CoRE Capacity Building Programme

ADB-CoRE Training Workshop: Indonesian Food and Drug Authority
Regulatory Oversight for Advanced Therapy Medicinal Products (ATMP)
11-14 November, Jakarta, Indonesia

Advanced therapies, covering the scope of cellular, tissue and gene treatment modalities, is a rapidly advancing field that offers exciting new life enhancing and saving therapeutic possibilities but constantly challenges the regulatory environment to expedite access to these new innovations. The field of advanced therapies is increasingly converging with biological products, and regulators who can understand the science and regulations of vaccines, biological products and advanced therapies will be able to enable innovations and support economic developments in these areas.

This course aims to provide a better understanding of the different frameworks and practices regulating advanced therapies, including requirements for product evaluation and dossier submission for an effective product life cycle management. The course will be productive for Indonesian Food and Drug Authority (BPOM) regulators to understand global trends in regulatory approaches and strengthen the skillsets to accommodate new innovation. There is also a focus on promoting convergence of regulatory approaches for advanced therapies.

SESSION 1: REGULATORY MANAGEMENT OF ATMP

Dr Natasha Brockwell
Program Lead
Indo-Pacific Regulatory Strengthening Program
International Regulatory Branch
Therapeutic Goods Administration (TGA), Australia

Dr Hiroyuki Nakagawa
Reviewer, Office of Cellular and Tissue-based Products
Pharmaceuticals and Medical Devices Agency (PMDA)
Japan

Ms Teo Jing Ting
Regulatory Affairs Director
Miltenyi Biomedicine

Mr Yueh-Tung Tsai
Technical Specialist
Division of Medicinal Products
Food and Drug Administration
Chinese Taipei

CoRE FACULTY

Asst Prof James Leong
Head,
Health Products & Regulatory Science

Asst Prof Tan-Koi Wei Chuen
Lead,
Regulatory Systems Strengthening

Asst Prof Eddie Tan
Co-Lead,
Health Regulation Group

Ms Jessalyn Chan
Research Associate,
Regulatory Systems Strengthening

SESSION 2: CMC EVALUATION

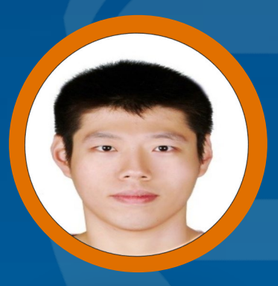
Dr Srinivasan N Kellathur
Pharma Technical Regulatory Policy, APAC
Roche, Singapore
Adj Asst Professor, CoRE
Duke-NUS Medical School, Singapore

SESSION 3: CLINICAL STUDIES AND REGULATORY DECISION FOR CTGTP

Mr Ranga Prakash
Director of Medical Affairs/Clinical Development
Miltenyi Biomedicine

Dr Tony Gill
Principal Medical Adviser
Director, Clinical Evaluation Section 6 (Advanced and Biological Therapies)
Therapeutic Goods Administration (TGA) Australia

Dr Hsu Chiao-Ying
Center for Drug Evaluation (CDE)
Chinese Taipei



Dr Ho Kun-Chin
Center for Drug Evaluation (CDE)
Chinese Taipei

SESSION 4: PHARMACOVIGILANCE AND POST-MARKET CONTROLS

Mr Stanley Soh
Senior Regional Quality Manager, APAC
Cencora/World Courier

Ms Phua Chwee Ping
Regional Head of Patient Safety, Asia-Pacific
Patient Safety & Pharmacovigilance
Novartis

Faculty Biographies

Mr Renadi Budiman
Deputy Country Director
Indonesia Resident Mission
Asian Development Bank

Mr Renadi Budiman is appointed Deputy Country Director, Indonesia Resident Mission (IRM), Southeast Asia Department (SERD) effective upon assumption of office.

Mr. Budiman, a national of Indonesia, holds a Master's degree in Business Administration, and a Bachelor's degree in Business Administration (Accounting and Finance) from Texas A&M University, United States.

