# GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

## PHARMACEUTICALS AND MEDICAL DEVICES

**C**ENTRE **o**f **R**EGULATORY **E**XCELLENCE


DukeNUS Medical School | Centre of Regulatory Excellence

DukeNUS Medical School | Centre of Regulatory Excellence

## VISION

To be a leading Centre enhancing regulatory capability and scientific excellence for health products and systems in Asia

## MISSION

To establish regional platforms and networks to grow competencies, enhance collaboration and promote thought leadership in innovative regulatory science and health policy

# EXECUTIVE DIRECTOR'S MESSAGE

## PROFESSOR JOHN LIM

**Executive Director**
*Centre of Regulatory Excellence*
*Duke-NUS Medical School*

**Core Lead (Policy)**
*SingHealth Duke-NUS Global Health Institute*

**Senior Advisor**
*Ministry of Health, Singapore*

**Chairman**
*Consortium for Clinical Research & Innovation, Singapore*

CoRE was established in 2014 in recognition of the need to grow the local and regional pool of regulatory talent, as part of the wider aim to strengthen regional regulatory systems for health-related products in Asia-Pacific. We believe that robust regulatory systems must be supported by skilled regulatory professionals equipped with up-to-date regulatory knowledge and critical skills to navigate the fast evolving and complex global regulatory environment. Structured regulatory training programmes with a focus on issues relevant to Asia and the Asia-Pacific region are essential to meeting this need as well as developing a talent pool of regulatory leaders.

We are pleased to offer the Graduate Certificate in Health Products Regulation – the first dedicated regulatory training that caters to your learning needs in Singapore, South-East Asia and Asia-Pacific – for regulatory professionals as well as healthcare professionals and researchers interested to know more about regulatory science. We welcome you to consider this opportunity to develop your knowledge and skills to advance your regulatory career and your effectiveness as a regulatory professional.

# DEPUTY DIRECTOR'S MESSAGE

## ASSOCIATE PROFESSOR SILKE VOGEL

**Deputy Director**
*Centre of Regulatory Excellence*

**Senior Associate Dean**
*Graduate Studies*

**Head**
*Centre for Lifelong Learning*
*Duke-NUS Medical School*

Education is one of CoRE's key strategic thrusts as it works towards enhancing regional health systems in Asia-Pacific. Taking on the Duke-NUS learning philosophy, we recognise that an effective learning experience goes beyond increasing knowledge and understanding, but also develops advanced technical skills and soft skills such as critical thinking and problem-solving skills. These are important traits to be found in regulatory professionals, given the increasing complexity and emerging challenges in the regulatory landscape.

We encourage you to explore the opportunities offered by the Graduate Certificate Programme, including a rich and fulfilling learning experience that equips you with the necessary knowledge and skills for a rewarding career in pharmaceutical regulatory affairs.



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CoRE provides a neutral academic platform for networking of health products regulatory stakeholders in the Asia-Pacific, with a special focus on South-East Asia, to promote capacity development and innovation.

# ABOUT DUKE-NUS

**Duke-NUS is a partnership between Duke University and the National University of Singapore.**

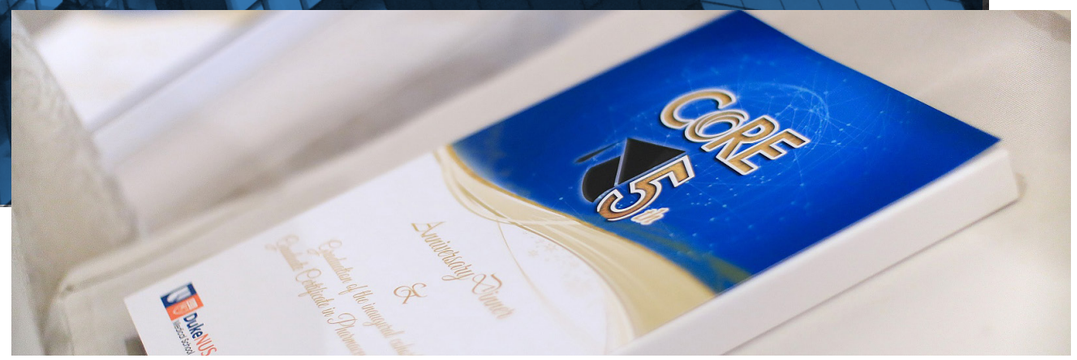

In 2005, with firm support from the Singapore government, the National University of Singapore (NUS) and Duke University, two academic institutions with strong track records in research and education, committed to combine the unique medical education curriculum at Duke University School of Medicine with the academic rigour and rich resources offered by NUS, and to offer students an enriching and innovative educational experience.

