BIEN4000C Regulatory Science and Engineering

Department of Chemical and Biological Engineering, Hong Kong University of Science and Technology (HKUST)

Instructors:	Mr. Donald Chong
Guest lecturers:	Dr. Henry Tong, Dr. Eddie Wong, Dr. Warren Tsang, Dr. Russel Chan, Dr. Lawrence Wong, Mr. Ernest Cheung, Ms. Lucilla Leung, Mr. Kevin Tai, Dr. Stijn van den Borne, Dr. Ian Chau, Mr. Bernard Tang
Format:	Lectures / 3 credits / Max: 50 students
Prerequisites:	None

Synopsis

This course aims at introducing basic principles of regulatory science and engineering as the foundation, while familiarizing students with the medical and engineering operations in the pharmaceutical and medical device industry, as well as the associated regulatory requirements, with an emphasis on Hong Kong and the nearby region. Students will be introduced to topics such as Good Manufacturing Practice (GMP), pharmaceutical product/ medical device registration, pharmacovigilance, and clinical trials. The course should prepare students for a career in both the pharmaceutical and medical device industry.

Intended Learning Outcomes

On completion of the course, students should be able to:

- Form a conceptual framework of regulatory science and engineering that underpins regulatory affairs of medical products and medical device worldwide;
- Outline the current practices of medical & engineering operations in the pharmaceutical and medical device industry;
- Describe the importance and processes of quality assurance / quality control in the manufacture of both pharmaceutical products and medical device;
- Outline how Good Manufacturing Practice (GMP) and Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) are implemented;
- Outline the roles of medical affairs, medical science liaison, and pharmacovigilance in the pharmaceutical and medical device industry;
- Describe the principles and practice of clinical trials and the importance of clinical trials in drug development;

Lecture Topics

Week	Date	Topic	Instructor
1	Feb 2, 2024 (3 hours)	Important terms in healthcare industry	Dr. Henry Tong
2	Feb 16, 2024 (3 hours)	Drug development process Medical device development process	Dr. Henry Tong & Dr. Eddie Wong
3	Feb 23, 2024 (3 hours)	QA, QC and GMP — What are they and what are their relationships?	Dr. Warren Tsang
4	Mar 1, 2024 (3 hours)	In-vitro diagnostic development process Wearable diagnostic development process	Dr. Russel Chan
5	Mar 8, 2024 (3 hours)	Overview of pharmaceutical and medical device industry	Mr. Lawrence Wong & Mr. Ernest Cheung
6	Mar 15, 2024 (3 hours)	Regulatory affairs — A science or an art? Audit inspection/ readiness in pharmaceutical and medical device industry	Ms. Lucilla Leung
7	Mar 22, 2024 (3 hours)	Regulatory affairs in medical device industry	Ms. Lucilla Leung
8	Apr 5, 2024 (3 hours)	Medical Affairs; Medical Information and Medical Science Liaison	Mr. Donald Chong
9	Apr 12, 2024 (3 hours)	Pharmacovigilance	Mr. Kevin Tai
10	Apr 19, 2024 (3 hours)	Bench to Bedside: The Art of Clinical Trials [1.5 hours] Clinical Research in Medical Device Industry [1.5 hours]	Dr. Stijn van den Borne Dr. Eddie Wong
11	Apr 26, 2024 (3 hours)	Intellectual property management [1.5 hours] Sales and marketing in device industry [1.5 hours]	Dr. Ian Chau Mr. Ernest Cheung
12	May 3, 2024 (3 hours)	Sales and marketing in pharmaceutical industry [1.5 hours] Career and personal development [1.5 hours]	Mr. Bernard Tang Dr. Russel Chan
13	May 10, 2024 (3 hours)	Student presentations Final wrap up	Mr. Donald Chong

* In each lecture, there will be pharmaceutical and medical device industry experience sharing, accounting for 15-30min respectively.

Assessment

- **Multiple-Choice Questions (30%, 2 x 15%)**
  - An open-book assessment consisting of multiple-choice questions will be conducted in class. The assessment will be based on completed lectures and related readings.
  - **Assessment date:**

MCQ 1	Apr 5, 2024
MCQ 2	May 3, 2024

- **Interview (30%)**
  - Students will be instructed to play the role of a journalist and interview a person working in the pharmaceutical/ medical device industry (e.g. a person / senior colleague at their workplace). The student is expected to find the candidate to interview himself/ herself. This is an opportunity to network.
  - Students are expected to write an article (at least 4 pages of A4, double spaced) on the individual.
  - Students should include a photo taken with the interviewee in the interview article.
  - **Submission Deadline:** May 17, 2024

