Report on Quality by Design (QbD) and Design of Experiments (DoE) – Hands-on Workshop

Organized by: Department of Pharmaceutics and Quality Club, JSS College of Pharmacy, Mysuru

Date: 16 April 2026

Venue: JSS College of Pharmacy, Mysuru

Organized by: Department of Pharmaceutics and Quality Club, JSS College of Pharmacy, Mysuru

Resource Person:
Mr. Zaheer Abbas
Senior Formulation Scientist
Pharmaceutical Technology and Development
AstraZeneca UK Limited

Collaborating Organization: Indian Foundation for Quality Management (IFQM)

Participants: 70 undergraduate and postgraduate pharmacy students

Introduction

The Department of Pharmaceutics in association with the Quality Club of JSS College of Pharmacy, Mysuru, organized a one-day hands-on workshop on **Quality by Design (QbD) and Design of Experiments (DoE)** on 16 April 2026. The workshop aimed to provide students with a comprehensive understanding of contemporary quality management approaches adopted in the pharmaceutical industry and to familiarize them with the practical application of QbD and DoE principles in pharmaceutical product and process development.

The workshop was conducted by Mr. Zaheer Abbas, Senior Formulation Scientist at AstraZeneca UK Limited, who brought extensive industrial experience and expertise to the session. The program was designed to bridge the gap between academic learning and industrial practices by providing both theoretical concepts and practical demonstrations.

Objectives of the Workshop

The workshop was organized with the following objectives:

1. To introduce students to the principles and regulatory significance of Quality by Design (QbD).
2. To provide an understanding of the systematic pharmaceutical development approach recommended by international regulatory agencies.
3. To explain the concept and application of Design of Experiments (DoE) in formulation and process optimization.
4. To familiarize participants with risk assessment methodologies and critical quality parameters.
5. To provide hands-on exposure to experimental design, data analysis, and interpretation.
6. To enhance students' readiness for pharmaceutical industry practices and research activities.

Proceedings of the Workshop

The workshop commenced with a brief introduction of the resource person and an overview of the importance of quality-centric approaches in pharmaceutical development. Mr. Zaheer Abbas initiated the session by discussing the evolution of pharmaceutical quality systems and the growing emphasis on science-based and risk-based development approaches.

Session on Quality by Design (QbD)

During the first part of the workshop, the resource person elaborated on the concept of **Quality by Design (QbD)** and its role in ensuring consistent product quality throughout the product lifecycle. Key topics covered included:

- Fundamentals and principles of QbD.
- Regulatory expectations and ICH guidelines related to pharmaceutical development.
- Quality Target Product Profile (QTPP).
- Identification of Critical Quality Attributes (CQAs).
- Critical Material Attributes (CMAs) and Critical Process Parameters (CPPs).
- Risk assessment tools and methodologies.
- Establishment of Design Space.

- Control strategies and lifecycle management.

The speaker emphasized that quality should be built into pharmaceutical products from the initial stages of development rather than relying solely on end-product testing. Practical industrial examples were presented to demonstrate how QbD contributes to robust product development, improved process understanding, and regulatory flexibility.

Session on Design of Experiments (DoE)

The second session focused on **Design of Experiments (DoE)** as a systematic statistical tool for optimizing pharmaceutical formulations and manufacturing processes. Participants were introduced to:

- Principles and advantages of DoE.
- Experimental design strategies.
- Screening and optimization studies.
- Factorial designs and response surface methodologies.
- Selection of independent and dependent variables.
- Statistical evaluation of experimental results.
- Interpretation of response plots and optimization outcomes.

The resource person demonstrated how DoE can reduce development time, minimize experimental runs, and generate scientifically sound decisions during formulation and process optimization.

Hands-on Training and Interactive Learning

A significant highlight of the workshop was the hands-on component, where students actively participated in practical exercises related to QbD and DoE applications. Through guided activities and case studies, participants learned:

- Identification of potential risk factors affecting product quality.
- Designing experimental matrices.
- Analysis and interpretation of experimental data.
- Decision-making based on statistical outputs.
- Application of QbD principles in real-world pharmaceutical scenarios.

The interactive nature of the workshop encouraged active participation, discussion, and problem-solving. Students had the opportunity to seek clarification on complex concepts and engage directly with the resource person regarding industrial applications and career opportunities in pharmaceutical development.

Outcomes of the Workshop

The workshop successfully achieved its intended objectives and provided valuable learning opportunities for participants. By the end of the program, students were able to:

- Understand the significance of Quality by Design in pharmaceutical product development.
- Recognize the relationship between product quality, process understanding, and risk management.
- Apply basic Design of Experiments concepts to formulation and process optimization.
- Interpret experimental data and evaluate the impact of formulation and process variables.
- Appreciate the practical implementation of modern quality systems in the pharmaceutical industry.

The workshop enhanced participants' technical knowledge and strengthened their understanding of regulatory and industrial expectations in pharmaceutical research and development.

Participation and Feedback

The workshop witnessed enthusiastic participation from approximately 60 students from various academic programs. The participants actively engaged in discussions, practical exercises, and question-and-answer sessions throughout the program. Feedback received from attendees indicated that the workshop was highly informative, relevant, and beneficial in understanding industrial approaches to pharmaceutical quality management.

Acknowledgements

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Special thanks are extended to **Mr. Zaheer Abbas**, Senior Formulation Scientist, AstraZeneca UK Limited, for sharing his extensive expertise, practical experiences, and industry perspectives. His insightful presentations and interactive teaching approach greatly enriched the learning experience of all participants.

The organizers also acknowledge the enthusiastic participation of students, faculty members, and volunteers whose contributions ensured the successful conduct of the workshop.

Conclusion

The Quality by Design (QbD) and Design of Experiments (DoE) Hands-on Workshop was a highly successful academic initiative that provided participants with a comprehensive understanding of modern pharmaceutical quality concepts and their practical implementation. The program effectively combined theoretical knowledge with hands-on learning, thereby equipping students with valuable skills relevant to pharmaceutical research, development, and industrial practice. Such initiatives continue to strengthen industry-academia interaction and contribute significantly to the professional development of future pharmaceutical scientists.