Term III : April – June 2018

BIOS5004 ICH – GCP Standard of Clinical Research (1 credit)

Course Coordinator: Prof. Benny Zee

Course Description

1.The objective of this course is to provide background of regulation of drugs, devices and biological development. We will apply the principles of ICH-Good Clinical Practice in clinical research and discuss the role and responsibilities of key parties described in the document. We will describe the requirements of essential documentation and adverse event reporting. Scenarios will be given to the students to strengthen their understanding of practical application of ICH-GCP to the clinical trial process. We will conclude the course with discussion on Addendum to ICH E6 (R2).

Prerequisite (s) or Recommended Background

1. Familiar with Declaration of Helsinki
2. Clinical Research Personnel

Learning Outcomes/Objectives

1. Understand the background of international standards and technical requirement of ICH-GCP
2. Describe the principles and structures of ICH-GCP
3. Understand the role of responsibilities of key parties of conducting clinical research
4. Demonstrate Informed Consent Process at workplace
5. Apply relevant knowledge for the process of Adverse Event Reporting
6. Familiar with the Essential Documents required by ICH-GCP

Course Schedule

Session	Date	Time	Venue
1	Mar 22, 2018 (Thu)	6:30 – 9:30 pm	School of Public Health Prince of Wales of Hospital Shatin, N.T., Hong Kong
2	Mar 29, 2018 (Thu)	6:30 – 9:30 pm	
3	Apr 12, 2018 (Thu)	6:30 – 9:30 pm	
4	Apr 19, 2018 (Thu)	6:30 – 9:30 pm	
5	Apr 26, 2018 (Thu)	6:30 – 8:00 pm	

Fee

Application Fee: $100
Course Fee: $4,600