DukeNUS Medical School | Centre of Regulatory Excellence | 昆山杜克大学 DUKE KUNSHAN UNIVERSITY

CREATInG Initiative

Regulatory Functional Training

Regulatory Management of IVD

10 to 12 November 2025

CREATInG Initiative

Regulatory Functional Training

Regulatory Management of IVD

This series of Functional Training workshops is part of the CREATInG Initiative, led by the Duke-NUS Centre of Regulatory Excellence (CoRE) and Duke Kunshan University.

This initiative delivers targeted training programmes designed to strengthen the technical regulatory knowledge of functional leaders, with a focus on product development and the regulatory management of in-vitro diagnostics. These workshops are developed for professionals involved in regulatory decision-making and manufacturing.

Programme Objectives

a. Comply with key regulatory requirements of IVD throughout the product life cycle for major markets

b. Apply good practices to comply with clinical and manufacturing regulatory requirements for IVD in the global environment

c. Optimise the Quality Management System for their assets with the ISO 13485

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Regulatory Functional Training - Workshop A

Regulatory frameworks and requirements for IVD

a) Differentiate product classifications across major markets and apply risk management based on global regulatory requirements

b) Comply with regulatory requirements for clinical performance of IVD

c) Apply good practices for IVD asset building and comply with required standards

10 Nov 2025

Overview of regulatory frameworks

1) Overview of differences across US FDA, EU and ASEAN regulatory frameworks
2) Dossier formats
3) Updates on EU IVDR and impact on manufacturers

Product risk classifications

1) Case Discussion: Product risk classifications
2) WHO Pre-qualification for IVD
3) Reliance mechanisms for market approvals of IVD
4) Considerations for market access

11 Nov 2025

IVD Life cycle management

1) Intro to life cycle management
2) Case Discussion: Key activities in life cycle management

Risk management

1) Handling changes in risk management
2) Case Discussion: Applying Annexes A and H

12 Nov 2025

Clinical performance and validation

1) Updates on guidelines and standards for IVD manufacturing
2) Pre-clinical and analytical performance
3) Clinical performance and validation

Complying with standards

1) Group work: IVD asset building

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Regulatory Functional Training - Workshop B

Meeting ISO13485 QMS requirements for IVD

a) Apply ISO 13485 requirements as integral part of product development and manufacturing processes for global markets

b) Optimise risk-based approach to Quality Management System (QMS)

c) Prepare for ISO 13485 inspections and handling of post-market processes

11 May 2026

QMS and ISO 13485

1) ISO13485 in product life cycle management
2) Global application of ISO 13485
3) ISO 13485 - Definitions

Interpreting ISO 13485

1) ISO 13485 – Application of clauses across product life cycle
2) Case discussion: ISO 13485 Clauses 0 to 6 (covering production, Design & Development, Verification & Validation

12 May 2026

Interpreting ISO 13485

1) Case discussion: ISO 13485 Clauses 0 to 6 (covering Medical Device File and Document controls)

Interpreting ISO 13485

1) Overview of ISO 13485 Clauses 7 and 8
2) Case discussion: ISO 13485 Clauses 7 and 8 (covering use of GSPR and EPSP)

13 May 2026

Risk-based QMS

1) Applying risk-based approach in QMS
2) Case discussion: Risk-based QMS across different IVDs

Inspections and audits

1) Experience sharing – Local audits (ISO 13485, ISO 19011)
2) Preparation for inspections

Faculty

Prof Fujie XU
Co-Director
Global Health Program
Duke Kunshan University

Prof Fujie Xu co-directs the Global Health Program at Duke Kunshan University (DKU), China. Prior to her appointment at DKU in January 2025, she was the Deputy Director for Health Innovation and Partnership at the Gates Foundation's China Country Office. Prof Xu's research interests focus on outbreak detection and health emergency response, and she was a "disease detective" in the global response to epidemics and pandemics, including the SARS outbreak and the H1N1 influenza pandemic. During "peace" time, her research focuses on the introduction of new vaccines, diagnostics and treatments against infectious diseases in the United States, China and other Asian countries.

She has published widely on various aspects of infectious diseases, particularly HIV/STD, viral hepatitis infections, and emerging and re-emerging infections and has extensive experience in health product innovations and in developing clinical and public health guidelines.