Duke-NUS is located on the main campus of the largest healthcare group in the country, Singapore Health Services (SingHealth). This group collectively delivers multi-disciplinary care among 42 clinical specialties across a large network of hospitals, national specialty centres and polyclinics. Together, Duke-NUS and SingHealth constitute a leading, world class Academic Medical Centre embodying the goal of delivering the highest levels of patient care, education and research.



# ABOUT CoRE

**CoRE was established to facilitate access to safe, high quality and effective medicines and medical devices through the strengthening of health product regulatory systems in the Asia-Pacific, with a special focus on South-East Asia.**




Guided by this theme, CoRE contributes to improving patient access to health products and also enhancing regional health systems and health security.

Launched in 2014 within Duke-NUS, CoRE engages and supports its stakeholders through the approaches of education, to enhance the competencies of regulatory professionals, think tank, to promote thought leadership and policy innovation, and to leverage on our expertise and networks to provide advisory support for our stakeholders.

CoRE's education activities serve as a key focus towards enhancing regulatory capabilities. Continuous, structured regulatory educational opportunities are necessary to enable stakeholders to keep pace with rapid advancements in technology, healthcare systems and the biomedical landscape. It is particularly important to address regulatory capacity needs to facilitate timely access to health products and to support the flourishing biomedical scene in Singapore and the Asia-Pacific.

CoRE aims to address these needs through the Graduate Certificate Programme in Health Products Regulation that is focused on the needs of the Asia-Pacific region. CoRE offers this programme within a neutral academic setting to facilitate learning, networking and collaboration, encouraging the growth of a community committed to regulatory excellence.

# STRATEGIC WAY TO DEVELOP YOUR CAREER

Through this Graduate Certificate Programme we aim to equip working professionals like yourself with updated scientific and regulatory knowledge and critical skills through application-based learning. The skillsets gained through this programme will help you assume diverse roles requiring regulatory science expertise within the public and private sectors.

An enhanced understanding of regulatory issues will better prepare you to facilitate innovation and health products development as well as provide a deeper appreciation of the basis of regulatory requirements, contributing to timely research and marketing authorisation decisions to support the healthcare systems.