Renadi has over 31 years of professional experience including more than 20 years in ADB. He joined ADB in November 2002 as Audit Specialist in the former Office of the General Auditor and has since held progressively responsible positions in the Office of Anticorruption and Integrity, Controller's Department, and Central and West Regional Department. In December 2018, he was promoted to Principal Country Specialist, Afghanistan Resident Mission. He transferred to the Lao Resident Mission in March 2020 as Principal Portfolio Management Specialist where he led and managed the portfolio of ADB-funded projects in Lao-PDR ensuring achievements of objectives through monitoring of their performance indicators. Prior to joining ADB, he was Global Risk Management Solutions Manager at PricewaterhouseCoopers, Indonesia. He obtained his Chartered Financial Analyst (CFA®) designation in 2002.

Prof. Dr. Taruna Ikrar
M.D., M. Biomed, Ph.D.
Chairperson
Badan Pengawas Obat dan Makanan (BPOM)
Indonesia

Prof. dr. Taruna Ikrar, M.D., M. Biomed, Ph.D., is an internationally recognized physician, biomedical scientist, and biomedical educator with more than 20 years of experience in:
• Practicing medicine as a licensed physician at both private and public government hospitals
• Conducting biomedical research in university & hospital settings
• Providing formal academic curriculum development & instruction for undergraduate, doctoral, and post-doctoral biomedical education programs in university and hospital settings.
• Exercising supervisory management and professional development of clinical/research staff in university and hospital settings.

Over the past decade, Prof. Ikrar's ground-breaking biomedical discoveries in biomedical sciences, pharmacology, cardiovascular sciences, and neurosciences have been published in numerous world-class peer-reviewed research journals including Nature, Neuron, Cells, Circulation, Molecular Therapy, American Journal of Cardiology, Journal of Physiology, Current Biology Journal, and Frontiers in Neural Circuits.
They have earned funding from the US National Institutes of Health (NIH). His current research activity is focused on advancing the understanding and treatment of degenerative and infectious diseases, including the Dendritic cell vaccine immunotherapy for COVID-19.
Prof. Ikrar has obtained lawful permanent residence in the United States by qualifying as a physician-scientist of extraordinary ability (EB-1 Visa, aka "genius visa"), and is thus recognized by the US Government as an individual with "a level of expertise indicating that the individual is one of that small percentage who has risen to the very top of the field of endeavour".

From August 19, 2020, to August 18, 2024, Prof. Ikrar served as the Chairman of the Indonesian Medical Council (Konsil Kedokteran Indonesia), appointed by the President of Indonesia.

Currently, as of August 19, 2024, Prof Ikrar has been inaugurated by the President of Indonesia as the Chairperson of the Indonesian Food and Drug Administration.

Ms Tri Asti Isnariani
Director of Drug, Narcotics, Psychotropics, Addictive Substances Standardization
Badan Pengawas Obat dan Makanan (BPOM)
Indonesia

Ms. Tri Asti Isnariani has over 22 years of experience as a regulator in medicine. She is currently the Director for Standardization of Drug, Narcotic, Psychotropics, Precursor, and Addictive Substances, Indonesian Food and Drug Authority (FDA). Previously, she held the position of the Director for Safety, Quality, and Export Import Control of Drug, Narcotic, Psychotropics, Precursor, and Addictive Substances. In her past roles, she has gained extensive experience in coordinating activities related to post-marketing surveillance, pharmacovigilance, export-import control, and promotion control.

Ms. Tri Asti is actively participated in regional and international initiatives addressing the key issues included regulatory convergence, mutual recognition arrangements, and strategies to address challenges in the pharmaceutical landscape. She was the Chair of ASEAN Consultative-Committee of Standard and Quality-Pharmaceutical Product Working Group (ACCSQ-PPWG) from 2022 until 2023 and currently the Chair of Working Group 2 (Regulatory Strengthening) in South-East Asia Regulatory Network (SEARN).

Ms. Tri Asti completed her Bachelor of Pharmacy from the Bandung Institute of Technology and received Master of Pharmacy in clinical pharmacy from University of Science Malaysia.

