HKU Med LKS Faculty of Medicine
The University of Hong Kong
香港大學李嘉誠醫學院

Regulatory Affairs – Hong Kong & Beyond (2023)

Coordinator(s)	Mr. Donald Chong, Honorary Lecturer, Department of Pharmacology and Pharmacy (Email: chongd@hku.hk) Dr. Aviva Chow, Assistant Professor, Department of Pharmacology and Pharmacy (Email: asfchow@hku.hk)
Description	This course provides an overview of the pharmaceutical regulatory frameworks in Hong Kong, Mainland China, Macao, Europe and the United States. Topics include drug development, pre- and post-marketing regulations, pharmacovigilance, quality assurance and pharmaceutical advertisements. The course is aimed to equip students with updated knowledge in the rapidly evolving field of regulatory affairs. Students will be learning from practitioners who are experts in their area of sharing, drawing on years of experience and insight. Speakers range from regulatory professionals in prestigious companies to private consultants in regulatory affairs.
Lecture Venue	TBC

The following table summarizes the features of the two study options offered to occasional students.

	Study Option A **MAPH7330 – Regulatory Affairs – Hong Kong & Beyond**	**Study Option B** **Certificate Course in Regulatory Affairs**
HKU Credits	**Yes – 6 credits** Students can apply to be considered for advanced standing for this course in future enrolment in the Master of Advanced Pharmacy programme within the next 5 years	**No**
Certificate of Completion	**No**	**Yes** ○ Completion of pre-recorded videos ○ Achieving pass on essay
Assessment	• MCQ Assessment (3 quizzes x 15% each = 45%) • Forum Activities (2 assignments x 7.5% each = 15%) • Reflection Essay – 500 words (15%) • Essay – 4 pages (25%)	• Written essay (500 words) – Pass/Fail
Cost	**13120 HKD**	**8750 HKD**

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Regulatory Affairs – Hong Kong & Beyond

Tentative Course Calendar

Date	Time	Venue	Session Topic	Speakers	Hours	Included in	
						Study Option A	Study Option B
Pre-Recorded Sessions							
Jan 16 – Jan 22, 2023		---	Regulatory Affairs in Hong Kong	Ms. Carmen Lai Mr. Benny Lee	2	Yes	Yes
Jan 23 – Jan 29, 2023			Special Topics in RA - Variation Change of Registered Particulars (CORP) in HK, Wholesale Dealer Licence (WDL), Manufacturing, Secondary Packaging, Import and Export	Mr. Sean Lee	1.5	Yes	Yes
			A Closer Look into Advertising and Regulating Pharmaceutical Products in HK	Ms. Mandy Chan	2	Yes	Yes
Jan 30 – Feb 5, 2023			Global Regulatory Affairs (Introduction) & Global Harmonization & Regulatory Dossier	Mr. Ryan Chan	2	Yes	Yes
Feb 6 – Feb 12, 2023			Global Supply Chain	Mr. Sheikh, Khalid Ahmad	2.5	Yes	Yes
Feb 13 – Feb 19, 2023			Chemistry, Manufacturing and Control II: Process of Dossier Submission & Approvals	Mr. Sheikh, Khalid Ahmad	1	Yes	Yes
Feb 20 – Feb 26, 2023			Product Development Process	Mr. Sheikh, Khalid Ahmad	3	Yes	Yes
Feb 27 – Mar 5, 2023			Pharmaceutical Labelling	Ms. Hoi Lam Chan	2	Yes	Yes
Mar 6 – Mar 12, 2023			Special Projects in RA: Electronic Prescribing Information (ePI) and Switch Projects - Booster to the Industry	Ms. Sunitha Shanmugam	1	Yes	Yes
			Regulatory Intelligence	Ms. Wai Keng Chai	1	Yes	Yes
Mar 13 – Mar 19, 2023			Lifecycle Management: Agency Commitments, Renewals, Variations and More	Mr. Ryan Chan	1	Yes	Yes
			Regulatory Affairs in Advanced Therapy Products (ATP)	Mr. Tony Li	1	Yes	Yes
Mar 20 – Mar 26, 2023			Regulatory Affairs in Medical Device	Ms. Lucilla Leung	2	Yes	Yes
Mar 27 – Apr 2, 2023			Accelerated and Priority Review: Reduced Data Requirement & Forum Case Introduction	Mr. Ryan Chan	1.5	Yes	Yes
			An Introduction to the EU Regulatory Affairs	Ms. Sarah Condon	1	Yes	Yes
Apr 3 – Apr 9, 2023			China Regulatory System & Innovation Ecosystem	Ms. Sara Wang	2	Yes	Yes
Apr 10 – Apr 16, 2023			Regulatory Affairs in the Asia-Pacific Region	Mr. Ian Adams	1	Yes	Yes