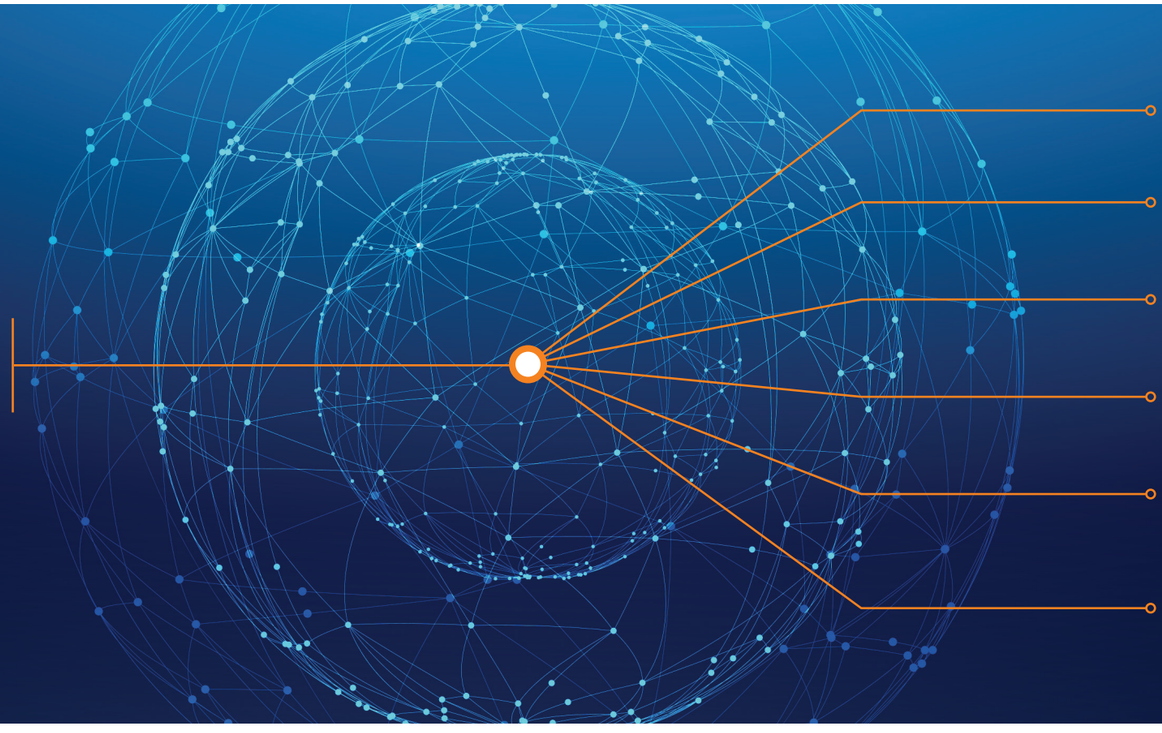
# DEVELOPING ADEPT PROFESSIONALS


The programme is targeted at professionals from the public and private sectors who wish to enhance their regulatory competencies. It is suitable for professionals from the healthcare and regulatory sector, including biomedical researchers, product developers and policy makers who are interested in gaining insights on the impact and contributions of regulatory science to the wider healthcare environment.

# BROADEN YOUR WORLDVIEW

Guided by the Duke-NUS and CoRE education philosophy, the programme aims not only to impart knowledge and understanding, but also to facilitate significant networking amongst regulators, industry and other stakeholders. You will have the opportunity to meet international and regional experts with different backgrounds and these interactions will expand your worldview by providing global and regional insights and enhancing your understanding of different perspectives.

The curriculum will promote interdisciplinary inquiry and cover different skill sets and technical areas. Graduates will be more adept at effectively working and communicating within a team with an international outlook, given the diverse and international backgrounds of course participants.



**Insights** from Asia-Pacific Leads

**Cutting-Edge** Topics

**Valuable Networking** Opportunities

**Robust** Foundation

**Product Life Cycle** Approach

**Powered by** Global Thought Leaders

**The Graduate Certificate curriculum is designed to expand your core skills and expose you to new competencies in pharmaceutical and medical device regulation.**

**We are committed to providing a holistic learning experience through a robust curriculum which is structured to:**

## IMPROVE

…technical competencies and understanding of the guidelines that influence key regulatory processes

## FACILITATE

…interaction and collaboration by providing opportunities for students to interact with regulatory stakeholders from different professional backgrounds and countries

## NURTURE

…critical thinking skills of students to enable quality in regulatory decision-making across the product life cycle

## DR MARGARET HAMBURG

**Chair**
*Centre of Regulatory Excellence*

**Former Foreign Secretary**
*U.S. National Academy of Medicine*

**21st Commissioner**
*U.S. Food and Drug Administration*

> To enable participants to make the greatest impact through their individual roles, CoRE's curriculum is enriched with invaluable guidance and real-world insights from global and regional thought leaders in regulatory affairs.




# PATH TO SUCCESS

As an advocate for continuous learning, we are excited to partner with you on your career development journey. To ensure that you are exposed to the full scope of knowledge, skills, and competencies for your career development, the course content is structured to broaden your perspectives and provide a holistic view of the regulatory ecosystem. Given the rise in significance of health products regulations in the healthcare industry, it aims to deepen your understanding of the science underlying health product regulation and regulatory frameworks, which includes pharmaceuticals, advanced therapies, biologics, as well as medical technology that cuts across devices, diagnostics and software applications. It will also provide you with a practical and realistic view of what regulatory science involves through interactions with experts and practitioners from industry and national regulatory authorities.

Through the course modules, you will strengthen your foundations in regulatory science and gain an enhanced understanding of the basis for managing regulatory submissions and processes, and making quality regulatory decisions. Review and discussion of cutting-edge scientific and regulatory topics will empower you to facilitate the development of regulatory strategy and policy, and strengthen your regulatory leadership capabilities.

To meet the objectives of the programme and achieve the learning outcomes, the Duke-NUS pedagogy framework has been incorporated. This pedagogy is an integration of lectures and Team-Based Learning, creating a novel approach that fosters the development of lifelong learners, problem solvers and critical thinkers. Emphasising the Duke-NUS Educational Philosophy, this framework promotes continuing education while offering the flexibility and accessibility required by working regulatory professionals.