Faculty Biographies

Dr Natasha Brockwell
Program Lead
Indo-Pacific Regulatory Strengthening Program
International Regulatory Branch
Therapeutic Goods Administration (TGA), Australia

Dr Brockwell is currently the Program Lead of the Indo-Pacific Regulatory Strengthening Program in the International Regulatory Branch at the Therapeutic Goods Administration.

Dr Brockwell has a PhD in Cancer Immunology and spent her PhD and post-doc working on immune based therapies, including mRNA therapies and CAR-T cells. Since joining the TGA Dr Brockwell has been an evaluator in the biologicals section where she evaluated CAR-T cell therapies and other biological and biological medicine products. Following this she joined the regulatory strengthening program as a senior regulatory scientist, providing technical assistance to partner countries in the South-East Asian and Pacific Region.

Dr Hiroyuki Nakagawa
Reviewer, Office of Cellular and Tissue-based Products
Pharmaceuticals and Medical Devices Agency (PMDA)
Japan

Dr Hiroyuki Nakagawa is a reviewer in the Office of Cellular and Tissue-based Products of PMDA for three years and in charge of consultation and review. He received his BS of pharmacy from the Nagoya City University in 2016, MS and PhD of Pharmacy from Graduate School of Pharmaceutical Sciences, Nagoya City University in 2018 and 2022.

Ms Teo Jing Ting
Regulatory Affairs Director
Miltenyi Biomedicine

Ms Teo is the Regulatory Affairs Director responsible for growing and bringing to the market innovative cell and gene immunotherapy products for Miltenyi Biomedicine, focusing on the Asia-Pacific region. One of the most advanced programme is a tandem CD20-CD19 CAR-T (zamtocabtagene autoleucel) for the treatment of DLCBL, currently in pivotal clinical trial phase.

Jing Ting has over 15 years of operational and strategic regulatory affairs experience in International and APAC regions, spanning from R&D and Clinical phases to lifecycle management of various product portfolios, covering therapeutic areas including Oncology/Hematology, Immunology and Rare Diseases. Her interest in innovative therapies and state-of-the-art technologies has led her to experience the joy and challenges of mostly biologicals therapies, such as monoclonal antibodies, RNAi and mRNA technologies. Prior to joining Miltenyi, Jing Ting has helped to pioneer the expansion of Southeast Asia businesses in a start-up company, Everest Medicines. She also has vast experience with other big pharmas including Sanofi/Genzyme, Novartis and Pfizer, where she was responsible for bringing innovative products to the market using various acceleration strategies. She has also been involved in representing the APAC region in Cell & Gene Therapy internal work streams and helped to shape policies and to devise regulatory strategies in support of the business.

Jing Ting received her Pharmacy degree from the National University of Singapore and is a registered pharmacist with the Singapore Pharmacy Council.

Mr Yueh-Tung Tsai
Technical Specialist
Division of Medicinal Products
Food and Drug Administration
Chinese Taipei

Mr Tsai graduated with a Bachelor of Pharmacy in Taipei Medical University and a Master of Health and Welfare Policy in National Yang Ming Chiao Tung University. He joined Taiwan Food and Drug Administration (TFDA) in 2013. He is currently a technical specialist at the Division of Medicinal Products. During his work in TFDA, he has experience in several areas, including pharmacy administration, GMP inspection, new drug application, post-marketing variation and regenerative medicine related affairs. Besides, he has been responsible for establishing regenerative medicine related regulations in Taiwan.