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Date	Time	Venue	Session Topic	Speakers	Hours	Included in	
						Study Option A	Study Option B
F2F Forums							
Feb 11, 2023 (Sat)	14:30-16:30	TBC	Forum I: Audit Preparation, Inspection and Ways of Handling	Mr. Donald Chong Mr. Denny Chan	2	Yes	No
Mar 11, 2023 (Sat)	14:30-16:30	TBC	Forum II: Advertising	Mr. Donald Chong Ms. Mandy Chan	2	Yes	No
Apr 22, 2023 (Sat)	14:30-16:30	TBC	Forum III: Post Marketing Approval – A Global Supply Chain Case (EU/China/US)	Mr. Donald Chong Mr. Ryan Chan	2	Yes	No

Course Coordinators

Speaker	Biography
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. Aviva Chow	Dr Chow is an Assistant Professor in the Department of Pharmacology and Pharmacy in the University of Hong Kong (HKU). Dr. Aviva Chow obtained his Bachelor degree of Chemical and Bioproduct Engineering from the Hong Kong University of Science and Technology (HKUST). He pursued his PhD in Pharmacy (Pharmaceutical Sciences) at the Chinese University of Hong Kong (CUHK). Prior to joining HKU, Aviva worked as a technical lead and research scientist at Jacobson Pharma Corporation Limited. He is also one of the principal investigators in Advanced Biomedical Instrumentation Centre (ABIC) at the Hong Kong Science and Technology Park.

Speaker Team

Speaker	Biography
Mr. Ian Adams	Ian Adams is a senior Therapeutics industry leader with experience across a range of multinational companies and broad geographical responsibilities – covering disciplines including Regulatory and Medical Affairs, Clinical Research, Product Development, Quality, Pharmacovigilance and Government Affairs. Ian currently works with the AusIndustry Entrepreneur's Programme supporting start-up companies and small-medium enterprises in the Australian Medical Technology and Pharmaceuticals sector – he also provides strategic Consultancy Services to the international Consumer Healthcare Sector.

	Prior to this, Ian had a 20-year international career with GlaxoSmithKline – most recently he was Vice-President, Global Regulatory Transformation for the GSK/Pfizer Consumer Healthcare Joint Venture ahead of the spin-off to form Haleon. Ian also held VP roles leading the Asia-Pacific and Middle East/Africa/Latin America Regional Regulatory Organisations for GSK Consumer Healthcare and was a member of the Global Regulatory and Regional Commercial Leadership Teams. He also held a range of Asia-Pacific Regional Medical Affairs, R&D, Regulatory, Government Affairs and Quality Leadership roles at GSK. Before joining GSK, Ian led Scientific Affairs & Professional Relations for Reckitt Asia-Pacific and held a Senior Management Consultancy role in London for the Deloitte Life Sciences Practice (where he was the lead consultant on the initial European Medicines Agency Feasibility study amongst other projects). Ian has also led international Product Development and Regulatory teams for Novartis in Switzerland and began his career as a Research Scientist at the Australian Department of Health (working on epidemiological studies supporting the Royal Commission on Vietnam Veterans Health). Ian has a Bachelor's of Science (Honours) from the University of Sydney, a Master of Science from University of Surrey (UK), and an MBA from Macquarie University. Amongst other professional affiliations, Ian is a Life Member of ARCS and a Member of the Australian Institute of Company Directors.
Ms. Wai Keng Chai	Wai-Keng is the Global Regulatory Intelligence and Policy Director for a leading consumer health company. She has more than 16 years of experience in biopharma and consumer health companies. She is experienced in navigating complex regulatory environment and stakeholder management, especially in areas to advocate for better self-care regulations, regulatory flexibility and convergence, as well as proactive management of new trends and issues. Wai-Keng received her Bachelor of Pharmacy degree from National University of Singapore. She went on to earn her Master of Public Health degree, specializing in Health Policy and Services from Saw Swee Hock School of Public Health, National University of Singapore. She is also a registered pharmacist with Singapore Pharmacy Council.
Mr. Denny Chan	Denny Chan has 15 years' work experience in the GMP pharmaceutical manufacturer, Hovione PharmaScience Ltd. in Macau with the headquarter based in Portugal. With the focus on Active Pharmaceutical Ingredient (API) manufacturing, he has worked in different roles along the years: QA technical experts with on-hands production operations experience, HSE Director (Health, Safety & Environment) managing the manufacturing site safety and sustainability. During his work focus on the quality assurance role, he managed to assure the manufactured API products and company Quality Management System in compliance with the cGMP, ICH Guidelines, 21 CFR Parts 210 and 211; ISO 9001 standards, and local regulatory requirements. He is experienced in managing company internal audits, external supplier audits on API Starting Materials and chemicals manufacturers in Asia (China, Taiwan, Japan), and regulatory inspections in the company from the local government body and the FDA.

