs Department, Boehringer-Ingleheim, India
15:00 – 16:00	Group activities (Exercises, Case studies)	Participants
16:00 – 16:15	**Tea/Coffee Break**	
16:15 – 16:30	Closing Remark	**Dr. Kuldeep Singh** Dean (Academics)
16:30 – 17:30	**EXIT ASSESSMENT**	**Participants**
17:30 – 18:30	Open Forum for Q & A Feedback Distribution of Certificates	All Faculty

HAPPY LEARNING