INDIAN SOCIETY FOR CLINICAL RESEARCH &
BLDE DU RESEARCH AND DEVELOPMENT CELL
SOUTH CHAPTER

presents

WORKSHOP ON GOOD CLINICAL PRACTICE

(GCP)

for the
Faculty of BLDE (Deemed to be University),
Bangaramma Sajjan Campus, B M Patil Road Vijayapura (Bijapur), Karnataka

24TH SEPTEMBER 2022

08.45 AM - 05.45 PM

COMPUTER ASSISTED LEARNING LABORATORY
DEPT. OF PHARMACOLOGY

IN-PERSON & VIRTUAL

ISCR Trainer

DR. GAURAV MATHUR
Senior Director, Regulatory Affairs, Parexel

ISCR Trainer

MS. MALA SRIVASTAVA
Co-Founder & Managing Partner Nextvel Consulting LLP, Bangalore

ISCR Trainer

MS. IRAM QAYUM
Senior Project Leader, Global Project Leadership, Parexel International

ISCR Trainer

DR. AKRAM NAIKWADI
Member Secretary IEC, BLDE (DU)

ISCR Trainer

MS. LAKSHMI ACHUTA
Asst. Principal Strategic Advisor - Biotech, Pharma & Medical Devices - AshRin Biorof BIMS Bidar

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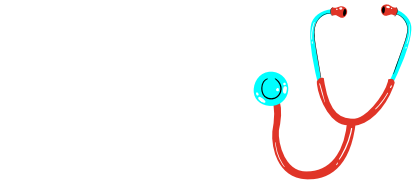

GCP

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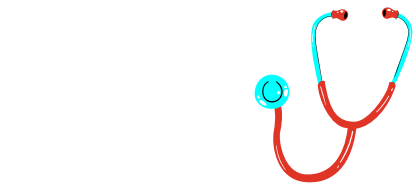
(GCP)

Time	Topic	ISRC Trainer
08:30 am – 08:45 am	Inauguration & Welcome Address	**Dr. R. S. Mudhol** Vice-Chancellor, BLDE (DU)
08:45 am – 09.45 am	Introduction to ISCR Highlights of NDCT Rules, 2019 & Regulatory considerations for conducting clinical trials in India	**Dr. Gaurav Mathur** Senior Director, Regulatory Affairs, Parexel International & Chairperson, South Chapter - Indian Society for Clinical Research (ISCR)
TEA BREAK - 09.45 am - 10.00 am		
10.00 am - 11.00 am	Overview of ICH-GCP E6 (R2) & Indian GCP	**Ms. Mala Srivastava** Co-Founder & Managing Partner Nextvel Consulting LLP, Bangalore
11.00 am - 12.00 am	Sponsor Responsibilities	
12.00 am - 01.00 pm	Investigator Responsibilities	**Ms. Iram Qayum** Senior Project Leader, Global Project Leadership, Parexel International



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(GCP)

Time	Topic	ISRC Trainer
LUNCH BREAK - 01.00 pm - 02.00 pm		
02.00 pm - 03.00 pm	Ethics Committee Responsibilities	**Dr. Akram Naikwadi** Member Secretary IEC, BLDE (DU)
03.00 pm - 03.45 pm	Safety Reporting & Compensation	**Dr. Gaurav Mathur** Senior Director, Regulatory Affairs, Parexel International
TEA BREAK - 03.45 pm - 04.00 pm		
04.00 pm - 05.00 pm	Importance of Quality and Essential Documents in Conduct of Clinical Trials	**Ms. Lakshmi Achuta** Principal Strategic Advisor - Biotech, Pharma & Medical Devices - AshRin Bio
05.00 pm - 05.30 pm	Q&A and Wrap up	**All Participants**
05.30 pm - 05.45 pm	Vote of thanks	**Dr. Chandrika. Doddihal** Deputy Director (R&D) BLDE (DU)

INDIAN SOCIETY FOR CLINICAL RESEARCH &
BLDE (DU) RESEARCH AND DEVELOPMENT CELL
SOUTH CHAPTER
Presents

WORKSHOP ON GOOD CLINICAL PRACTICE
ISCR Trainer
08.45 AM - 05.45 PM
24TH SEPTEMBER 2022
(GCP)

INDIAN SOCIETY FOR CLINICAL RESEARCH
South Chapter
Presents
"Workshop on Good Clinical Practices (GCP)"
(In-person & Virtual)
Saturday, September 24th, 2022
for the
Faculty of BLDE (Deemed to be University),
Bangaramma Sajjan Campus, B M Patil Road Vijayapura (Bijapur), Karnataka

