ST FRANCIS DE SALES COLLEGE
Permanently Affiliated to Bangalore University Electronics City, Bengaluru - 100
Accredited with NAAC "A" Grade || Recognised under 2(f) & 12(b) of the UGC Act
A FRANSALIAN INSTITUTE OF HIGHER LEARNING

WORKSHOP ON
GOOD LABORATORY PRACTICES
IN CLINICAL RESEARCH

Dept: Department of Science and IP, research cell

Date: 10-11 August 2018

Venue: Business Lab

Resource Persons: Mr.Chandrappa and Dr.Jennifer

A REPORT ON

WORKSHOP ON GOOD LABORATORY PRACTICES IN CLINICAL RESEARCH

Dept: Department of Science and IP, research cell

Date: 10 -11 August 2018

Venue: Business Lab

Resource Persons: Mr.Chandrappa and Dr.Jennifer

In the clinical research arena, **good laboratory practice** or **GLP** is a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests. So, a good laboratory is a place where reliable results are produced. So how to develop a laboratory into a good laboratory is always a challenge, especially while conducting clinical research. Then, it becomes very important to know what good laboratory practices, its significance are and how to practice it. This course has been designed specifically for chemistry students, researchers and teachers who are required to face many challenges in their laboratory where they study or work. It concentrates exclusively on the skills you need to make the working process easier which leads to reliable results which are authentic and clear.

The workshop was conducted for two days from 10-08-2018 to 11-08-2018. Over the two-day workshop, delegates learn how to implement practice good laboratory practices in the conducting clinical research. They could improve report writing skills, learning the techniques through group discussion, exercises and working on real examples.

The workshop focused on the following drills and hands-practices:

- Identifying the priorities of your lab.
- Making Standard operating procedures (SOP) for a particular lab
- Maintenance of record of very work as per SOP
- Significance of good laboratory practices in clinical research

OBJECTIVES

The objectives of this two-day workshop were as follows:

- To introduce the concept of good laboratory practices
- To develop standard operating procedures (SOP) for a particular experiment
- To develop Standard operating procedures (SOP) for a particular lab
- Maintenance of record of very work as per SOP
- To learn to implement good laboratory practices

Day One: 10-08-2018

Inaugural session

The two-day workshop started with a short inaugural session. The inaugural session commenced at 09.30 am. The gathering was welcomed by Ms. Jyothi Smitha, III BSc (PCM) .and Mr. Prabhu Chetan, V sem BSc (MEC) briefed the profiles of the chief guest and resource person for the post lunch sessions (Technical session 1 and 2) Mr. Chandrappa, Formerly Senior Manager, Quality Control, Strides Shasun Ltd, Bangalore. Mr. Chandrappa who has 32 years experience in Quality, Production and regulatory affairs with major India Pharma companies is presently working as a free Lance pharma consultant and trainer , Excels in New Product Development including requirement analysis, finalizing specifications, design, GA, assembly& part drawings, prototype development, pilot production & testing with key focus on quality, cost & delivery.

Dr. Roy, Principal and Vice Principal Fr. Jijo Manjackal were also present in the inaugural session. Dr. Nebula Murukesh, Coordinator, Department of Science gave an overview of the two-day workshop. Prof. Roshini Anne Koshy delivered the vote of thanks. Later on, the resource person took over the session.

Technical session 1(10:00am- 11:15 am): Introduction to good laboratory practices

The resource person started with definition of good laboratory practice, GLP. He made it clear that it is a FDA regulation. The session detailed on the reason for the creation of GLP. Also the session has thrown light into the purpose and principles of GLP. Mr. Chandrappa explained what are the things that has to done in a laboratory for GLP and what are its benefits. The main points of the session were as follows;

- GLP was first introduced in New Zealand and Denmark in 1972, and later in the US in 1978 in response to the Industrial BioTest Labs scandal. It was followed a few years later by the Organization for Economic Co-operation and Development (OECD) Principles of GLP in 1992; the OECD has since helped promulgate GLP to many countries.
- GLP applies to non-clinical studies conducted for the assessment of the safety or efficacy of chemicals (including pharmaceuticals) to man, animals and the environment.
- GLP, a data quality system, is not the same as standards for laboratory safety - appropriate gloves, glasses and clothing to handle lab materials safely.
- The principles of GLP aim to ensure and promote safety, consistency, high quality, and reliability of chemicals in the process of non-clinical and laboratory testing.
- GLP is not limited to chemicals and also applies to medical devices, food additives, food packaging, colour additives and other non-pharmaceutical products or ingredients.

