

Objectives and Course Content

This is a stand-alone course ideal for those who have experience in the clinical trial process and wish to develop their skills.

Agenda

Time	Topic	Speaker
08.00 – 08.30	ลงทะเบียน และพิธีเปิด	
09.00 – 9.30	How much do you know about GCP? Interactive Q&A to refresh your GCP knowledge	
9.30 – 10.00	The new ICH GCP E6 R2 regulations	
10.30 – 10.45	break	
10.45 – 12.00	Investigator oversight of clinical trials Inspection readiness Good and poor practices relating to the oversight of trials and delegation of responsibilities Ethical issues Informed consent Protocol compliance	
12.00 – 13.00	Lunch break	
13.00 – 14.30	Source documents and documentation Pitfall and common findings Workshop & discussion	
10.30 – 10.45	break	
14.30 – 16.00	Safety detection and reporting & Study drug management Workshop & discussion	
16.00 –16.15	Q & A	

หมายเหตุ : กำหนดการอาจมีการเปลี่ยนแปลงตามความเหมาะสม