# STAY AHEAD

**The curriculum is tailored to be relevant, contemporary, and accessible through an emphasis on three themes that run across all the modules to:**

### ENHANCE

…proficiency in regulatory submissions and reviews across product life cycle, and support good regulatory management and quality in decision-making.

### SUPPORT

…innovation of product development and regulatory processes for timely access to new health products.

### PROMOTE

…convergence, collaboration and partnership across stakeholders for an efficient and effective regulatory environment.

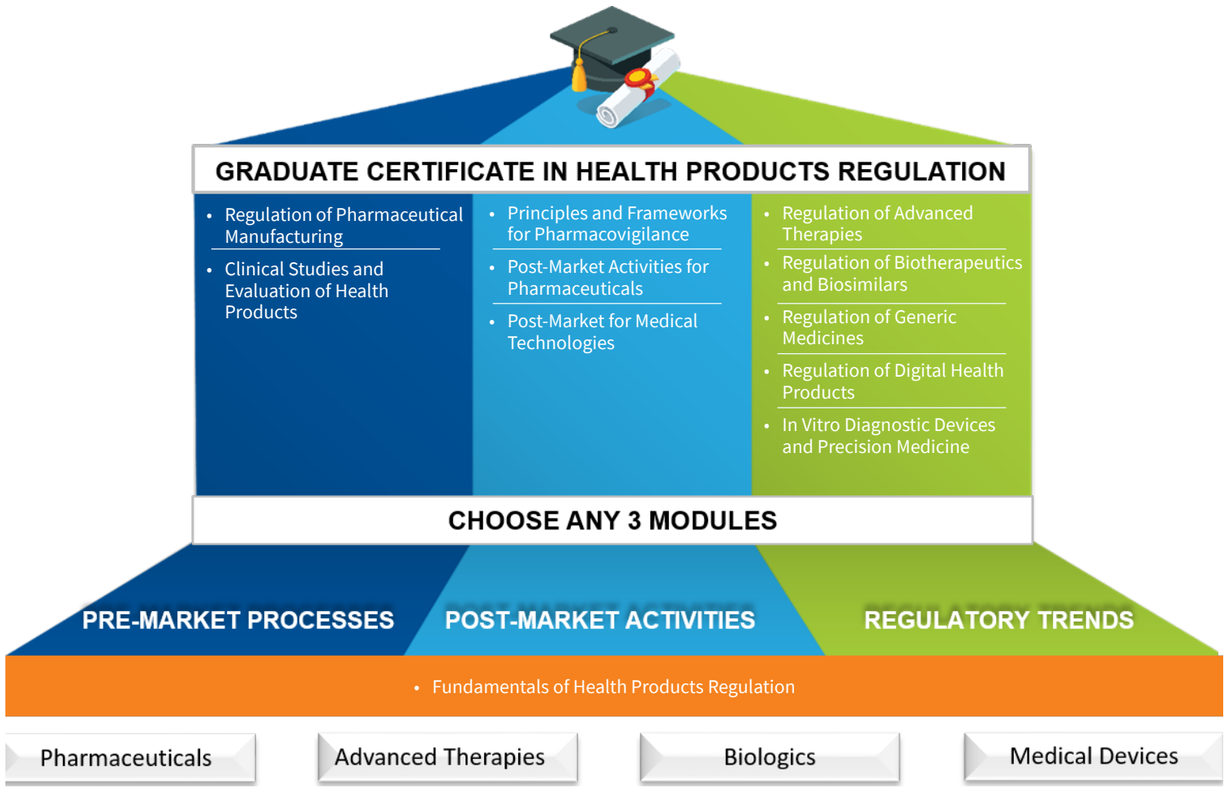
Building on these common themes, the programme will provide you with the relevant skillsets and mindset to deepen your understanding and lead you through the modules. With an emphasis on 'how to', you will leave with actionable plans on how to:

- Use knowledge of various regulatory systems and principles of product life cycle management to support quality decision-making in your organisation
- Leverage current regulatory platforms and resources to adopt and implement good regulatory practices
- Relate technical datasets to regulatory requirements and support good practices
- Advocate the role and contributions of regulatory professionals to the wider healthcare system

# CURRICULUM

**The programme structure below outlines the 4 subject areas you will focus on. To graduate, you will be required to complete a total of 4 modules out of the 11 modules offered.**

Students have the flexibility to choose from any subject area of interest.