- **Presentation (40%)**
  - The presentation may be an individual or a group assignment, depending on the class size.
  - Students will be instructed to prepare a PowerPoint presentation which covers ALL the following content:
    a. Among the pharmaceutical and medical device industry topics covered in the lectures, students can choose **1-2 area(s)** that they are interested in (e.g. regulatory affairs for medical device, QA, clinical trial etc.) and explain why.
    b. Also, students should share **1 "hot topic"** in the pharmaceutical/medical device industry and elaborate on how this "hot topic" may create opportunities/challenges in that 1-2 areas they have chosen. Students are expected to delve deeper and do more research by themselves.
       - "Hot topic" examples: electronic prescribing information and Prescription-to-OTC switch

Teaching Team:

Mr. Donald Chong	Donald Chong, BSc (Pharmacy, University of British Columbia, Canada) and MBA (Health Services Management, University of Hull, U.K.) is currently the Regulatory Affairs Director of GlaxoSmithKline Consumer Healthcare (Hong Kong) Limited. Besides being a licensed pharmacist in both Hong Kong and Canada, he is a Certified Master NLP Coach awarded by the American Association of NLP (Neurolinguistic Programming). He is also a certified coach awarded by the Worldwide Association of

	Business Coaching. Besides his regular work, he has myriad contribution in coaching, patient education and university teaching experience. He is presently honorary lecturer of the University of Hong Kong (HKU) and helps develop courses relating to the pharmaceutical industry. He is the preceptor for the pharmacy students at the School of Pharmacy at the Chinese University of Hong Kong as well as the HKU. He has also been invited by various patient associations and hospitals to deliver training of various kinds over the past few years. More noticeably, he is the course developer for the course "Understanding Western Medicine" at the Open University of Hong Kong. In his leisure time, he also contributes articles to the Hong Kong Pharmaceutical Journal in areas such as diseases and treatments as well as more lately in leadership and coaching. He is currently the section editor of the Pharmacy Practice and Education of the journal. With his experience of over 25 years in the pharmaceutical industry, he wishes to make more positive impact to other people's lives and well-being through coaching and teaching.
Dr. Henry Tong	Dr. Henry H. Y. Tong received his B.Pharm.(Hons) degree with a 1st Class Honors from the School of Pharmacy, Chinese University of Hong Kong in 1997, Ph.D. degree in Pharmaceutical Technology in Chinese University of Hong Kong in 2003, Master of Public Health degree in University of Hong Kong in 2011, a Certificate in Medical and Health Science Education in University of Hong Kong in 2013, and a Master of Public Administration degree in Chinese Academy of Governance in 2015. Dr. Tong is currently the Professor in Division of Biomedical Science, Faculty of Health Sciences and Sports, and the Professor & Director in Center of Artificial Intelligence driven Drug Discovery, Faculty of Applied Science, Macao Polytechnic University. In 2005–2022, he has been the Programme Coordinator in Division of Biomedical Science, covering three allied health professionals, i.e., speech and language therapists, medical laboratory technologists, and pharmacy technicians. Apart from his teaching duties in healthcare related subjects, he is actively conducting academic research in the area of pharmaceutical sciences. His research interests include pre-formulation studies, formulation development and drug information services. To date, he has published 61 articles in SCIE-listed journals, 3 book chapters in scientific collections and 7 patents. He is a member of the editorial board of 2 academic journals and has served as a reviewer for 20 SCIE-listed journals. In academia-industry collaboration, he has participated, and has assisted, the R&D activities in 2 Phase II candidates, 2 Phase I candidates, 10+ preclinical drug candidates, and numerous generic drugs, medical foods, health supplements, and cosmetic products. Some of which are brand name products reputable in overseas countries, China, and Greater Bay Area, Guangdong province.
Dr. Eddie Wong	Dr. Wong received his B.Sc. in Applied Physics from the City University of Hong Kong and a Ph.D. in Electrical and Electronic Engineering from The University of Hong Kong. His research focus includes biomedical imaging utilizing electrical impedance tomography (EIT), functional magnetic resonance imaging (fMRI), optogenetics, pharmacological inhibition, behavioral conditioning, and auditory processing in neuroimaging. He had worked in a certification company with expertise in areas of technical assessments on electronic consumer products and regulatory protocols on product's safety before his PhD. After the postgraduate study, he was the co-founder and COO of a Hong Kong start-up company, Gense Technologies Ltd., driving the product development of the portable imaging and spectroscopy systems for biomedical applications functional assessment of solid organs. He also setup and managed multiple clinical trials and collaborations with international universities, hospitals, and industries on the developed technologies and medical devices. Currently, he is a consultant in Hong Kong Centre for Cerebro-Cardiovascular Health Engineering (COCHE) to facilitate

