

**BHARATIYA VIDYA BHAVAN'S
M.M COLLEGE OF ARTS, N.M. INSTITUTE OF SCIENCE, H.R.J COLLEGE
OF COMMERCE**

**SKILL DEVELOPMENT WORKSHOP [UNDER DBT STAR SCHEME]
ON
GMP, INSTRUMENTATION, MOLECULAR BIOLOGY TECHNIQUES,
FACING FDA AUDITS & JOB INTERVIEWS**

Resource Person – Dr Anil Fokmare, Director GISM

Dates of workshop – 29th, 30th APRIL & 02nd MAY [9 AM TO 4 PM]

MEMBERS OF ORGANIZING COMMITTEE

1. Prof (Dr) Zarine Bhathena – Principal, Head of the Department
2. Dr. Shruti Samant – Associate Professor, Dept of Microbiology & DBT Star Coordinator
3. Dr. Rajesh Patil – Associate Professor, Department of Microbiology
4. Dr. Savanta Raut – Associate Professor, Department of Microbiology
5. Mr. Rutam Mulay – Lecturer, Department of Microbiology
6. Ms. Leena Pilankar – Lecturer, Department of Microbiology
7. Mr. Bony Dasari – Lecturer, Department of Microbiology
8. Ms. Madhavi Sagwekar – MSc Coordinator, Dept of Microbiology
9. Ms. Sohini Dasgupta – PhD student
10. Ms. Ruchi Malik – PhD student
11. Ms. Aarti Potphode – PhD student
12. Ms. Supriya Yadav – PhD student
13. Mr. Niranjana Patil – PhD student

Summary Report

Background:

A three day skill development program was organized at Bharatiya Vidya Bhavan's M.M College of Arts, N.M. Institute of Science; H.R.J College of Commerce Bhavan's College [Autonomous], by Department of Microbiology under the DBT Star scheme from 29th April to 2nd may 2022 from 9am to 4pm. The resource person invited for the program was an eminent speaker Dr. Anil Fokmare, Director of GISM. The program was successfully conducted under the guidance and vision of our honorable Principal Madam, Dr. Z. P. Bhathena and Dr. Shruti Samant [DBT Star Coordinator] who provided us with valuable suggestions and ideas towards the program. Program Convener, Dr. Rajesh Patil [Associate Professor] provided his constant support for the smooth conduction of the program. Dr. S. V. Raut [Associate Professor] gave his informative ideas that helped in the organization of the program.

The program's main objective was to bridge the gap between academia and industry by enlightening the students about the different aspects of working in an industry; with topics including handling of various instruments, the students were able to grasp the basic principle behind the use of various instruments. Students were provided with information on Good Manufacturing Practices (GMP), which would help them understand the key principles involved in manufacturing. Apart from that the guest speaker highlighted points on how to face FDA audits and Job interviews, which helped train the students & gain experience on how to tackle interviews, and stand out of the crowd.

Day 1:

The program began sharp at 10:00 am, with lighting of the lamp by the dignitaries. A warm introduction of the Guest speaker was given by Ms. Supriya Yadav. The Guest speaker Dr. Anil Fokmare was felicitated by Dr. S.V. Raut, and welcomed on the dais. Dr. Fokmare began the session by reminiscing memories of the earlier event held in the year 2020, a slideshow was presented, where photographs of the previous event were shown. Some words of encouragement were also shared.

The topics for Day 1 were focused on the role of GMP in pharmaceutical industry, and the importance of quality was also highlighted. While explaining these points the guest speaker shared an incident of Thalidomide & Sulphanilamide drug tragedy, stating the effects of the drugs during the 1950's and why it had to be taken off the market. The incident highlighted the gravity of GMP & quality of drugs being marketed. The session continued to explain the origin of GMP where the history, principles were explained.

The first activity was based on this topic where the GMP daily manual was shared, and the importance of following of rules & regulations performed. A second activity where the students were explained the significance of contamination, 10 students were asked to squat on the ground with their hands touching the ground. They were then offered a piece of chocolate to eat. A video on the proper protocols to follow while entering a microbiological laboratory was shown.

Good Laboratory Practices (GLP) was explained, in which the validation of Lab instruments, cleaning procedures analytical processes were explained. A video showing an

inspection of a manufacturing plant was shown; this was to give an idea of how the GLP is followed in industries. The program was adjourned for lunch break at 01:30 pm.