The flexible curriculum is designed to accommodate your busy work schedule, allowing you to plan your course of career development to meet your needs and interests. The programme is taught with a blended learning approach, engaging students through an online learning management system that delivers content, enables assessments, and allows for interaction. Each module will also feature a 5-day face-to-face workshop, specifically designed to accommodate the demanding work schedule of your full-time job.

# ASSESSMENT MODE

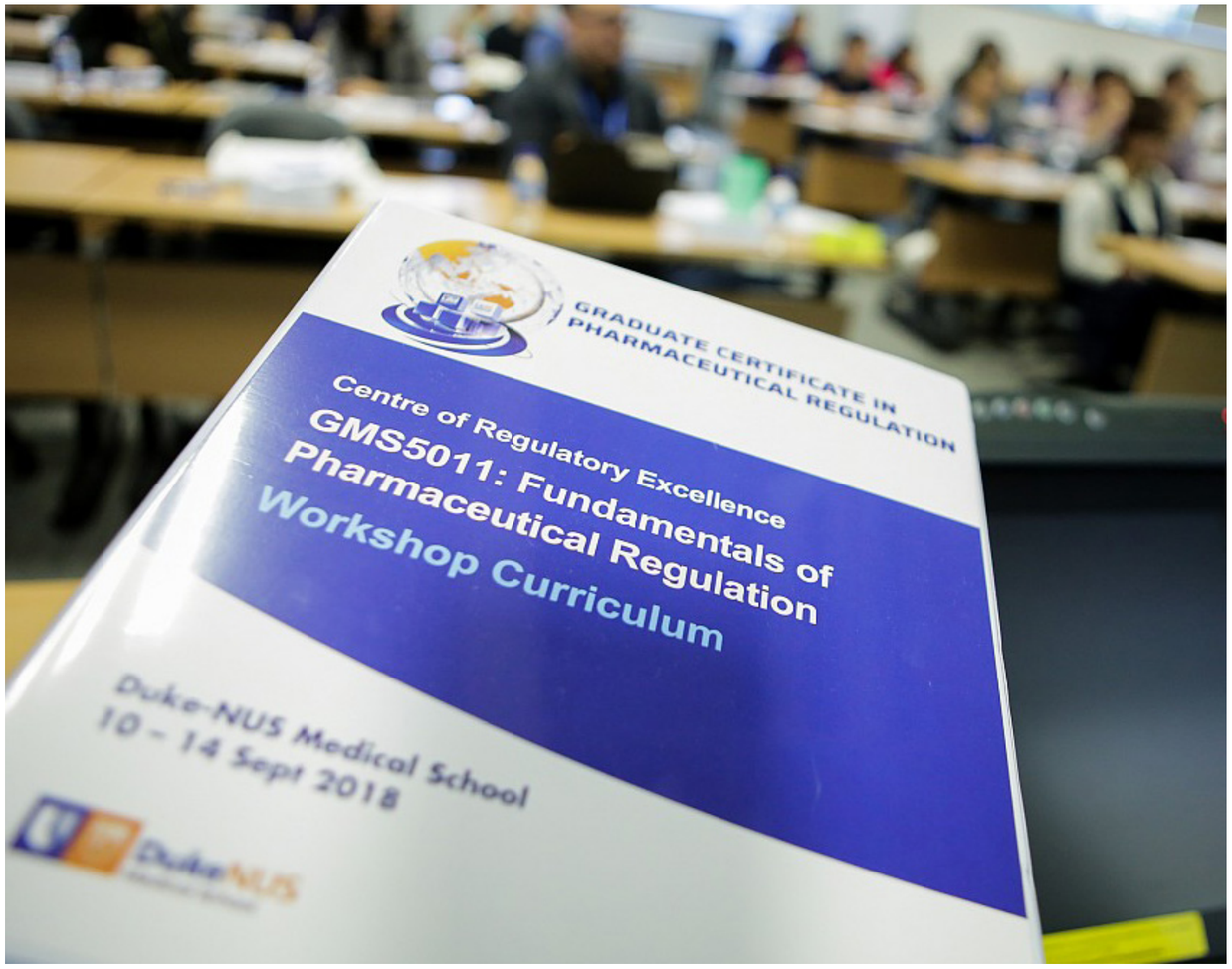
Activities during the course will be graded to fulfil academic requirements. Each course module will include formal and informal assessments guided by the Duke-NUS teaching pedagogy. You will be graded on individual and group tests as well as group presentations during class discussions.

