

Workshop on

QUALITY CONTROL AND QUALITY ASSURANCE IN PHARMA
INDUSTRY

held on 12th July 2024



Conducted by Pharma Training Institute (PTI)

In Collaboration with

Department of Biochemistry

Mount Carmel College, Autonomous

Bengaluru

Aim of the Workshop

To enhance employability of M.Sc. Biochemistry students on good manufacturing practices followed by the Pharmaceutical industry and provide a platform for interaction with industry experts.

Participation - A total of 52 participants (45 students + 7 faculty members)

Inaugural session

The inaugural session commenced at 8.30 am with the arrival of the guest speakers. **Mr. Uma Nandan Misra**, Director, Pharma Training Institute (PTI), **Mr. Venu Gopal Rao** (Manager, AstraZeneca Pharma India Limited), and **Mr. Maheshwarayya** (Quality Assurance Professional). The event started with an Invocation to the Almighty through reading from the Holy Bible and Invocation song. This was followed by a Welcome address by **Dr. Kavitha G. Singh**, Dean – Research and Publications, **Dr. Myrene R. Dsouza** introduced the Theme of the lecture workshop and **Dr. Thilagavathy** briefed the audience about Pharma Training Institute.

Here we present the detailed report of the sessions:

Session 1: Mr. Venu Gopal Rao, Ex-Manager, AstraZeneca Pharma India Limited

Topic - “Overview on Quality Control function”

Mr. Venu Gopal Rao, a seasoned manager at AstraZeneca Pharma India Limited, discussed the pharma industry's role in medical innovation, focusing on New Chemical Entities (NCEs) and gene therapy. The industry involves creating new generic drugs and assigning generic names to medicines, following strict marketing guidelines from regulatory bodies like the CDSCO, USFDA, and MHRA to ensure safety and effectiveness. High-quality manufacturing is also emphasized in the pharmaceutical industry.

Medications are used for treating diseases (therapeutic) and preventing illnesses (prophylactic), playing a key role in improving public health. Enteral administration involves

giving medications through the digestive tract, while parenteral administration delivers drugs directly into the bloodstream via injections. Dosage is the specific amount of medication to be taken at one time or over a period.

Good Manufacturing Practices (cGMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and Good Distribution Practice (GDP) are practices that ensure safety and quality in production, research, clinical trials, and distribution. Quality Control (QC) and Quality Assurance (QA) are crucial in the pharmaceutical industry. QC tests products to ensure they meet standards and are defect-free, while QA is proactive, focusing on designing manufacturing processes to prevent defects and ensure consistent quality. Together, QC and QA ensure that pharmaceutical products are safe, effective, and meet regulations.

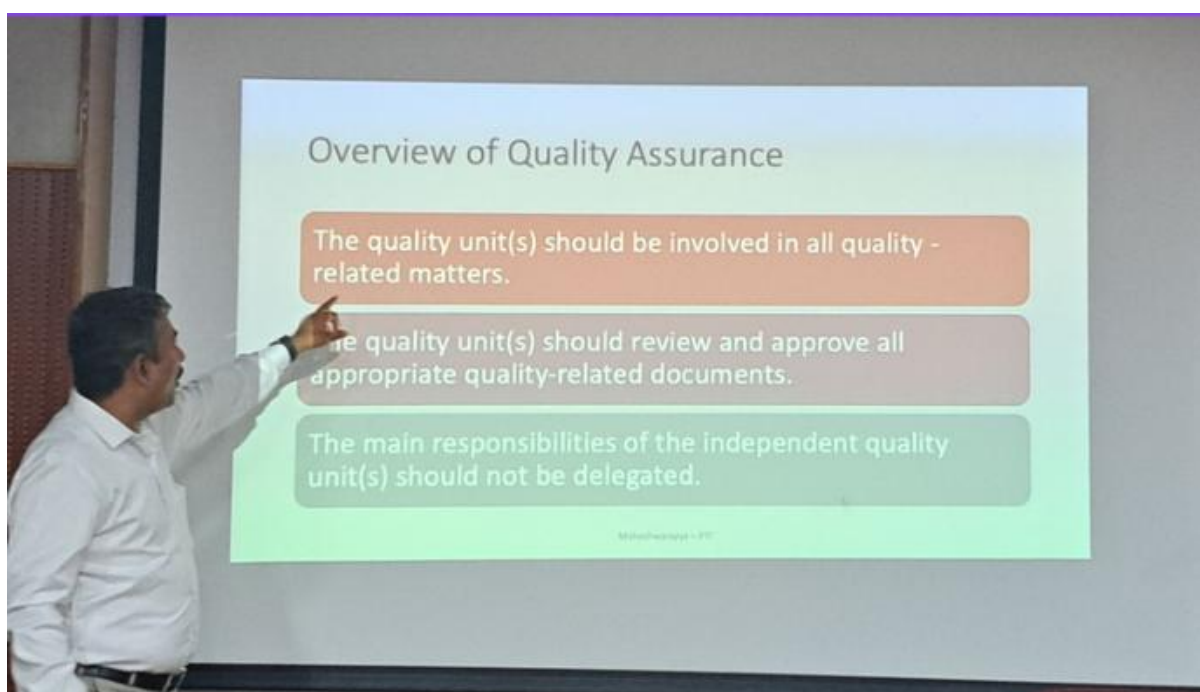


Session 2: Mr. Maheshwarayya Benchimath, Quality Assurance Professional

Topic- “Overview on Quality Assurance function”

