Subject Description Form

Subject Code	ABCT5104
Subject Title	Regulatory Science for Biotech Products
Credit Value	3
Level	5
Pre-requisite	Nil
Co-requisite	Nil
Exclusion	Nil
Objectives	1. To provide Quality by Design training 2. To provide GMP regulatory science training using module-based approach. 3. To train students to operate independently according to GMP compliance
Intended Learning Outcomes	Upon completion of the subject, students will be able to: a) acquire knowledge of GLP and GMP requirements. b) plan and execute GLP and GMP to fulfil the requirements of the regulatory bodies c) understand FDA requirements.
Subject Synopsis/ Indicative Syllabus	**1. Site Master Plan and Manufacturing Facility Layout Proposal and review (4 hours)** - Site Master Plan and Manufacturing Facilities Layout (conceptual and basic) proposal according to the company's scopes and needs - Review and consult the company existing layout and/or provide PCM service - Lecture and training for the company staff about the basic GMP manufacturing facility maintenance. **2. GLP training (4 hours)** - GLP concept - Establishing and implementing GLP QC lab (sterility lab, EM, chemical and microbiology lab) **3. GMP training (8 hours)** - GMP concept - Review the current status of the company GMP compliance. **4. Quality Management System (8 hours)** - Establishing site master file, Quality Manual, Site Quality Committee, validation process - Train and implement 6 quality systems (template and case studies) **5. Facility Management System (4 hours)** - Establishing the basic manufacturing logistic systems and production schedule for warehouse.

	-Facility chemical/biological safety manual **6. Project Management system (4 hours)** - Basic concept (TCQ/R) of PM for biotechnology - Project monitoring, risk assessment and tools to manage the projects **7. Bioprocess Development Management system (4 hours)** - ICH guidelines and FDA requirements for bioprocess development in the CMC sections - Concept of DoE, Process Analytical Technology (PAT), Process Critical attributes such as PCR and FEMER **8. Product Characterizations Management system (3 hours)** - ICH guidelines and FDA requirements for product characterizations in the CMC sections - Concept of Bioanalytical Technology
Teaching/Learning Methodology	Lectures, Written Assignment, presentation 1. In-class participation – Students are expected to attend the classes and participate in the in-class activities including discussion and quizzes. 2. Presentation - Students will be guided to conduct in-depth research on relevant topics, followed by preparing and delivering presentations. This approach fosters a deeper understanding of GLP and GMP requirements, FDA regulations, and quality management systems. Group projects and peer evaluations will be used to enhance collaborative skills and critical feedback. Interactive sessions, including Q&A and discussions, will ensure active participation and reinforce learning outcomes. Presentations will be assessed based on content accuracy, clarity, and engagement. 3. Written Assignments – Students will be asked to write an essay on a selected topic. They will be assessed on their understanding of the topic's content. In their essays, students must also express their own opinions to demonstrate their problem-solving skills and critical thinking abilities. ~~4. Final Examination - Written exams assess how much students have learned about the concepts of GLP and GMP, as well as how they can be achieved in industrial settings.~~

Assessment Methods in Alignment with Intended Learning Outcomes

Specific assessment methods/tasks	% (weighting)	Intended subject learning outcomes to be assessed (Please tick as appropriate)		
		a	b	c
1. In-class participation	10	√		√
2. Presentation	55	√	√	√
3. Written Assignments	35	√	√	√
Total	100 %			

	Students are allowed to use GenAI tools to support their writing of and essays. If GenAI tools are used to support their essay writings, students must declare the use of such tools and how they have been used in the assessments. It should be noted that submitting a work generated by GenAI, in part or in whole, as your own (even in paraphrased form) constitutes an act of academic dishonesty; it is no different from asking another person to write your assignment or claiming others' ideas as yours.	
Student Study Effort Expected	Class contact:	
	▪ Lecture	26 Hrs.
	▪ Tutorial	13 Hrs.
	Other student study effort:	
	▪ Assignment	15 Hrs.
	▪ Self study	63 Hrs.
	Total student study effort	117 Hrs
Reading List and References	1. Weinberg, S. (2009). Guidebook for Drug Regulatory Submissions (1st ed.). Wiley. ISBN: 9780470371381 2. Carpenter, D. P. (2014). Reputation and power: Organizational image and pharmaceutical regulation at the FDA (1st ed.). Princeton University Press. ISBN: 9781400835119	