**Candidature**
The module credits which are valid for a period of five years, will provide the necessary flexibility for planning your schedule to complete this course, based on your work commitment.

**Continuation and Graduation Requirements**
If unable to complete or pass a module, you are allowed to re-take the module once. You may also choose to take a different module if applicable within the Graduate Certificate course.


Guest of Honour, Former Minister for Health Mr Gan Kim Yong (center) congratulates the inaugural graduating cohort of the Graduate Certificate Programme in Pharmaceutical Regulation, as they receive their certificates from Dean of Duke-NUS Medical School, Professor Thomas Coffman (center left) and Executive Director of CoRE, Professor John Lim (center right) during CoRE's 5th Anniversary Dinner.

# COURSE DETAILS




## FUNDAMENTALS

### FUNDAMENTALS OF HEALTH PRODUCTS REGULATION

GMS5003 • 4 MODULAR CREDITS

Regulation of health products is controlled by standards, guidelines and legal frameworks. The interactions among these and the stakeholders – industry, regulatory authorities, healthcare professionals and patients – are required for effective governance for timely access and safe, quality and efficacious medicines and medical devices for patients.

This fundamental module provides the understanding of the contribution of the various stakeholders, functions and guidelines that shape the regulatory environment and impact the healthcare management scene. The concept of product life cycle will be also be explored among other contemporary regulatory approaches.

**Learning Outcomes:**

- Explain the foundational basis of regulatory management and decision-making for health products, and the essential principles in managing pharmaceuticals and medical devices across their life cycles.
- Understand the regulatory requirements for the different product development phases, and learn about the real-life settings in regulatory decision-making through hands-on practical sessions.
- Learn about the major regulatory organisations steering the innovation of regulatory processes and focus.




# PRE-MARKET PROCESSES

### REGULATION OF PHARMACEUTICAL MANUFACTURING

GMS5004 • 4 MODULAR CREDITS

Ensuring quality of healthcare products is one of the key pillars in regulatory responsibilities, for industry, manufacturers and regulators. The contribution of Chemistry, Manufacturing and Controls (CMC) to a successful control of quality in pharmaceutical products spans from product development and manufacture, process validation to post-market variation changes, as well as an optimal quality management system.

This module provides the foundation in understanding the regulatory science behind the development, manufacturing and control of pharmaceuticals, including the global guidances that shapes the regulatory processes. Besides promoting good submissions and evaluation practices, the module aims to enhance regulatory convergence and cooperation on CMC regulation.

**Learning Outcomes:**

- Explain the importance of manufacturing and quality control for pharmaceuticals.
- Learn about the strict controls and regulatory requirements, particularly on product stability and specifications, in addition to the practical skills obtained through mock reviews of dossier materials.
- Understand the utility of a system approach to quality control, and the new regulatory trends upcoming in this domain.

### CLINICAL STUDIES AND EVALUATION OF HEALTH PRODUCTS

GMS5108 • 4 MODULAR CREDITS

The effective regulation of pharmaceuticals and medical devices for safety and efficacy depends on the availability, understanding and appropriate implementation of relevant guidelines and the processes designed to ensure quality in decision-making. The requirements are frequently different from traditional clinical trials and specific to regulatory affairs.

This module provides the understanding for the unique requirements of clinical trials and clinical data meant to support regulatory evaluation and approvals.

**Learning Outcomes:**

- Explain an overview of the design and phases of human clinical trials, as well as the regulatory requirements to support market approvals of pharmaceuticals, medical devices and technologies.
- Understand the standards and processes for submitting an application and evaluating the benefit-risk profile of a health product using a structured framework.
- Appreciate the contribution of these regulatory controls on the product life cycle and the role in ensuring quality, safety and efficacy of the products.


# REGULATORY TRENDS

## REGULATION OF ADVANCED THERAPIES

GMS5005 • 4 MODULAR CREDITS

Advanced therapies, covering the scope of cellular, tissue and gene treatment modalities, is a rapidly advancing field that offers exciting new therapeutic possibilities and constantly challenges the regulatory environment to expedite access to these innovations.