Mr. Benchimath started this session by the simple definition of quality assurance. He gave a brief introduction to GMP (Good Manufacturing process) and its important aspects in quality control. He mentioned the reason for initiating GMP which was due to the sulphanilamide disaster that occurred in the US in 1937 where people died by taking Sulphanilamide elixir which was taken as a cough medicine. Another such reason was the Thalidomide disaster that

occurred in Germany during the 1960s due to the extensive distribution of this medication among pregnant women to treat nausea which led to deformities formed in children. Lastly, he gave a brief overview of Quality Assurance and its few steps like making sure that critical deviations are investigated, approving all specifications, approving all procedures impacting the quality of drug product, making sure the internal audits are performed, performing product quality reviews etc.



Session 3: Mr. U. N. Misra, Dean, Pharma Training Institute, Bengaluru

Topic- “Overview on Manufacturing function, Overview on Pharma Industry in India and the world”

Uma Nandan Misra, a seasoned professional with 45 years of experience in the pharmaceutical industry, led sessions on "Pharmaceutical Manufacturing" and "Pharma Plant Performance Monitoring" at Pharma Training Institute (PTI). He discussed the complex process of drug production, including the production of Active Pharmaceutical Ingredients (APIs) and their formulation into various dosage forms. API manufacturing typically begins with chemical synthesis, fermentation, or biotechnological methods, followed by purification and quality

control to ensure purity. APIs are then formulated into various dosage forms, such as tablets, capsules, ointments, liquids, and aerosols. Tablets are manufactured through granulation, compression, and coating processes, while ointments blend the API with a suitable base and homogenize. Liquid formulations require dissolving the API in a solvent, capsules are encapsulated in gelatin or HPMC shells, and aerosols are suspended in propellants for inhalation therapies.

Production pharmacists play a crucial role in pharmaceutical manufacturing, overseeing the manufacturing process, ensuring compliance with regulatory standards, and managing documentation. They coordinate with departments to ensure environmental, health, and safety protocols are followed, reducing risks to workers and the environment. Production pharmacists also play a key role in quality assurance, conducting regular inspections and audits to maintain high standards.



Session 4: Mr. U. N. Misra, Dean, Pharma Training Institute, Bengaluru

Topic - "Life skills in the Pharma Industry"

We recently had the pleasure of hosting an insightful talk session on 'Life Skills in the Pharma Industry' by Mr. U.N. Misra, the esteemed Dean of the Pharma Training Institute in Bangalore, organized by our very own Mount Carmel College, Bangalore." He talked about the importance of adolescent personality development which are self-awareness, autonomy and independence and curious, adventurous, experimental behaviour of individuals. He also talked about the life skills which are the abilities that help promote mental wellbeing and competence in young

people as they face the realities of life. UNICEF has defined life skills as the behaviour change or behaviour development approach. WHO defined life skills as the abilities for adaptive and positive behaviour that enables individual to deal effectively with the demands of everyday life. Some different types of life skills are decision making, creative thinking, problem solving, negotiation skills interpersonal relationship, self-awareness, empathy, effective communication and coping with stress and emotions.

He concluded the session by talking about the steps for a responsible decision making such as identifying or defining the problem, consider the consequences or outcomes, consider family, consider family and personal values, choose one alternative and implement the decision. The different stages of proper decision making are as follows: identifying the problem or issue, collecting information or knowledge, associated physical, emotional, physiological feelings, possible ways of solving, effective communication skills, alternative solutions and mutual decisions and also how to cope with emotions and stress that is recognizing effects of emotions on others and ourselves, being aware of how emotions influence our behaviours and able to respond to emotions appropriately. He also pointed about the significance of life skills like to be able to explore alternatives, weigh pros and cons and make rational decisions. He also insisted on taking major life decisions by remembering some important points namely goals, choice, coping up and lastly career.



Session 5: Mr. U. N. Misra, Dean, Pharma Training Institute, Bengaluru

Topic - “Job Opportunities in Pharma Industry”

Mr. Misra began the meeting by informing the students of the many promising professions in the biological sciences. He stressed the importance of having faith in oneself and setting a specific objective. Self-belief, perseverance, an action plan, self-commitment, and facts are the five most important components in one's career cycle. Initial discussion focused on the wide range of career paths open to those with expertise in the life sciences. He then elaborated on how the pharmaceutical sector is connected to a number of other fields. Sir enthusiastically shared several anecdotes from his own career to acquaint us with the business's inner workings. The final portion of the seminar focused on the skills and character characteristics participants should develop in preparation for the workforce. The success triangle, keys to success, and SWOT analysis were all explained to us. This session's wealth of information has given us new avenues to explore in terms of employment, particularly in the pharmaceutical sector.

Valedictory and Final Vote of Thanks

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