AGENDA

Time	Topic	ISCR Trainer
08:30 – 08:45 hours	**Inauguration & Welcome Address**	**Dr. R. S. Mudhol** *Hon'ble Vice-Chancellor BLDE (DU)*
08:45 – 09:45 hours	**Introduction to ISCR Highlights of NDCT Rules, 2019 & Regulatory considerations for conducting clinical trials in India**	**Dr. Gaurav Mathur** *Senior Director, Regulatory Affairs, Parexel International & Chairperson, South Chapter - Indian Society for Clinical Research (ISCR)*
Tea break 9:45 – 10:00 am		
10:00 – 11:00 hours	**Overview of ICH-GCP E6 (R2) & Indian GCP**	**Ms. Mala Srivastava**
11:00 – 12:00 hours	**Sponsor Responsibilities**	
12:00 – 13:00 hours	**Investigator Responsibilities**	**Ms. Iram Qayum** *Senior Project Leader, Global Project Leadership, Parexel International*
Lunch break 13:00 – 14:00 hours		
14:00 – 15:00 hours	**Ethics Committee Responsibilities**	**Dr. Akram Naikwadi** *Member Secretary IEC, BLDE (DU)*
15:00 – 15:45 hours	**Safety Reporting & Compensation**	**Dr. Gaurav Mathur** *Senior Director, Regulatory Affairs, Parexel*
Tea break 15:45 – 16:00 hours		
16:00 – 17:00 hours	**Importance of Quality and Essential Documents in Conduct of Clinical Trials**	**Ms. Lakshmi Achuta** *Principal Strategic Advisor - Biotech, Pharma & Medical Devices - AshRin Bio*
17:00 - 17:30 hours	**Q&A & wrap up**	**All Participants**
17:30 – 17:45 hours	**Vote of thanks**	**Dr. Chandrika. Doddihal** *Deputy Director (R&D) BLDE (DU)*

The one day workshop on GCP (Good clinical practice) was organised by BLDE(DU)'s R & D cell in collaboration with **INDIAN SOCIETY FOR CLINICAL RESEARCH ,South Chapter on** 24/9/2022. Total 50 faculties were participated. The resource persons from ISCR were covered many of the information and updates related to the GCP during the workshop.

The resource persons were focused on the New drugs and Clinical trials rules 2019 (New rules) was introduced on 19th March 2019 by Government of India. New rules have set specific requirements for ethics committee (EC). The EC is required to follow requirements set as per New rules and to forward their report to Central Licensing Authority (CLA). This document is divided into different sections like definitions and applicable chapter & schedules for EC; changes related to registration of clinical studies and biomedical and health research; changes related to constitution, functions, proceedings, responsibility of EC for clinical trial; maintenance of records by EC; suspension and cancellation of registration of EC, post-trial access of drugs, changes and clarity related to academic clinical trials and role of ECs in compensation and medical management process.

Also, summarizes major changes affecting ethics committee (EC) after coming into force of the New Drugs and Clinical Trials Rules 2019 (New rules), i.e. GSR 227 (E) by India's Ministry of Health and Family Welfare (MoHFW).

EC means, for the purpose of:

i. Clinical trial (CT), EC, constituted under Rule 7 and registered under Rule 8 of the New CT rules
ii. Biomedical and health research, EC, constituted under Rule 16 and registered under Rule 17 of the New CT rules.

There are two chapters which are dedicated to EC. The new rules have separated the ethical governance system by having two different types of ECs with two authorities for their registration and monitoring

Overview of ICH-GCP E6 (R2) & Indian GCP :The International Council for Harmonisation (ICH) is committed to developing timely technical requirements for pharmaceuticals for human use in a manner that is responsive to the needs of the global community. ICH is committed to stakeholder engagement and transparency in the development of its guidelines. ICH E6 Good Clinical Practice (GCP) Guideline is widely used by clinical trial researchers beyond the membership and regional representation of ICH itself and has a significant impact on trial participants and patients. Acknowledging the wide and substantial impact of ICH E6, the ICH Management Committee is making available a draft, work-in-progress version of the updated principles that are currently under development by the ICH E6(R3) Expert Working Group (EWG). The principles are interdependent and should be considered in their totality to assure ethical trial conduct, participant safety, and reliable results of clinical trials. The renovation of ICH E6(R2) will set out principles which will be aligned with the principles in ICH E8(R1) Revision of General Considerations for Clinical Studies. ICH E8(R1) includes a framework for designing quality into clinical trials, stakeholder engagement, trial design, proportionate trial management and focus on factors critical to the quality of trials. When complete, ICH E6(R3) will be composed of an overarching principles document (the document of which a draft is now made public), Annex 1 (addressing interventional clinical trials), and Annex 2 (providing any needed additional considerations for non-traditional interventional clinical trials). The overarching principles document and Annex 1 will replace the current ICH E6(R2). Although the EWG's work is continuing and the group is still progressing towards Step 2 of the ICH guidance development process (https://ich.org/page/formal-ich-procedure), the ICH