This module provides a better understanding of the various frameworks and practices regulating advanced therapies, including requirements for product evaluation and dossier submission for an effective product life cycle management. The module will interest students who are keen in global trending regulatory approaches and strengthening the skillsets to accommodate new innovation. There is also a focus on promoting convergences of regulatory approaches for advanced therapies.

**Learning Outcomes:**
- Understand and define advanced therapy products and differentiate them from chemical and biological entities.
- Describe the lifecycle for advanced therapy products and the factors that influence the effective and safe use of these products.
- Explain the regulatory frameworks governing advanced therapy products and appreciate different regulatory requirements set by major national regulatory agencies.

## REGULATION OF BIOTHERAPEUTICS AND BIOSIMILARS

GMS5006 • 4 MODULAR CREDITS

The advent of biotherapeutics and biosimilars highlighted the need for regulatory affairs to accommodate the rapidly evolving medical sciences, necessitating timely revisions in policies, processes and the technical knowledge in managing these new innovations and facilitating access to meet medical needs.

This module provides the background to the rise of these biologicals in healthcare, and the defining differences from traditional pharmaceuticals and generics. There is a focus on post-market activities which serve as the main guards for ensuring the safe use of these products.

**Learning Outcomes:**
- Understand the good practices and standards in managing biotherapeutics and biosimilars.
- Describe the regulatory requirements at various development stages of the biologics, as well as articulate the differences in managing original biotherapeutics and the generic biologics.
- Gain basic skills in the assessment of dossier materials relating to the clinical data, benefit-risk assessment and post-market monitoring of these innovations.



## REGULATION OF GENERIC MEDICINES

GMS5007 • 4 MODULAR CREDITS

Generic medicines are becoming increasingly important as a means of providing access to affordable healthcare by helping to suppress rising healthcare costs. This module aims to equip students with skills to assess the therapeutic equivalence of a generic medicinal product relative to a comparator, specifically with respect to bioavailability (BA) and bioequivalence (BE).

In this module, students will learn how to design and conduct appropriate bioavailability and bioequivalence studies in accordance with established international guidance documents, and to analyse the data from such studies.

**Learning Outcomes:**
- Understand the important role of generic medicines in public health, and also the different regulatory requirements in managing these health products.
- Gain basic skills for reviewing market approvals of generics, which are largely based on studies of bioavailability and bioequivalence. The technical aspects of these critical review processes will be taught in this module, and also
- Explore trends in the assessment of other dosage forms beyond solid oral medicines.

## REGULATION OF DIGITAL HEALTH PRODUCTS

GMS5106 • 4 MODULAR CREDITS

In today's digital world, technologies and software play an increasingly important role in healthcare management - diagnosis, treatment, patient monitoring and Real World Data collection. While software-based medical devices products are currently controlled via medical device regulation, they differ significantly from traditional medical devices requiring a more streamlined and efficient regulatory oversight. Software standards and guidelines published by standards development organisations (eg., ISO, IEC) and regulatory agencies/forums are important tools for effective governance for safe, quality and efficacious health products and timely access for patients.

This module provides the foundation in understanding established standards, guidelines and regulatory principles on conformity assessment of medical device softwares.

**Learning Outcomes:**
- List and describe the relevant standards and guidances required in Digital Health products verification and validation
- Describe regulatory activities through medical device software development, testing and documentation
- Describe key regulatory considerations in the product life cycle including change management and post-market activities

## IN VITRO DIAGNOSTIC DEVICES AND PRECISION MEDICINE

GMS5107 • 4 MODULAR CREDITS

In Vitro Diagnostic Medical Devices (IVDs) are a key component of healthcare, and pivotal to advancing technology solutions for patient centric care, such as precision medicine and companion diagnostics. This module covers an overview of the technical documentation and available international standards for IVDs, providing a fundamental understanding of the principles behind effective regulation of IVDs.

This module provides the foundation in IVDs regulatory principles, use in precision medicine and companion diagnostics. It also provides an introduction to standards and guidelines playing a pivotal role in meeting requirements to ensure product safety, quality and performance.

**Learning Outcomes:**
- Describe key regulatory requirements of IVDs through the total product life cycle
- Explain the conformity assessment methods by major authorities
- Identify the relevant standards and its role in product design verification and validation for regulatory submissions
- Explain the regulation of IVDs in the use of precision medicine

# POST-MARKET PROCESSES

## POST-MARKET FOR MEDICAL TECHNOLOGIES

GMS5114 • 4 MODULAR CREDITS

Post market vigilance is a key regulatory function in the total product life cycle. Continual monitoring and reporting of medical device adverse events is critical in ensuring the marketed devices are free from unacceptable risk.