Mr. Chandrappa's lecture was a breakthrough on industrial exposure for physical science aspirants. Mr. Chandrappa explained "Good laboratory practices in clinical research in a very professional but comprehensible way which can be understood by any physical science student. The session followed a tea break.

Technical Session 2 (11.30am to 1.00pm): GLP Principles

Mr. Chandrappa continued with the post tea break session on the principles of GLP. The resource person detailed the ten principles of GLP as the following:

- Organization and Personnel
- Quality assurance program
- Facilities
- Equipment, reagents and materials
- Test systems
- Test and reference items
- Standard operating procedures
- Performance of study
- Reporting of results
- Archival - Storage of Records and Reports

Each of these principles was explained in detail with examples. At the end of the session, the delegates were ask to identify the test systems available in the laboratory as a group and any one of the group member were asked to present how they will validate the system. Mr. Chandrappa instructed the delegates to start the practising GLP for their lab in graduate and post graduate levels which may help them in future while working in any lab. At the end of the session, Prof. Senthil Kumar, Asst. Professor, Department of Science thanked and felicitated Mr. Chandrappa. We then adjourned for lunch break.

Technical session 3 (1.30pm to 3.00pm): Introduction to SOP

The post lunch session started with the introduction of the resource person Dr. Jennifer, Assistant Professor, Oxford College of Science, Bangalore. The resource person is an experienced laboratory person with and is an expert in the design and synthesis of heterocyclic molecules for therapeutic targets related to Cancer and antimicrobial activity, retro analysis, development of synthetic protocols for various chemical scaffolds, development of process development and trouble shooting in chemical reactions. Moreover, a well experienced person in coordinating interdisciplinary drug discovery efforts with excellent communication & interpersonal skills and Good Team Player. Dr. Jennifer was welcomed to take over the session.

The resource person started the session by asking about what the participants have learned from the last two sessions. They could reply well with the concepts introduced to them in the last sessions. The term SOP was introduced and the participants were asked to write each and every step that they follow in a particular reaction of their choice. At the end of the activity the participants could realise that SOPs define how to carry out protocol- specified activities which are most often written in a chronological listing of action steps which are written to explain how the procedures are suppose to work.

Technical session 4 (3.00pm to 4.30pm): Development of SOP

Technical session 4 was followed with the previous session with snacks and tea served on each seats. The resource person explained further on routine inspection, cleaning, maintenance etc. She emphasised on keeping records, reporting, storage and analytical methods. As the participants were enjoying the refreshments they were asked to develop a sop for the same experiment for which they have written the procedure in the last session. The standard procedures required for the development was given as a template. The session ended with thanks to the resource person. The participants were given an assignment to write a study plan for a given problem and submit on the next day.

Day 2: 11-08-2018

Technical session 5 (9.30am to 11.15am): Test systems and test facilities

The second day of the workshop started with the technical session 5 on one of the principles of GLP, which is performance of study and reporting of study results. Dr. Anil Kumar R., Team leader, Strides Shasun Ltd, Bangalore was the resource person for the day. With more than 15years of experience in GLP and development of SOPs he started the session with a brief introduction on test systems. Later on in the session the resource person explained the physical, chemical and biological test systems. He detailed on the records of source, date of arrival and arrival conditions. Also he emphasised on cleaning and sanitation of containers and pest control agents. Later on he gave an overview of stability of tests. After a detailed session on test systems the break for tea.

Technical session 6 (11.30pm to 1.00pm): Performance of study & reporting of study results

The post tea break session started with the assignment given on the previous day on development of study plan. This session was conducted in the chemistry lab and the participants were asked to perform the experiment as per the test method given and report the results. Then a template was given as per the SOP and asked to fill in the details. Thus they understood how planning and reporting of a study is carried out as per GLP. The resource person was felicitated and thanked and the session adjourned for a lunch break.