Faculty Biographies

Dr Srinivasan N Kellathur
Pharma Technical Regulatory Policy, APAC
Roche, Singapore
Adj Asst Professor, CoRE
Duke-NUS Medical School, Singapore

Dr Kellathur is currently the Roche Pharma Technical Regulatory Policy Lead for APAC based in Singapore. At Roche he drives regulatory convergence initiatives with a focus on CMC and ensures the implementation of reliance pathways across the region. Prior to joining Roche, Srini was with the Health Sciences Authority, Singapore heading the Advanced Therapy Products Branch and implemented the cell, tissue, and gene therapy products regulations in 2021, the first country to implement in ASEAN. In addition, to promote and advance prospective regulatory convergence efforts, he is representing the BIO as a sub-champion for advanced therapy products priority work area established under the auspices of Asia Pacific Economic Cooperation. Srini also an adjunct assistant professor at the Centre of Regulatory Excellence, Duke–NUS Medical School.

Mr Ranga Prakash
Director of Medical Affairs/Clinical Development
Miltenyi Biomedicine

With a career spanning over 20 years in both Contract Research Organizations (CRO) and the pharmaceutical industry, Mr Ranga Prakash has held key strategic Medical Affairs operational roles across leading organizations, including more recently at Biogen and Bristol-Myers Squibb (BMS)/Celgene. Throughout his career, he has gained extensive expertise in managing and launching several new therapies in both the oncology and neurology spaces, bringing life-changing treatments to patients in need thereby contributing to significant advancements in science.

As a regional expert in Southeast Asia, Japan and Australia, Ranga has been instrumental in driving market strategy and expanding access to innovative therapies across these regions. His leadership has been critical in the successful launch of multiple therapies, earning him a reputation for his strategic acumen and deep understanding of regional healthcare dynamics. During his time with ICON, Syneos Health and IQVIA, Ranga managed several large, pivotal complex clinical trials across the Asia-Pacific region, further cementing his reputation as a leader in clinical development and trial management.

Currently, Ranga serves as the Director of Medical Affairs & Clinical Development at Miltenyi Biomedicine, where he is spearheading efforts to introduce the company's groundbreaking CAR-T asset, Zamto-Cel, for the treatment of relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) in Asian markets in a Point of Care setting. His leadership continues to shape the landscape of medical innovation, helping to bridge the gap between cutting-edge science and patients in need.

Dr Tony Gill
Principal Medical Adviser
Director, Clinical Evaluation Section 6 (Advanced and Biological Therapies)
Therapeutic Goods Administration (TGA) Australia

Dr Tony Gill is a public health physician who is a Principal Medical Adviser in the Therapeutic Goods Administration (TGA) and heads up the Clinical Evaluation Section 6 (Advanced Biological and Therapies) in the Prescription Medicines Authorisation Branch, Medicines Regulation Division. In this role he heads up a section involved in the clinical evaluation and market authorisation decision making for gene therapies and cell therapies as well as being involved in developing policy on emerging advanced therapies.

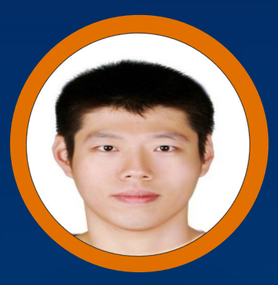
He commenced work at the TGA in February 2010 following 25 years in the Australian Army and has filled various roles including acting Chief Medical Adviser of the TGA and Senior Medical Adviser roles until before moving to his current position in February 2022. In the TGA he has been involved in the regulation of unapproved therapeutic goods, the clinical evaluation of medicines, biologicals and medical devices, and the scheduling of medicines. As well Dr Gill was the lead for the introduction of TGA's medicine shortages section and its medicinal cannabis section.

Dr Gill is the current President-elect of Australasian Faculty of Public Health Medicine within the Royal Australasian College of Physicians.

Faculty Biographies

Dr Hsu Chiao-Ying
Center for Drug Evaluation (CDE)
Chinese Taipei

Chiao-Ying Hsu is a medical doctor and specialized in Nephrology. During the 9 years in clinical practice, she involved in both investigator and sponsor initiated clinical trials. Qualified in GCP training and participated in all aspect of clinical trials including protocal discussion, patient enrolllment, follow-up, SAE evaluation, and data analysis. In 2015, she entered Devision of New Drug, Center for Drug Evaluation, Taiwan as a medical reviewer. She is well experienced in reviewing new drug application, bridging study evaluation and investigational new drug (IND) clinical study application. Since 2022 October, she served as the Clinical Section Chief in responsible for IND review works.