Mr. Hoi Lam Chan	Hoi Lam is currently a Global Labeling Lead responsible for creating and maintaining the Core Data Sheet and the US and EU Prescribing Information at Pfizer. Prior to this, she has worked in the pharmaceutical industry in various disciplines such as Medical Information, Medical Affairs, Medical Operations and Medical Compliance in local, regional and global capacities. She has also been a hospital and community pharmacist and continues to be a registered pharmacist in both Hong Kong and Australia. Hoi Lam is an ASQ Certified Manager of Quality/Organisational Excellence and also holds a Master of Public Health from University of New South Wales. She serves as a mentor for the School of Public Health, Chinese University of Hong Kong, the University of New South Wales and The Women's Foundation. She has lectured at the School of Continuing Education, Hong Kong University and is currently a committee member for the APAC Healthcare Businesswomen's Association (HBA).
Ms. Mandy Chan	Mandy holds a Bachelor of Pharmacy degree and Master of Science degrees in Epidemiology and Biostatistics from the Chinese University of Hong Kong. As a registered pharmacist, Mandy demonstrated the important role of pharmacist in MNC pharmaceutical companies, especially in Medical Affairs, Medical Science Liaison and Medical Information. Mandy will share the essential skills needed to excel in Medical Function during the course.
Mr. Ryan Chan	Ryan holds a Master of Pharmacy degree from the University of Bath, UK and is an UK-registered pharmacist. Having initially been trained in community pharmacy, Ryan moved on to an industrial setting post-qualification and has worked in various roles within pharmaceutical manufacturing, before joining Global Regulatory Affairs, specializing in Chemistry, Manufacturing and Control matters in Small Molecule products. He has experience in various dosage forms, and has expertise in post-approval lifecycle management for globally supplied products.
Ms. Sarah Condon	Sarah holds a Master of Pharmacy degree from Nottingham University. During her studies, Sarah completed an industrial placement year at GlaxoSmithKline (GSK) working as an Oral Solid Dose Technologist. In her final year at university, she continued to work with GSK as their Brand Ambassador promoting careers in industry to students. She then completed her pre-registration training at both Cambridge University Hospital as a Trainee Clinical Pharmacist (6-months) and at GSK as a Process Engineering Scientist (6-months). Sarah then returned to Ireland and worked as a Locum Community Pharmacist for 5 months before joining the Health Products Regulatory Authority (HPRA) as a Pharmaceutical Assessor in the veterinary sciences department. Sarah has recently taken up the role as an Associate Director of GSK, where she is responsible for the labelling development and strategy of GSK pharmaceutical products.
Ms. Carmen Lai	Carmen is a qualified pharmacist in Canada and Hong Kong with over 15 years of regulatory experience in leading regional/local regulatory strategy programs within the biopharmaceutical sector in Asia Pacific (APAC) region. As Senior Regulatory Affairs Manager of Amgen Hong Kong Limited, she has proven track record of biopharmaceutical product registrations and clinical trial applications/notifications (CTAs/CTNs) for Hong Kong & South East Asia countries. Prior to joining Amgen, she worked at Hospira, managing regulatory, quality and pharmacovigilance activities for generic pharmaceutical products and medical devices in China and Hong Kong. Carmen is a clinical pharmacist by training where she previously practiced at the Scarborough Hospital, Canada, specialized in cardiology, medicine and surgery. She holds a Bachelor of Science degree in Pharmacy from the University of Toronto, Canada.

