UNIVERSITY of BRADFORD

Module Descriptor

Module Details	
Module Title	Process Analytical Technologies (PAT) and Quality by Design (QbD)
Module Code	PHA7050-B
Academic Year	2024/5
Credits	20
School	School of Pharmacy and Medical Sciences
FHEQ Level	FHEQ Level 7

Contact Hours	
Type	Hours
Lectures	18
Tutorials	6
Laboratories	18
Directed Study	158

Availability	
Occurrence	Location / Period
BDA	University of Bradford / Semester 2

Module Aims

The aim is to provide specialist knowledge of the principles of Quality by Design (QbD) and Process Analytical Technology (PAT) and applications in pharmaceutical product development, manufacturing and quality assurance.

Outline Syllabus

The syllabus includes an introduction into the concepts of QbD as applied to pharmaceutical product development and manufacture and how process understanding and quality assurance have been key drivers to recent changes within the industry. The fundamentals of vibrational spectroscopy analytical techniques and equipment and their applications to in-line process monitoring will be explored within the context of both primary and secondary pharmaceutical manufacturing. A number of industrial case studies and recent research examples will be presented and discussed. The practical demonstrations will include application of PAT strategies for in-line analysis of products produced by hot melt extrusion with use of experimental design for evaluation and optimization of a granulation process. Course work will be focused on recent literature research examples, a critical oral presentation and written summary of research papers in both PAT and QbD will allow students to gain valuable knowledge in identifying critical process parameters and critical quality attributes of the products, as well understanding the key process analytical chemistry techniques used for in-line measurements. In addition reviewing recent research will enable students to understand how design of experimental techniques and statistical manipulation of complex data can lead to a fundamental understanding of complex processes and ultimately lead to a new way of thinking within the industry. A design of experiments workshop will also introduce industry standard software tools to enable manipulation of experimental results to gain valuable information on process parameters and ultimately lead to a deeper understanding of the process. This module will give students of various backgrounds the opportunity to collectively tackle a series of experiments in a small group lab project. The group report should include the minutes of the group meetings and a 500-word reflection on the process of working as a group, including lessons learned and specific challenges encountered and addressed. The report should also describe the sustainability of the resources used in the experiments and the potential of replacing them with an environmentally friendly alternative.

Learning Outcomes

Outcome Number	Description
01	Evaluate and describe with critical awareness the principles of PAT & QbD and their implementation within the pharmaceutical industry.
02	Critically explain the fundamentals of Vibrational Spectroscopy & its implementation in PAT.
03	Evaluate and apply knowledge and understanding of the theories of the analytical techniques in PAT & how the data is manipulated using multivariate statistical approaches.
04	Evaluate the concepts of statistical approaches to 'Design of Experiments'.
05	Apply PAT and QbD principles to deconstruct recent research papers, write a critical assessment and deliver a group presentation based on your key findings.
06	Use industry standard software to design experiments, manipulate data and evaluate the results in line with the concept of QbD.

Learning, Teaching and Assessment Strategy

Lectures will explore the concepts, history and key commercial and regulatory drivers for QbD and PAT within the pharmaceutical industry and use case studies to demonstrate how they are applied to pharmaceuticaldevelopment, manufacturing and quality assurance. In addition the fundamental concepts of PAC will beexplored as well as the applications of in-situ analysis in process understanding and development.

Using recent literature research examples, the applications of PAT and QbD in pharmaceutical unit operations and technology will be explored in depth, giving an understanding of the key analytical chemistry techniques and equipment, highlighting knowledge engineering concepts in defining experimental space (with respect to critical process parameters and quality attributes) and investigating typical statistical approaches to handling real-time data. A critical presentation and written summary of recent research papers in both PAT and QbD will demonstrate an understanding of the key aspects of the research strategy and science.

Mode of Assessment			
Type	Method	Description	Weighting
Summative	Presentation	Journal Club - QbD oral presentation of recent literature paper as a part of a team (30 Mins)	30%
Summative	Presentation	Journal Club - PAT oral presentation of recent literature paper as part of a team (30 Mins)	30%
Summative	Laboratory Report	ObD Lab Report (2500 words)	40%

Reading List
To access the reading list for this module, please visit https://bradford.rl.talis.com/index.html

Please note:
This module descriptor has been published in advance of the academic year to which it applies. Every effort has been made to ensure that the information is accurate at the time of publication, but minor changes may occur given the interval between publishing and commencement of teaching. Upon commencement of the module, students will receive a handbook with further detail about the module and any changes will be discussed and/or communicated at this point.

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