Prof Xu received her medical training at Peking University in China and earned a doctoral degree in epidemiology at Emory University in the United States. She also completed her post-doctoral training as an Epidemic Intelligence Service officer at the US Centers for Disease Control and Prevention, where she worked for 17 years.

Asst Prof James LEONG
Head
Health Products & Regulatory Science
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

As the Head of Health Products & Regulatory Science at the Centre of Regulatory Excellence, Asst Prof 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.

Faculty

Mr Andrew HO
Co-Founder & Business Development Director
DH RegSys

Mr Andrew Ho is the co-founder of DH RegSys in Singapore in 2010 and started his journey in the medical device industry with primary responsibility on development of business for DH RegSys' QARA consulting services.

He is the key liaison with the company's regional partners to provide regulatory services across the region (like in Malaysia, Thailand, Philippines, Indonesia and Vietnam). Besides consulting services; Andrew has also been focusing on delivery of training to the industry via seminars (example - Medical device regulatory workshop for ASEAN plus China and Japan) and workshops (examples - SaMD / IEC62304; Risk management).

Mr Eustace CHAI
Regulatory Affairs Consultant
DH RegSys

Mr Eustace Chai joined DH RegSys in 2019 as Consultant for QARA services. His primary area of focus is in Quality Management Systems (ISO13485 and GDPMD) and he works closely with DH RegSys' Principal Consultant (HweeEe) to help clients to set up, improve and optimization of management systems.

Mr Chai also supports clients regarding regulatory matters. Since joining the medical device industry in 2019, he has worked with medical device manufacturers in a variety of products including IVD (example Covid19 test kits) and general medical devices.

Mr Jaineet ARORA
Education Associate II
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

Mr Jaineet Arora is an Education Associate at Centre of Regulatory Excellence at Duke-NUS Medical School, where he works to advance regulatory education in the medical device sector through strategic collaboration, curriculum development, and instructional design. In this role, he co-develops and coordinates multi-day workshop programs by engaging subject-matter experts from both regulatory agencies and industry partners, designing interactive learning components like case studies and practicums.

Armed with a Master of Science in Engineering Design and Innovation from the National University of Singapore, Jaineet brings a background in Biomedical Engineering, which has honed his eye for precision and the delicate balance between form and function in the realm of science and design.

He draws on significant experience as a Validation Analyst in the GxP space, where he was responsible for consulting on qualification activities for computerized systems and analytical instruments. Jaineet is proficient in applying key tools such as ISPE GAMP5 and Quality Risk Assessment (ICH Q9) to determine validation strategy. Furthermore, he has provided regulatory compliance consultations on Data Integrity and 21 CFR Part 11 Electronic Record/Signature requirements for systems like EDC and ELN.

Faculty

Ms Jessalyn CHAN
Research Associate
Regulatory Systems Strengthening
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

As Research Associate at CoRE, Jessalyn's work focuses on regional and international projects to facilitate access to essential health products through strengthening regulatory systems. These include advising the Asian Development Bank on vaccine regulation in Asia and the Pacific and on the Gates Foundation-funded CREATInG project to build regulatory capacity for in-vitro diagnostics (IVD).

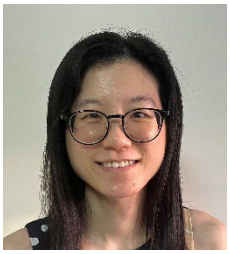
Jessalyn is experienced in strategic planning and outbreak risk management, having served as a senior pharmacist and Lead of the Supply Chain and Procurement and Outpatient Pharmacy Services teams at the National Centre for Infectious Diseases (NCID) in Singapore. She was awarded the in-service scholarship from the National Healthcare Group and received a Master of Science (Infectious Diseases) from the London School of Hygiene and Tropical Medicine. She is trained in infectious disease modelling and skilled in health technology assessment, having received a Graduate Certificate in Health Economic Evaluation from Duke-NUS Medical School. She is also a Board Certified Pharmacotherapy Specialist.

Dr Susie BRANIFF
Scientist
Prequalification Assessment
Medical Device Team
World Health Organization

Dr Susie Braniff is a scientist in the Prequalification Assessment of Medical Devices Team at WHO Headquarters. Key responsibilities of her role are coordination of product dossier review and team focal point for the Collaborative Registration Procedure. For over a decade she has been working in the field of quality assurance of diagnostics tests, including working with public health laboratories and regulatory authorities in LMIC to deliver high quality diagnostic testing. Prior to joining WHO in 2019, she was the Team Lead of the IVD Evaluations department at the National Reference Laboratory in Melbourne, Australia.