Mr. Benny Lee	Benny holds a BSc Degree in Science from the University of Hong Kong, major in Food & Nutritional Science and is now the Senior Regulatory Affairs manager in GSK Consumer Healthcare (Hong Kong) Limited. Benny has been working in food industry for many years before switching to the consumer healthcare industry. After his graduation, Benny worked in an UK based flavour house and stationed in their factory in China before joining the R&D department to support the new product development in overseas markets for a local beverage company. Afterwards, Benny was employed to play a regional regulatory role in an international coffee company for another 10 years. Now, he continues to explore the regulatory environments of different categories of products and acquire the relevant experience & expertise after joining a consumer healthcare company. Until now, Benny has been working in the field of regulatory affairs in both food & consumer healthcare industry for more than 15 years.
Mr. Sean Lee	Sean Lee is a registered pharmacist and registered authorized person in Hong Kong. He worked in pharmaceutical manufacturing and distribution leading the quality and regulatory functions for over 10 years. In recent years, he held the position of Head of Regulatory Affairs in Pfizer Upjohn then Viatris. Sean holds a Bachelor of Pharmacy degree from the Chinese University of Hong Kong, and a BSc Management degree from the University of London.
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. Tony Li	Mr. Tony Li is the Senior Quality Assurance Manager at the Stem Cell GMP Laboratory of the LSK Faculty of Medicine and a teacher-practitioner at the Department of Pharmacology and Pharmacy. He is involved in the GMP development and training of Advanced Therapy Products at the faculty. Mr. Li obtained his Master of Pharmacy degree with First Class Honour at the University of London and Postgraduate Diploma in Pharmaceutical Quality & Good Manufacturing Practice with Distinction at the University of Strathclyde. In 2016, he was awarded his MBA from the Hong Kong University of Science and Technology. Mr. Li is a registered pharmacist and a registered Authorized Person with experience in the pharmaceutical industry and hospital pharmacy. He has worked with all major pharmaceutical dosage forms including Advanced Therapy Products, biologics, and small molecule drugs.
Ms. Sunitha Shanmugam	Ms. Shanmugam has been a registered pharmacist for 29 years and is currently the Regulatory Affairs & Quality Director at H&H. She has over 20 years of experience in managing the regulatory portfolio for consumer healthcare products which include OTC medicines, health supplements, traditional medicines, medical devices, cosmetics and food products. Her expertise includes regulatory strategy for New Product Development, CMC & new claims, product reclassification and switch, advertising efforts, government affairs, pharmaceutical formulation & manufacturing, and site and commercial quality. Working with the various regulatory agencies across ASEAN, Asia &ANZ, she holds regulatory/technical working groups in the industry associations with top priority to focus on strategic regulatory work.

Dr. Sheik, Khalid Ahmad	Dr. Sheikh studied Pharmacy at the University of the Punjab, Pakistan, undertook MPharm at the University Sains Malaysia, and obtained PhD degree in Pharmaceutical Technology from the University of Strathclyde, Glasgow. He has previously worked as an academic at the International Medical University (IMU), Malaysia, for 9 years, an Industrial Pharmacist at the Prime Pharmaceuticals for 3 years and a Locum pharmacist at the Pure Pharmacy, Malaysia, for 5 years. Dr Sheikh is currently working as a Teaching Fellow in the Department of Pharmaceutics and is the Director of the Q3P Course at the UCL School of Pharmacy.
Ms. Sara Wang	Sara Wang has over 30 years of working experience in the healthcare industry including Regulatory Affairs, Research and Development, Clinical Operations and Medical Affairs. In July, 2018, Sara joined RDPAC (R&D-based Pharmaceutical Association Committee, China Association of Enterprises with Foreign Investment) as the Head of Science & Regulatory Affairs. Sara led RDPAC member companies to actively participate in the regulatory advocacy activities, support the implementation and transformation of ICH guidelines in China, and advance China's participation in the simultaneous R&D and registration of global innovative drugs. She has led a number of research projects in RDPAC, which have conducted in-depth research and analysis on relevant topics in drug review and approval and clinical research system, sharing international experience and put forward suggestions. Before joining RDPAC, Sara worked in Novartis, GSK, Baxter and Institute of Material Medica, Chinese Academy of Medical Sciences for many years, taking different roles in Regulatory Affairs and R&D.