Technical session 7 (1.30pm to 3.00pm): Group Practice

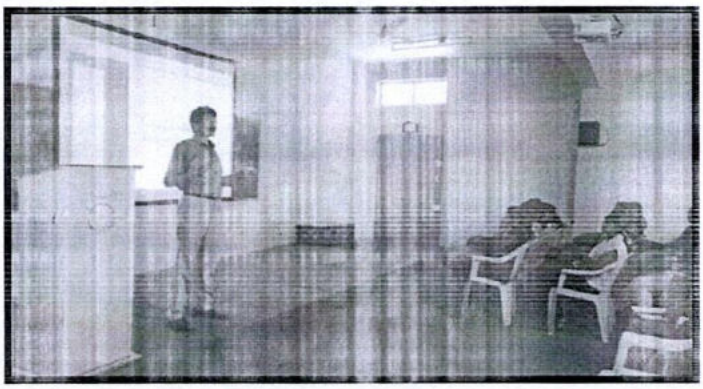
The post lunch session was conducted by Dr. Nebula Murukesh, Coordinator, Department of Science. The participants were divided into groups of six members and asked to identify the responsibilities various levels of organisation and personnel as Management, Sponsor, Study Director, Principal Investigator, study Personnel. Also they were asked to develop a GLP for a given laboratory. Later on the GLPs of each group were evaluated by other groups as a mock inspection.

Valedictory Session (3.00pm to 3.30pm)

The technical session 7 was immediately followed by valedictory session in which the certificates for the participants were distributed and the concluding remarks were made. The feedback from the participants was collected.

Co-ordinator
Internal Quality Assessment Cell
St Francis de Sales College
Electronics City Post, Bangalore - 560 100.

PRINCIPAL
St. Francis de Sales College
Electronics City Post, Bangalore - 560 100.



Co-ordinator
Internal Quality Assurance Cell (IQAC)
St Francis de Sales College
Electronics City Post, Bangalore - 560 100

PRINCIPAL
St. Francis de Sales College
Electronics City Post, Bangalore - 560 100

ST FRANCIS DE SALES COLLEGE

Permanently Affiliated to Bangalore University | Electronics City, Bengaluru - 100

Accredited with NAAC "A" Grade || Recognised under 2(f) & 12(b) of the UGC Act

A FRANSALIAN INSTITUTE OF HIGHER LEARNING

ATTENDENCE SHEET

DATE- 10, 11 AUGUST 2018

EVENT- WORKSHOP ON GOOD LABORATORY PRACTICES IN CLINICAL RESEARCH

SL NO	NAME	ROLL NO	SIGNATURE
1	MONICKA SHALU A	P03MB22M015003	
2	JAGADESH S	P03MB22M015004	
3	MEENA.E	P03MB22M015005	
4	M Prashantha	P03MB22M015006	
5	Balaji N	P03MB22M015007	
6	Bennyhinn. M	P03MB22M015008	
7	Jagadish S	P03MB22M015009	
8	SHANKAR V R	P03MB22M015010	
9	PAVITHRA L	P03MB22M015011	
10	D Surya Babu	P03MB22M015012	
11	Pushpa S G	P03MB22M015013	
12	SIVA KUMAR S	P03MB22M015014	
13	SURESH S	P03MB22M015015	
14	Nithin T	P03MB22M015016	
15	Prajwal P	P03MB22M015017	
16	Ajay kumar	P03MB22M015018	
17	Santhosh Kumar C	P03MB22M015019	
18	SANJAYKUMAR S	P03MB22M015020	
19	VIKAS Reddy S	P03MB22M015021	
20	ANJALI SINGH	P03MB22M015022	
21	Manas C	P03MB22M015023	
22	Karthik S	P03MB22M015024	
23	JANANI R	P03MB22M015025	
24	Ramya R	P03MB22M015026	
25	Rakesh P	P03MB22M015027	
26	Deepa B	P03MB22M015028	
27	Santhosh A R	P03MB22M015029	
28	Chandrashekar B R	P03MB22M015030	
29	RAMACHANDRA PAWAR	P03MB22M015031	
30	Swamy R	P03MB22M015032	
31	Lavanya C G	P03MB22M015033	
32	SAHANA C	P03MB22M015034	
33	Srijala V C	P03MB22M015035	

ST. FRANCIS DE SALES COLLEGE * Bengaluru - 100 *

34	Venu.v	P03MB22M015036	Venu.V
35	Srinivas B V	P03MB22M015037	Srinivas