Report of Workshop on
"Quality, Manufacturing and Pharma Industry Orientation"
held on 16th-18th January 2020

Conducted by Pharma Training Institute (PTI)

In Collaboration with

Department of Biochemistry

Mount Carmel College, Autonomous

Bengaluru

Aim of the Workshop

To enhance knowledge of the M.Sc. Biochemistry students on good manufacturing practices followed by the Pharmaceutical industry and expose them by way of industrial visits.

Participation - A total of 64 participants (58 students + 6 faculty members)

Inaugural session

The inaugural session commenced at 9.00 am with the arrival of the guest speakers. **Mr. Uma Nandan Misra**, Director, Pharma Training Institute (PTI), Mr. Venu Gopal (Ex-Manager AstraZeneca) and Ms. Smitha Rao (Ex-Assistant Manager AstraZeneca). The event was started with an Invocation to the Almighty through reading from the Holy Bible and Invocation song. This was followed by Lighting of the lamp by the dignitaries. **Dr. Kavitha G. Singh** (HOD, Dept. of Biochemistry) rendered the Welcome address while **Dr. Myrene R. Dsouza** introduced the Theme of the lecture workshop. **Dr. Thilagavathy** briefed the audience about Pharma Training Institute.

Lighting of the Lamp

Introduction to the Theme

Introduction to PTI

Audience

Here we present the detailed report of the sessions:

Day 1 (16th January 2020)

Session 1: Mr. Uma Nandan Misra, Dean, Pharma Training Institute, Bengaluru.
Topic: "Overview of Pharma Industry: An interactive session with students"

An interactive session in which students were asked to present answers to the questions previously provided to them. Some answers were self-explanatory while others needed to be revised as per latest statistics available. This session was marked and the students scored an overall of 75%. In addition, Mr. Misra spoke about the various types of research including basic, process, formulation development, analytical, packing development and clinical research.

Session 2: Mr. Venu Gopal Rao, Ex-Manager, AstraZeneca Pharma India Limited
Topic: "Introduction to Quality Control and Good Laboratory Practices"

Mr. Rao began his lecture with insights into regulated and non-regulated markets whilst briefing the audience about the various organizations involved in the same. He then explained the various departments and their respective roles in the support the manufacturing process. The different dosage forms and their merits and demerits were highlighted. Terms like API and IPI were defined. The activities of Quality control in the pharma industry were well illustrated. Topics like analysis of raw materials, sampling devices, forced degradation, ICH guidelines,

GLP, OOC and OOT were well discussed. This session thus gave an overall understanding of the roles and process of QC.

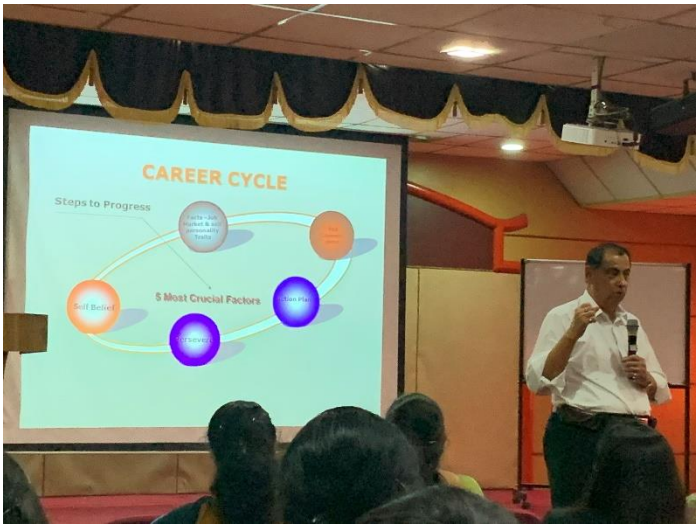
Session 3: Ms. Smitha Rao, Ex-Assistant Manager QC, AstraZeneca Pharma India Ltd
Topic: "Pharmaceutical Microbiology"

Ms. Smitha Rao commenced her session with an interactive discussion about the importance of preventing microbial contamination in a pharmaceutical manufacturing setup. The dangers of contamination w.r.t reduction of API's therapeutic activity, presence of bacterial endotoxin in injectables/parenterals, product recall etc. were highlighted up. Sources of such contamination – materials, personnel, facility and equipment were discussed along with ways of prevention. The speaker listed the roles of the microbiology department such as analysis of raw materials and finished products, depyrogenation, validation, water testing, environmental control etc.

Session 4: Mr. Uma Nandan Misra, Dean, Pharma Training Institute, Bengaluru.
Topic: "Pharmaceutical Manufacturing"

Mr. Misra provided in depth insights into the process of tablet of manufacturing ranging from concepts of choosing the best formulation type, dispensing, sifting and milling, granulation, drying, blending with fillers, compression, coating and finally packaging. The main differences between ointment and liquid manufacturing processes were highlighted. The lecture was concluded with a list of roles and responsibilities of a production pharmacist such as planning, organizing, implementation of operation manuals, production plants and programs, checks to be done on raw and packaging materials and preparation of daily reports. He stressed on the application of EHS on QC implementation and possible ways to avoid errors.

