BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI-HYDERABAD CAMPUS

Course Handout (Part II)

In addition to Part I (General Handout for all courses appended to the time table) this portion gives further specific details regarding the course.

Course No. **: PHA G547**

Course Title **: Quality by Design in Pharmaceutical Product Development**

Instructor In-charge **: PUNNA RAO RAVI**

Instructor : Ekta B. Prasanthi

1. Course Description:

This course will provide an insight into the underlying principles of Quality by Deign (QbD) and tools required for QbD based pharmaceutical product development and manufacturing. The various essential elements of QbD approach to pharmaceutical product development like basic risk analysis techniques, constructing the quality target product profile (QTPP), identification of critical quality attributes (CQAs) and critical process parameters (CPPs), design of experiments (DoE), identifying the design space and control strategy will be covered. As a part of DoE, selection of critical factors using various screening designs and optimization of factors using various experimental designs with details on how to analyze and interpret the data will be covered. The course also provides introduction to process analytic technologies (PAT) and how they can work in conjunction with QbD in pharmaceutical product development and manufacturing.

2. Scope and Objective of the Course:

The objective of the course is to impart knowledge on how apply the concepts of quality by design (QbD) in pharmaceutical product development in order to produce drug products of highest quality. The students will gain knowledge on the various essential elements of QbD and design experiments to identify and optimize the various factors influencing the quality of drug product. The students will also learn the various process analytical technologies (PAT) and know how to apply PAT in pharmaceutical product development.

3. Learning Outcomes (course benefits):

After completing the course the student must have gained the following knowledge, skills and competencies:

- Summarize the principles of the QbD approach in pharmaceutical development and manufacturing
- Demonstrate basic knowledge about risk management, Design of Experiments (DoE) and PAT
- Demonstrate basic knowledge about the relationship of the QbD approach into design space and further into the regulatory framework
- Apply basic risk analysis and experiment design techniques into practical cases
- Plan and implement a basic design of experiments (DoE) approach
- Suggest a QbD approach for constructing a design space

4. Text Books:

1. Pharmaceutical Quality by Design: A Practical Approach. Edited by Walkiria S. Schlindwein, Mark Gibson. Wiley-Blackwell.

2. Pharmaceutical Experimental Design. Edited by Gareth A Lewis, Didier Mathieu and Roger Phan-Tan-Luu. Marcel Dekker Inc. 1999.

5. Course Plan:

Lec. No.	Learning objectives	Topics to be covered	Chapter in the Text Book
1-4	Introduction to Quality by Design (QbD)	Evolution of Regulatory Framework on Quality of Pharmaceutical Products. Definition of Pharmaceutical QbD.	Lecture Notes; TB 1 Ch 1
5-8	Define the Elements of QbD and Quality Target Product Profile	What are the various essential elements of QbD? What is QTPP and what are the components of QTPP? How to define the QTPP for a pharmaceutical product being developed?	Lecture Notes; TB 1 Ch 6
9-15	Relate Critical Material Attributes (CMAs), Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs) to QbD	What are CMAs, CQAs and CPPs? How to relate QTPP with CMAs, CQAs and CPPs?	Lecture Notes; TB 1 Ch 6
16-19	Formulate Quality Risk Assessment/Management in pharmaceutical product development	What is Quality risk management (QRM)? Role of risk assessment in pharmaceutical product development. Steps to be followed in risk assessment. Various methodologies available for assessment of risk.	Lecture Notes; TB 1 Ch 2
20-30	Design of Experiments	What is DoE? Methodology of DoE. What are the various screening designs and experimental designs available for designing experiments? How to analyze and interpret the data. What are the various diagnostic tools to check the validity of the results obtained from the model evaluation?	Lecture Notes; TB 1 Ch 7; TB 2 Ch 2-6
31-34	Design a Control Strategy	How to develop control strategy? How to implement the control strategy?	TB 1 Ch 4-6
35-40	Implement Process Analytical Technology (PAT) in pharmaceutical product development	What is the role of PAT in pharmaceutical product development? What are the various PAT being currently used in pharmaceutical Industries? How to use Pat in conjunction with QbD for product development?	TB 1 Ch 9

6. Evaluation Scheme:

EC No.	Evaluation component	Duration	Weightage	Date and Time	Nature of Component

1	Pre-Mid Term Assignment	60 min.	10	Will be announced in class	CB
2	Mid-Term Exam	90 min.	25	30/9 , 09:00 – 10:30 AM	CB
4	Post-Mid Term Assignment	60 min	10	Will be announced in class	CB
5	Lab Sessions	-	20	Regular lab sessions	OB
6	Comprehensive	3 hrs.	35	09/12 AN	CB (15) +OB (20)

*Assignments include study of certain topics and research articles from reference books and/or journals for Evaluation Component. Laboratory assignments will be given during the semester including use of computer software in Design of Experiments (DoE) for pharmaceutical product development. CB-closed book, OB-open book.

7. Chamber Consultation Hour: To be announced in the class.

8. Notices: The Notices concerning this course will be displayed only on the **Pharmacy Department** Notice Board.

9. Academic Honesty and Integrity Policy: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

Instructor-in-charge
PHA G547