After the break, the students were divided into 2 groups for instrument handling & demonstration session. Ms. Madhavi Sagwekar demonstrated the Gel electrophoresis explaining the working principle and its use. After which the theory part of different instruments like Autoclave, Incubator, HPLC, Gas Chromatography, etc. were explained.

Another activity was organized in which 11 students participated to explain the importance of communication in pharmaceutical industry, the activity was orchestrated with gestures and actions passed from guest speaker to a student and then on, to explain the modifications that take place during communications. A short tea break was taken at 04 pm.

The final session for the day involved explaining different career opportunities in pharmaceutical industries and ended with a demonstration of some instruments.

Day 2:

The second day program began at 09:30 am, with the discussion of material system RM/PM receipt, along with this the sampling, testing, dispensing IPQA/testing and dispatch was discussed. The first activity was to explain the importance of color labels and material bags used in pharmaceutical industry, students were asked to wear yellow, green & red t-shirts/tops. Each color represented the status of the materials in the industry. After the activity, manufacturing & packaging in the facility was explained, packaging & labeling system points were highlighted, in this the primary packing, IPQA testing, secondary packing and dispatch were explained. Also the maintenance of the facility was explained, where the cleaning, calibration of the instrument was discussed. The importance of AMC for an instrument & the measures taken when instrument malfunctions explained.

Second activity was performed to explain Corrective Action Preventive Action (CAPA), the important terminologies from pharmacopeia were explained. The important terminologies explained were Aseptic gowning: CFR 211.28(C), contamination in Laboratory, Cleanroom, environmental monitoring, first air, and Air classification.

A lunch break was taken at 01:30 pm, after which demonstration of FTIR, Potentiometer and Viscometer was done. Along with this stability chamber, requirements for stability and parameters involved for stability testing were discussed. A short tea break was taken at 04:15 pm after which discussion on, different chemical analysis in pharmaceutical industries which include chlorine test, loss on drying water testing, oxidizable substances, residue on evaporation were discussed. Traditional methods for analysis of microbes, and importance of coordination and communication in pharmaceutical industry were discussed and a verbal feedback session was done concluding for the day.

Day 3:

The program began at 10:00 am with the discussion of data integrity, its importance and how it is regulated. Along with this documentation CFR regulations linked to data integrity, quality and management were explained. A case study on the effect of packaging on tablet coating was explained, where the data was not integrated and managed due to which the quality of the tablet was compromised. Explanation of ALCOA, consequences of data integrity, discussion about the

real cultural issues was given. Followed by this, FDA inspection selection & training of SME's, discussion on how to handle different interview questions was done. An activity was performed to simulate the different questions that one may come across in the interview. Tips on how to successfully crack the interview were shared by the guest speaker. The program adjourned for lunch at 02:00pm.

After the lunch break demonstration of the different instruments like UV spectrophotometer, Colorimeter & Microscope was done, students actively asked doubts on how to troubleshoot in case of errors. A skit demonstrating a live interview was done, students participated in the skit. The interview was a simulation to the students demonstrating the type of questions faced during the interview. A short tea break was taken at 04:15 pm. After which verbal feedback from the participants was taken by the guest speaker. The program concluded with the vote of thanks extended by Ms. Leena Pilankar.

PHOTO GALLERY



Prof (Dr) Zarine Bhatena, Principal, Bhavan's College with Dr. Anil Fokmare, Director GISM



Dr. S.V. Raut felicitating and welcoming Dr. Anil Fokmare



Dr. Anil Fokmare addressing the students during the workshop



Dr. Anil Fokmare with the students in Chemistry Laboratory



Dr. Anil Fokmare explaining students about Fermentor in Microbiology Laboratory



Dr. Anil Fokmare explaining students about analytical balance



Dr Anil Fokmare conducting a mock interview drill with a participant



Vote of thanks extended by Ms Leena Pilankar

SUCCESS STORY

After the successful completion of the workshop, 5 students were enrolled for internship at Parle Agro. & Zytex India. Apart from these invitations for internship has come from Shreya Life Sciences Pvt Ltd. Aurangabad. The success of this program has led to addition in the profiles of many of those students who had participated. We are also in touch with many industries for internships & campus placements in the near future.