Dr Ho Kun-Chin
Center for Drug Evaluation (CDE)
Chinese Taipei

Dr. Kun-Chin Ho started working at Center for Drug Evaluation, Taiwan in 2017 and is a senior reviewer in the Pharm/Tox section. He involves in the establishment/revision of regulations/guidelines regarding clinical trials and marketing approval for cell and gene therapy since 2019. He is one of the Taiwan representatives in the IPRP Cell & Gene Therapy Working Group since 2019 and in the ICH Cell & Gene Therapy Discussion Group since 2023. Dr. Kun-Chin Ho received his PHD degree from National Taiwan University in 2014, with a focus on immunology and cancer biology.

Mr Stanley Soh
Senior Regional Quality Manager, APAC
Cencora/World Courier

Stanley Soh is Senior Regional Quality Manager for Asia Pacific at World Courier. He is responsible for ensuring the compliance of the countries in Asia Pacific to World Courier's Quality Management System which includes both ISO9001 and Good Distribution Practice (GDP).

Stanley has wide experience in the Transportation and Logistics Industry having previously worked in Singapore Airlines in several countries around the world and DHL in Singapore before joining World Courier in 2005. In 2009, he moved to his current position in Quality when the Quality Management System incorporating GDP was introduced.

Stanley obtained his Honours Degree in Social Sciences from the National University of Singapore and an MBA specialising in Strategic Management from the Nanyang Technological University. He is also a certified Dangerous Goods Instructor and holds an advanced certificate in Training and Assessment.

Ms Phua Chwee Ping
Regional Head of Patient Safety, Asia-Pacific
Patient Safety & Pharmacovigilance
Novartis

Chwee Ping earned her Master of Science (Clincal Pharmacy) degree from Queen's University of Belfast, Ireland and her Bachelor of Science (Pharmacy) degree from National University of Singapore.

Chwee Ping joined Novartis in 2008 and worked as Regional Pharmacovigilance Manager, Asia-Pacific, Middle East & African Countries (AMAC). In 2012, her role was redefined to focus on Asia- Pacific Region and in 2017, she was promoted to Regional Head of Patient Safety, Asia Pacific. Her main role was to ensure that the region achieve excellent levels of pharmacovigilance compliance with Novartis global and local procedures, national and international regulatory requirements/standards/guidelines.

Prior to joining the organization, Chwee Ping served as Senior Medical Services Associate, ASEAN+ at Bristol-Myers Squibb, where she was responsible for handling safety reporting and medical enquiries for the region. She also has extensive experience working as Principal Pharmacist in Singapore General Hospital.

Faculty Biographies

Asst Prof James Leong
Head,
Health Products & Regulatory Science

As the Head of Health Products & Regulatory Science at the Centre of Regulatory Excellence, Dr James Leong is in charge of identifying the educational needs for the various stakeholders involved in regulatory affairs in the Asia Pacific region, and establishing education roadmaps, priorities and deliverables. In this role, he actively conducts roundtable discussions on policy with regulatory affairs professionals across Asia Pacific, as well as research on advancing regulatory sciences. He draws his regulatory experience from his years as a senior regulatory specialist with the Health Sciences Authority of Singapore, where he is a clinical reviewer in addition to managing the post-market benefit-risk assessments and regulatory actions, as well as oversees the training of clinical assessors. In addition to his Masters in clinical pharmacy, he is also Board-certified in pharmacotherapy. His previous clinical experiences include leading the hospital drug information services and heart failure clinic. He obtained his PhD from Cardiff University, focusing on benefit-risk assessment frameworks, communication of regulatory decisions and innovation of regulatory approaches.