	technology-transfer and commercialization process of the developed technologies and interventions.
Dr. Warren Tsang	Dr. Warren Tsang joined the Wai Yuen Tong Medicine Holdings in September 2018 and he is currently the Director (Technical) of both the Wai Yuen Tong Medicine Company and the Luxembourg Medicine Company. Dr. Tsang received his BSc (Pharm)(Hons) degree at the Aston University and the PhD degree at the University of Sydney. He is a registered pharmacist and a registered Authorized Person of the Pharmacy and Poisons Board of Hong Kong. He has more than 20 years of experience in the pharmaceutical industry. Academically, Dr. Tsang was the Honorary Associate Professor of the Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, the University of Hong Kong from 2010 to 2023 and he is currently the Adjunct Associate Professor, College of Life Sciences and Technology, the School of Professional and Continuing Education, the University of Hong Kong. Regarding professional services, he was the Chairman of the Pharmacy Central Continuing Education Committee from 2003 to 2017 and he was responsible for continuing education of all registered pharmacists in Hong Kong. He is currently the Managing Editor of the Hong Kong Pharmaceutical Journal.
Dr. Russel Chan	Dr. Russell Chan is the CEO of Hai Kang Life Corporation Ltd. (HKLife) and a senior consultant at COCHE (Hong Kong Center for Cerebro-cardiovascular Health Engineering). He received his B.Eng. in biomedical engineering and Ph.D. in electrical and electronic engineering from The University of Hong Kong. He was a post-doc at Stanford University in Neurology and Neurological Sciences, and New York University in Neuroscience, Tech4Health, and Ophthalmology. He was the co-founder and Chief Technology Officer (CTO) of a Forbes Asia 100 to Watch Hong Kong Startup. His focus is the research, development, application and commercialization of state-of-the-art multi-modal and multi-scale biomedical imaging and *in vitro* diagnostic (IVD) devices to advance biotechnology and quality of life. Dr. Chan is an elected Junior Fellow of International Society of Magnetic Resonance in Medicine (ISMRM), a prestigious and highly selective award for young scientists from the leading global MRI society. He is the lead of the R&D focus group and a committee member of the Hong Kong Institute of Engineers (HKIE) Biomedical Division. He is the Vice-Chair of the Hong Kong Academy of Engineering Sciences (HKAES) Young Member Section. He is the Vice President of HKBIO (Hong Kong Biotechnology Organization), and Vice President of the global biotech conference and exhibition BIOHK since 2023. He has published more than 25 journal papers and 75 conference papers, including Proceedings of the National Academy of Sciences (PNAS) and Neuron. He is an inventor for more than 10 patents/provisional patents. He is a reviewer for Nature Protocols, Frontiers in Neuroscience and Neurology, ISMRM, and Institute of Electrical and Electronics Engineers (IEEE) Engineering in Medicine and Biology Society (EMBS).
Mr. Lawrence Wong	As the General Manager of Ferring Pharmaceuticals Limited in Hong Kong since 2016, Lawrence is responsible for all commercial operations. Prior to this position, he has been working in the company in various roles including marketing, sales, management, and business development, in both local and APAC regional scopes. Throughout the period, he was involved in continued interactions with different stakeholders in the industry, in particular with healthcare professionals in Hong Kong for academic and scientific collaborations. Lawrence is also the Vice President of the Hong Kong Association of Pharmaceutical Industry (HKAPI), following previous role as a Board member in two consecutive terms of 2018–20 and 2020–22, leading task forces to foster R&D eco-system and to expedite medical advancements respectively. He is also member of Joint Management Committee for GMP Cell Processing Facility with PIC/S GMP (HKSTP, CUHK), a member of Assessment Panel for HKSTP Clinical Translational Catalyst (CTC) and Panel Member of the Pharmacy and Poisons Appeal Tribunal,