Management Committee decided that sharing the draft version of the principles would facilitate transparency and common understanding. Although public comments are not requested at this time, once the updated ICH E6 Guideline achieves Step 2 of the ICH guidance development process, public input will be invited and considered. Step 2 will involve simultaneous publication of both the draft principles and Annex 1, along with an introduction and a glossary. Public comment will be invited at that point since the principles need to be seen and commented on alongside the details in Annex 1. The ICH E6(R3) EWG is organizing a web conference to present the current draft of the GCP principles as a work in progress. Additionally, the general ICH process will be presented with a focus on the ICH E6(R3) development process.

THE PRINCIPLES OF ICH GCP

2.1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).

2.2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

2.3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

2.4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

2.5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

2.6 A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.

2.7 The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

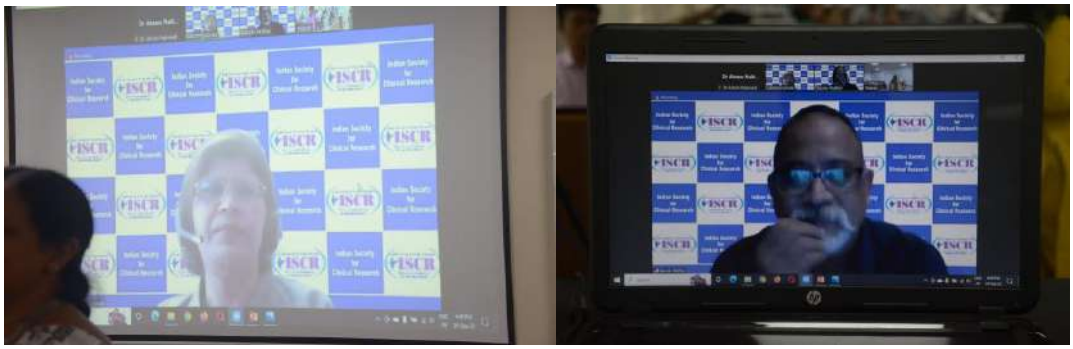
2.8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

2.9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.

2.10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

Sponsors Responsibility:

The sponsor is responsible for supplying the investigator(s)/institution(s) with the investigational product(s).



The sponsor should not supply an investigator/institution with the investigational product(s) until the sponsor obtains all required documentation (e.g., approval/favourable opinion from IRB/IEC and regulatory authority(ies)).

The sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and

return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s)).

The sponsor should:

(a) Ensure timely delivery of investigational product(s) to the investigator(s).

(b) Maintain records that document shipment, receipt, disposition, return, and destruction of the investigational product(s) (see 8. Essential Documents for the Conduct of a Clinical Trial). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice 28

(c) Maintain a system for retrieving investigational products and documenting this retrieval (e.g., for deficient product recall, reclaim after trial completion, expired product reclaim).

(d) Maintain a system for the disposition of unused investigational product(s) and for the documentation of this disposition.

The sponsor should:

(a) Take steps to ensure that the investigational product(s) are stable over the period of use.

(b) Maintain sufficient quantities of the investigational product(s) used in the trials to reconfirm specifications, should this become necessary, and maintain records of batch sample analyses and characteristics. To the extent stability permits, samples should be retained either until the analyses of the trial data are complete or as required by the applicable regulatory requirement(s), whichever represents the longer retention period.

Adverse Drug Reaction Reporting:

The sponsor should expedite the reporting to all concerned investigator(s)/institutions(s), to the IRB(s)/IEC(s), where required, and to the regulatory authority (ies) of all adverse drug reactions (ADRs) that are both serious and unexpected.

2 Such expedited reports should comply with the applicable regulatory requirement(s) and with the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

The sponsor should submit to the regulatory authority (ies) all safety updates and periodic reports, as required by applicable regulatory requirement(s).

Clinical trial documents also **demonstrate the degree of compliance of the investigator(s), sponsor and monitors with applicable regulations and GCP guidelines**. They are usually audited by the Sponsor and inspected by the regulatory authorities to confirm data validity and integrity.

The workshop ended with the vote of thanks with feedback by the participants.

ATTENDANCE

PARTICIPANTS LIST OF GCP WORKSHOP ON 24TH SEPTEMBER 2022

Venue:- Computer Assisted Laboratory ,First Floor Dept. Of Pharmacology

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