

“Regulatory Frameworks and Requirements for IVD”

10 - 12 November 2025

CREATInG Initiative Launches Regulatory Training at Duke Kunshan University, China

Purpose | Collaboration | Impact

34
Participants

3 Day
Interactive Training

In- Country
Bespoke Workshop



The CREATInG Initiative has marked an important milestone in its efforts to build regulatory capacity, for in-vitro diagnostics (IVD) companies across Asia with the launch of its first Functional Training titled, ***“Regulatory Frameworks and Requirements for IVD”***, held from **10-12 November, 2025**.

Commissioned by the Gates Foundation, the training was jointly organised with **Duke Kunshan University** and designed specifically for regulatory professionals of IVD manufacturers based in Asia.

Regulatory capacity building is a key component for the success of innovative and quality IVD's to reach global markets. Responding to this need, a three-day bespoke workshop, brought together 34 participants which included professionals from China and Korea.



The workshop introduced participants to Duke-NUS team-based learning approach grounded in diverse expertise, shared problem-solving, and real-world application, with the mission to strengthen the ability of IVD manufacturers to navigate complex regulatory pathways and reach global markets.

The Functional Training was facilitated by CoRE's faculty led by Asst/Prof James Leong, Head of the Health Products and Regulatory Science, and Asst/Prof Wei Chuen Tan-Koi, Lead of Regulatory Systems Strengthening.

The course was enriched by insights from experts at the Singapore's Health Sciences Authority, the World Health Organisation's Prequalification IVD Assessment Team, Professor Yao Chen from Peking University First Hospital, and the team from DH RegSys, including co-founders Ms Hwee Ee Tan and Mr Andrew Ho who brought together more than 50 years of regulatory and industry experience.

Grounded in real-world case studies, participants engaged in interactive case discussions and applied the newly acquired regulatory skills in creating their own regulatory filing strategy.



“Since inception, the CREATiNG Initiative has received overwhelming support for our International Roundtable, Executive Development Programme, and Regulatory Functional Training.

United by a common purpose, we're excited to continue collaborating with like-minded partners to address regulatory and access gaps for innovative and affordable IVD solutions - building stronger, more resilient health systems across Asia-Pacific and beyond.”

Asst/Prof Wei Chuen Tan-Koi
Lead of Regulatory Systems Strengthening
CoRE



Professor Fujie Xu
Co-Director
Global Health Research Center,
Duke Kunshan University

"There is a saying about the difference between giving a man a fish and teaching him to fish. Our ambitions here go beyond this as we strive to shape the learning ecosystem itself, for fish to grow healthier. Similarly, for IVD manufacturers, complex regulatory pathways remain a challenge. This is precisely why our partnership with Duke-NUS CoRE is so important in providing the necessary foundation to address these challenges and drive meaningful, lasting progress."

Asst. Prof James Leong
Head, Health Products &
Regulatory Science, CoRE

"It is ever more urgent now to build an ecosystem that enables regulators, innovators and product developers to support a sustainable growth for improved IVD access to patients. The rapid pace of clinical sciences requires all stakeholders to be in tandem, and these capability-building efforts are pivotal in forming a collaborative foundation for other initiatives towards a stronger ecosystem."



Participant feedback by Zhao Han
Founder and CEO
Beijing Fangtang Hanhe Biotechnology Co., Ltd.

"It was a great learning experience!"

Thanks to all the staff for their hard work in organizing and teaching this successful workshop. Also, deep appreciations to our amiable and collaborative classmates who are a critical part of this very pleasant and efficient experience. Hopefully, our friendships and collaborating experience will last and may lead to collaboration in the future."



About the CREATInG Initiative

Launched in 2024, the CREATInG Initiative is commissioned by the Gates Foundation and a joint effort between CoRE and Duke Kunshan University (DKU).

The programme aims to accelerate access to in-vitro diagnostics (IVD) for critical global health needs through strategic leadership development and regulatory systems strengthening through international conferences, executive training, and capacity-building programmes.

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