Asst Prof Tan-Koi Wei Chuen
Lead,
Regulatory Systems Strengthening

Tan-Koi Wei Chuen is Assistant Professor and Lead of Regulatory Systems Strengthening at the Duke-NUS Centre of Regulatory Excellence (CoRE). Asst. Prof Tan-Koi's work focuses on health policy research and capacity building in biomedical innovation and regulatory science. She is consultant for the Asian Development Bank-CoRE Vaccine Regulation Project and faculty member in international capacity building programmes including the Asia-Pacific Economic Cooperation Pharmacovigilance Centre of Excellence Pilot Programme and the ASEAN Vaccine Security and Self-Reliance Vaccine Human Resource Development Programme for Enhancing Vaccine Development and Deployment Capacities.

Prior to joining Duke-NUS Medical School, Asst. Prof Tan-Koi was Regulatory Consultant and Team Lead of the Regulatory Research and Risk Communication teams at the Singapore's Health Sciences Authority. A pharmacist by training, Asst. Prof Tan-Koi was awarded the Singapore Health Manpower Development Plan Fellowship for Graduate Research Programme in Public Health and received her doctoral degree from the NUS Saw Swee Hock School of Public Health.

Asst Prof Eddie Tan
Co-Lead,
Health Regulation Group

Dr Eddie Tan has a keen interest in integrating scientific advancements into modern medicine. He is currently an Assistant Professor with the Duke-NUS Centre of Regulatory Excellence (CoRE) and co-lead for Health Services Research at CoRE, where his team manages regulatory landscaping research with Singapore's Ministry of Health to address emerging healthcare topics, such as Advanced Therapies, Precision Medicine and Artificial Intelligence.

Prior to joining CoRE, Eddie had spent 6 years as the Scientific Officer in the National Cell Therapy Pilot Program housed under the Blood Services Group of the Health Sciences Authority of Singapore (HSA). In his role with HSA, he was responsible for engaging with medical, scientific and regulatory experts to address Chemistry Manufacturing and Controls (CMC) matters to translate pre-clinical research into GMP-compliant manufacturing for early-phase clinical trials in Singapore. As a cell therapy specialist under the Translational Services and Regulatory Management portfolio at the Advanced Cell Therapy Research Institute of Singapore (ACTRIS), he was instrumental in the planning and establishment of ACTRIS as an effort to develop a new national GMP Facility for Cell and Gene Therapy Manufacturing.

Eddie graduated with a BSc (Hons in Biological Sciences) and a PhD (Biological Sciences) from Nanyang Technological University. He is a member of the International Society for Cell & Gene Therapy (ISCT), where he has served on the Asia Pacific Industry Committee and Asia Regional Early-Stage Professionals Committee. Additionally, he contributes to the Association for the Advancement of Blood & Biotherapies (AABB) as a member of the Asia Pacific Group Cellular Therapy Section (APG) and was in the inaugural batch of professionals awarded the Certified Advanced Biotherapies Professional (CABP) designation by AABB in 2022. He is also a registered member of The Organization of Professionals in Regulatory Affairs (MTOPRA).

Ms Jessalyn Chan
Research Associate,
Regulatory Systems Strengthening

Jessalyn Chan is currently Research Associate with the Centre of Regulatory Excellence (CoRE) at the Duke-NUS Medical School. As part of the Regulatory Systems Strengthening Group, she works with the regulatory think-tank team to advise the Asian Development Bank on health systems strengthening across Asia and the Pacific, for the project, "Support to Enhance COVID-19 Vaccine Access". This project promotes resiliency in vaccine regulatory systems, aligned with her mission to promote public health and lives through equitable healthcare and vaccine access.

Prior to joining CoRE, Jessalyn was a senior pharmacist and in-charge of the outpatient pharmacy team at the National Centre for Infectious Diseases (NCID). As Team Lead of NCID Supply Chain and Procurement, she was also part of the team involved in strategic planning for outbreak risk management particularly during the COVID-19 pandemic. Jessalyn has a special interest in health policy on infectious diseases prevention and outbreak management. She holds a Master of Science (Infectious Diseases), from the London School of Hygiene and Tropical Medicine. She is also a Board Certified Pharmacotherapy Specialist with the American Pharmacists Association.