Session 5: Mr. Uma Nandan Misra, Dean, Pharma Training Institute, Bengaluru.
Topic: "Career Opportunities for Science Graduates"



The session commenced with Mr. Misra briefing the students about career options available to lifescience students. He emphasized the importance of staying abreast with new developments in the pharma industry and to constantly strive to gain knowledge. Mr Misra explained 5 factors crucial to career growth. He then went on to explain some of the disciplines that are directly or indirectly linked to the pharma industry. The session proceeded with opportunities in the industry such as medical representatives, clinical trials, QC, QA, supply chain, PPIC, biomedical informatics, training, HR and HSE. SWOT analysis was explained in detail to enlighten the students about their weakness and strengths that would enable them to set goals. The talk was concluded with 12 key points to success.

<u>Day 2 (17th January 2020)</u>

Session 6: Mrs. Vasundhara Rama Iyengar, Quality Head, GSK India Pharmaceuticals Ltd., Vemgal
Topic: "Current Good Manufacturing Practice (cGMP) and Product Release"

Mrs. Vasundhara commenced her lecture with the importance of Risk based approach in Pharma industry to be run along with ICH guidelines. The role of applying quality checks at various stages in the procurement of raw materials, laboratory control, stability testing, control of microbial contamination, batch release, production record and calculation of product yield

was highlighted. An analogy of pharma industry with checks followed in the automobile industry was done. An example of thalidomide toxicity and how it could have been avoided with cGMP process was discussed. Ways to maintain consistent quality during the manufacturing process and its impact on financial returns for the company was explained.

Session 7: Mrs. Matilda George, Pharmaceutical Quality Consultant & Trainer
Topic: "Quality Management System, Change Control, Customer Complaints"

This session encompassed concepts on quality management systems, change control and customer complaints. Mrs George described a six-system approach to quality control. Change management process is a long process involving steps such as request, impact analysis, approval/denial, implement change and review/reporting. Deviations from approved instructions, the consequences and handling of such deviations was also discussed. Focus on OOC and OOT, failure investigation protocol, corrective and preventive action (CAPA), customer/ market complaints were given with due importance to handling of feedback. Overall, the session was well structured raising crucial topics faced by the pharma industry.

Session 8: Dr. Deepak Shankar, Global Safety Physician, AstraZeneca Pharma India Limited
Topic: "Clinical Trials and Technical Writing"

The session by Dr. Deepak started with the various steps involved in the clinical trial process. He discussed the duration and cost to company for the movement of a drug candidate from lab to market. The role of a biochemistry graduate in understanding PK and PD of the drug candidate was emphasized and the students were encouraged to take this up as a career option. Ethical principles such as fair selection of subjects, informed consent and upholding social and clinical values to be followed during the clinical trial process was highlighted. The second half of the talk focused on medical writing and the various opportunities in this field such as regulatory and non-regulatory.

Session 9: Ms. Vijaya Nalini, Senior Manager Supply Chain
Topic: "Inspiring Success Story"

The session started with Mrs Vijaya Nalini quoting an example about the 'Elephant's chain syndrome' which refers to how human beings tend to confine ourselves in a smaller and comfortable space rather than think out of the box. This was an interactive, life skills developing session were pointers to becoming successful were discussed – belief, learning from problem, practice, perseverance, happiness, analyzing personal strengths and uniqueness.

Valedictory and Final Vote of Thanks

The certificates for participation in the workshop were distributed to the students by Mr. Misra and Dr. Kavitha G. Singh. The Final Vote of Thanks was proposed by Dr. Shlini P. She gratefully acknowledged Pharma Training Institute for organizing the 3-day workshop. The college Management was thanked for their encouragement and support. All the participants were acknowledged for their active participation.

Day 3 (18th January 2020)

Industrial visits to Microlabs and Stabicon

A one-day visit to Microlabs and Stabicon was made as part of the workshop. Both facilities had only the manufacturing unit accompanied by Quality control. Both companies manufacture ophthalmics and injectables. All these products are produced in accordance to the regulations of different markets based on client requirements. The final products fall under the category of sterile products and hence all levels of sterility are maintained in the facility.

The three lines in manufacture were noted as BFS for three-piece containers, ampoules and vials for injectables. Packaging and dispatch too were done according to market requirements and specific regulations of the country of sale. The students interacted with employees of the QC and QA departments to obtain a thorough understanding of regulations to be followed. The visit was hence a good opportunity to learn about the manufacturing plant of a pharmaceutical industry and all the supporting departments that go with it.