Dr Braniff obtained her PhD in Molecular Biology from Monash University in 2007 and Master of Public Health from the University of Melbourne in 2015.

Faculty



Ms Shuhui LIU
Senior Regulatory Specialist
Medical Device Cluster
Health Products Regulation Group
Health Sciences Authority (HSA)
Singapore

Liu Shuhui is a highly experienced medical device regulator with over 13 years of expertise in the medical device industry, currently serving at Singapore's Health Sciences Authority (HSA). With Master's degrees in Biomedical Engineering and Public Health, she brings a rare blend of technical depth and policy-level insight to the regulatory landscape.

Throughout her career at HSA, Shuhui has played a pivotal role in shaping and implementing regulatory strategies for a wide range of medical devices, ensuring compliance with international standards. Her responsibilities have included evaluating device submissions for both general medical devices and in vitro diagnostic medical devices and providing technical guidance under the Medical Devices Innovation Office, which conducts priority reviews for product registration and provides pre-market consultations to industry stakeholders, startups, and research institutions. Shuhui also specializes in post-market surveillance, with a focus on adverse event reporting. Her work plays a critical role in ensuring the ongoing safety and effectiveness of medical devices in the market. She is responsible for evaluating incident reports, conducting benefit-risk assessments, and recommending regulatory actions to mitigate risks to patient health.

With her multidisciplinary training, especially in areas involving risk assessment, post-market surveillance, and health technology evaluation, Shuhui is empowered to bridge scientific innovation and public health priorities, while ensuring standards of safety and effectiveness of medical devices.

Ms Hwee Ee TAN
Founder & Principal Consultant
DH RegSys

Ms Hwee Ee has more than 30 years work experience in QA & RA roles the medical device industry. Her career started in the manufacturing industry and in both QA & RA roles and held positions as Engineer and as Senior Manager. Ms Ee is the Co-founder and Principal consultant for DH RegSys since 2010.

Her advisory services cover areas like Quality Management Systems (eg US FDA GMP for medical devices; ISO13485) and Regulatory affairs (example CE, US FDA and ASEAN regulatory approvals). Besides these advisory services; HweeEe has been actively involved in conducting training, both public and also in-house training. Hwee Ee is a member of Work Group 7 (WG7) Quality Management Systems, GHWP.

Faculty

Prof Chen YAO
Director
Medical Statistics Office
Peking University First Hospital

Prof Chen Yao currently serves as the Director of the Medical Statistics Office at Peking University First Hospital and Deputy Director of the Peking University Clinical Research Institute. He holds key academic roles, including Chair of the Evidence-Based Medicine Professional Committee of the Chinese Medical Doctor Association, Vice Chair of the Statistical Theory and Methods Professional Committee of the Chinese Health Statistics Association, and Vice President of the Real-World Research Professional Committee of the World Federation of Chinese Medicine Societies. Additionally, he is the Deputy Director of the Oncology Medical Division of the Wu Jieping Medical Foundation, a Guest Professor at the Advanced Training Institute of the National Medical Products Administration (NMPA), an expert in the NMPA Drug/Device Review Expert Database, and the Head of the Expert Group on Real-World Data Research in the Boao Lecheng Pilot Zone.

Prof Yao is dedicated to research on data management and the application of statistical analysis methods in clinical research. He was the first to propose a standardized general management process for hospital-based clinical research source data. His innovative contributions have advanced data management practices in clinical research, enhancing the quality and reliability of research outcomes. In addition to his research, Prof Yao has been deeply involved in clinical research design education and training for many years. Working closely with clinicians, he has contributed to numerous clinical research projects involving new drugs, medical devices, and investigator-initiated studies, further strengthening collaboration between statistical methods and clinical practice.

Asst Prof Wei Chuen TAN-KOI
Lead
Regulatory Systems Strengthening
Centre of Regulatory Excellence (CoRE)
Duke-NUS Medical School

Asst Prof Wei Chuen Tan-Koi is Lead of Regulatory Systems Strengthening at CoRE. Her work focuses on health policy research and capacity building in biomedical innovation and regulatory science. Her portfolio includes international capacity building programmes, as well as regulatory systems strengthening projects funded by the Asian Development Bank and the Gates Foundation on vaccine and in-vitro diagnostic regulation.

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.