	Department of Health, The Government of Hong Kong SAR. Lawrence holds a BSc Degree in Biochemistry from the University of Hong Kong, and an MBA Degree from the University of London (International Programme).
Mr. Ernest Cheung	Mr. Ernest Cheung is an experienced professional in Pharmaceutical, Medical Devices and Diagnostics industries where he held different position in Sales, Marketing, Strategy and Business Development and Management at local, Asia Pacific Region and global level in Hong Kong and USA. Ernest currently is Head of Sales & Marketing – Stryker Hong Kong and Macau where he oversees all Sales, Marketing, Business Development and Customer Care. Prior to Stryker, he was with Johnson and Johnson where he was Sales Managers for Hong Kong and then transited to Regional and Global Product Manager – Laboratory Automation and Software based in New Jersey, USA in order to develop and execute regional and global marketing strategies. Prior to Medical Device and Diagnostic Industries, Ernest also had extensive experience in pharmaceutical industry where he managed Sales Team in Leo Pharma and Abbott Pharmaceutical. Ernest graduated from the City University of Hong Kong with a Bachelor's degree in Applied Chemistry. He also received a Master of Business Administration (General Management) degree with The Hong Kong Polytechnic University.
Ms. Lucilla Leung	Lucilla holds a Bachelor of Pharmacy degree from the University of Alberta, Canada and is a registered pharmacist in both Canada and Hong Kong. She has earned a Post-graduate Diploma in Epidemiology and Biostatistics at CUHK. In career, Lucilla has held different positions in various multinational pharmaceutical companies in diverse areas ranging from quality assurance, pharmacovigilance, medical affairs to regulatory affairs. Lucilla is specialized in regulatory affairs involving pharmaceuticals, nutritional products and medical device.
Mr. Kevin Tai	Kevin is currently the Senior Regional Pharmacovigilance (PV) Officer in Asia Pacific region at MSD. He has 8 years of experience in drug safety at the local and regional level in the pharmaceutical industry setting including case processing, regulatory compliance, PV agreement management, PV training, and audit/inspection readiness etc. His strong passion in PV is driven by finding solutions to streamline internal processes to establish compliance standards as well as to meet the external PV requirements from health authorities. Kevin holds a BSc in Toxicology from the University of Toronto, a BSc in Pharmacy from the University of British Colombia, and an MBA from the Hong Kong Polytechnic University. He is also a registered pharmacist in Canada.
Drs. Stijn van den Borne	Drs Van den Borne obtained his degree in Biomedical Sciences from the University of Amsterdam in 2003 with a GPA of 8/10. After graduating, Mr. Van den Borne took a course in Good Clinical Practices, before joining Kendle International (now INC Research - a Contract Research Organisation [CRO]) as Clinical Research Associate, to be immediately outsourced to Pfizer Netherlands supporting various oncology and cardiovascular clinical research projects. In 2007, he transitioned to Hong Kong SAR to join the local Pfizer affiliate as the Associate Manager Clinical Research (Projects) and later as the Oncology Research and Scientific Specialist, a Medical Liaison function, sharing responsibility for the local medical strategies for marketed and pipeline oncology products with Medical Affairs. After leaving Pfizer in 2012, he joined a startup CRO named TRE APAC Ltd in the capacity of Project Manager. TRE APAC Ltd was a research organisation directly linked to a non-profit organisation named the Organisation for Oncology and Translational Research (OOTR) with offices in Hong Kong and Kyoto. His responsibilities included setting up non-industry sponsored clinical research studies, medical writing of study proposals and research protocols, as well as writing about research in general. In 2016 Mr. Van den Borne left TRE APAC Ltd and started medical writing, first as a freelancer but eventually he opened an office in 2019

	hiring his first staff. The company - initially named MediPaper Medical Communications Ltd and now rebranded to ['mediPr] - currently has 13 staff and serves doctors, healthcare organisations, and the pharmaceutical and medical devices industries in the production of various medical communications including manuscript writing.
Mr. Ian Chau	Ian is currently a practicing solicitor. Ian graduated from the HKU Biomedical Engineering Program with 1st Class Honours in 2011. He then obtained his Juris Doctor Degree in CUHK in 2019 and completed the Postgraduate Certificate in Laws in CUHK in 2021. Prior to pursuing a legal career, Ian was the Quality Assurance Manager and members of the extended leadership team in Pfizer Corporation Hong Kong Limited. He worked in Pfizer HK for 9 years. Throughout his career in Pfizer HK, he worked in different departments such as Medical Affairs, Medical Quality Compliance and Quality Assurance which enabled him to understand the business dynamic in a MNC. In 2017, Ian was being selected to join a 2-year Pfizer Global Leadership Development Program in which he was one of the only two Asian participants for the program. In 2018, he joined the IP ambassador program organized by the HKSAR Intellectual Property Department to promote the IP awareness in local primary, secondary and tertiary institutions. Starting from 2020, he is invited to be one of the guest speakers at HKU SPACE for the program "Medical Operation in Pharmaceutical Industry" to provide an introduction of QA in pharmaceutical industry. In the years to come, Ian hopes to contribute more to education and to the industry as a whole. He finds it meaningful to teach in order to help growing the future pillars of Hong Kong.
Mr. Bernard Tang	Bernard holds a Bachelor of Pharmacy degree from King's College London and is a registered pharmacist in the UK and Hong Kong. He has earned an Executive MBA from Imperial College London, specialized in Healthcare Industry. In career, he is trained and worked as Clinical pharmacist at a London teaching hospital focused in cardiology with a Certificate of Clinical Pharmacy Practice. He also enriched his work experience in community pharmacy in UK and HK. In recent 10 years, he has held different commercial positions with marketing and business development roles in various MNC such as Pfizer, AbbVie, Amgen, covering Rheumatology, Immunology, Paediatrics, Oncology and Haematology areas.