香港中文大學(深圳)
The Chinese University of Hong Kong, Shenzhen

Course code	PHM3001
Course title (English)	Quality Assurance and Pharmaceutical Analysis
Course title (Chinese)	质量保证和药物分析
Units	2
Language of Instruction	English
Description (English)	This undergraduate course focuses on the principles, techniques, and regulatory requirements associated with quality assurance and pharmaceutical analysis in the drug development and manufacturing process. Emphasis is placed on the importance of quality control, analytical techniques for drug identification and quantification, and compliance with regulatory standards to ensure the safety and efficacy of pharmaceutical products. Students should have completed basic courses in pharmaceutical analytical chemistry and fundamentals of pharmaceutics to understand the applied concepts described in this course. Together with the advanced course such as Drug Discovery, Development and Regulation, students are able to address the practical aspects of quality assurance and analytical methodologies employed in the pharmaceutical industry and gain an understanding of the role quality control plays in the development of new drug products.
Description (Chinese)	本科探讨药物研发和制造过程中与质量保证和药物分析相关的原则、技术和监管要求，阐释质量控制的重要性、药物鉴定和定量的分析技术，以及符合监管标准以确保药品的安全性和疗效上。本科学生应完成药学分析化学及药剂学基础等课程才能理解本科的应用性概念。协同本课程的基础知识以及高年级的课程（如药物发现、开发和监管），学生将习得质量保证和分析方法学在制药行业中的实际应用知识，并对质量控制在新药产品开发中的作用有所了解。

Learning Outcomes

After completing the course, students should be able to:

- describe the fundamental principles and importance of quality assurance in the pharmaceutical industry;
- describe the the regulatory requirements and guidelines governing drug analysis for quality assurance
- design basic analytical studies in terms of the execution and interpretation of methodologies involved in quality assurance and pharmaceutical analysis.
- develop problem-solving thinking in the context of pharmaceutical analysis and quality assurance

Indicative Teaching Plan

Week	Topic	Format
	INTRODUCTION TO DRUG QUALITY ASSURANCE	
1	General principle of drug quality assurance	Lecture
	Regulatory landscape: NMPA, FDA, EMA guidelines	Lecture
2	Drug quality standards – Pharmacopeia I	Lecture
	Drug quality standards – Pharmacopeia II	Lecture
	QUALITY MANAGEMENT SYSTEMS	
3	Overview of quality management system	Lecture
	Documentation, record-keeping and inspections	Lecture
4	Risk management and risk-based approach to quality	Lecture
	QUALITY CONTROL AND ANALYTICAL METHODS	
	Overview of quality control in a pharmaceutical setting	Lecture & On-site practical
5	Sampling techniques and sample preparation	Lecture & On-site practical
6	Identification and purity testing of raw materials	Lecture & On-site practical
7	In-process control and finished product testing	Lecture & On-site practical
8	Stability testing and shelf-life determination	Lecture & On-site practical
	MICROBIOLOGICAL QUALITY CONTROL	
9	Overview of microbiological quality control	Lecture
	Microbiological testing I	Lecture
10	Microbiological testing II	Lecture
	QUALITY ASSURANCE OF COMMON DRUGS	
	Quality assurance of common drugs I	Lecture
11	Quality assurance of common drugs II	Lecture

	Quality assurance of common drugs III	Lecture
	GMP and GLP	
12	Understanding GMP and its application in drug manufacturing	Lecture
	GLP principles and their importance in maintaining data integrity and reliability	Lecture
	QUALITY ASSURANCE IN CLINICAL TRIALS	
13	Overview of clinical trials and their relevance to quality assurance	Lecture
	Good Clinical Practices (GCP) and clinical trial monitoring	Lecture
	PHARMACOVIGILANCE AND POST-MARKET SURVEILLANCE	
14	Overview of pharmacovigilance and its importance in quality assurance	Lecture
	Post-market surveillance and life-cycle management of drug products	Lecture