This module introduces the key activities and roles essential for effective post-market vigilance, including adverse events, field safety correcting action and change management.

**Learning Outcomes:**
- Describe the post-market regulatory requirements of medical devices
- Explain the activities involved in Adverse events and Field safety corrective action
- Describe the benefit-risk assessment of manufacturer's Corrective Action Preventive Action (CAPA).
- Explain key regulatory considerations in product changes from safety issues
- List harmonised guidance documents related to post-market vigilance

## PRINCIPLES AND FRAMEWORKS FOR PHARMACOVIGILANCE

GMS5115 • 4 MODULAR CREDITS

Pharmacovigilance is one of the key regulatory function that monitors the safe effective use of pharmaceuticals in the real-world healthcare setting. It has progressively included risk management planning, which encompasses appropriate drug use, signal detection and other risk minimisation activities, for better product life cycle management.

Within this module, the principles, frameworks and processes for pharmacovigilance will be introduced. Various platforms and partnerships among regulatory stakeholders for ensuring adequate and quality pharmacovigilance data will be also covered.

**Learning Outcomes:**
- Understand the significant contributions of pharmacovigilance in completing the management of a pharmaceutical product's life-cycle, and the various platforms across the world that facilitate the collation of important safety alerts for timely interventions.
- Explain the basics of causality assessment, and how risk management plans can be optimised to suit local populations.
- Combine an understanding of epidemiology to the regulatory requirements in ensuring the safe and appropriate use of medicines.

## POST-MARKET ACTIVITIES FOR PHARMACEUTICALS

GMS5116 • 4 MODULAR CREDITS

The assurance of safe and quality medicines in the market depends on a range of vital activities after the approval of a medicine by the authorities. This includes the continual monitoring offered by inspections and audits of facilities and testing of product quality. In this globalised environment, there is also an increasing need to leverage on networks to effectively detect lapses in product quality and services in a timely manner.

This module introduces the key activities and roles essential for effective post-market control, including management of failures of conformance and compliance. Topics covered will include collaborations and networks for optimising post-market communications, and handling of substandard and falsified pharmaceuticals.

**Learning Outcomes:**
- Understand the damaging implications of poor quality medicines to public health, as well as the evolving challenges in minimising the entry of these substandard medicines and falsified products.
- Explain the regulatory controls along the entire distribution and supply chain of medicines, and the good practices and standards expected.
- Gain practical insights on the assessment of quality defects and detection of falsified medicines.

## PROFESSOR GUIDO RASI

**Former Executive Director**
*European Medicines Agency*

**Advisory Board Member**
*Centre of Regulatory Excellence*

"The Graduate Certificate participants emerge from the Programme as learned, well-equipped, future-ready individuals, armed with the latest skills and knowledge to meet the demands of a rapidly changing regulatory landscape."


# HEAR FROM OUR STUDENTS

> This course presented some real-life problems with the “current & practical” solutions and thought processes to resolve those challenges, and not just simply some textbook answers. What I appreciate most was the experts sharing their train of thought to identify, dissect, and analyse all the post-market surveillance challenges.

> Although I completed the Programme in 2018-2019, I still refer back to the clear and concise presentation files that was prepared for our online course work - when necessary in the line of my work. The more simplified and smooth the lecture comes through, the greater must be the work behind the scenes. Kudos to the team!

> The content was good, well organised, with good speakers. The practicum helped us to understand the topics better.

# READY TO LEAD FROM ASIA- PACIFIC

The Certificate Programme meets the need for a dedicated regulatory training programme in Asia-Pacific, as currently available training opportunities are mostly catered to learners in the U.S. and Europe. With a curriculum designed to meet specific regional needs, as well as being based in Singapore, students will be able to gain relevant knowledge to serve the needs of their respective countries while appreciating the increased accessibility to training opportunities and flexibility offered by the curriculum model. We envision new generations of skilled and confident professionals equipped to make science-based and quality regulatory decisions for a positive impact on healthcare.

# INTERNATIONALLY RECOGNISED EXPERTS

CoRE's academic setting, prominent reputation and strong international networks enable us to engage key opinion leaders as our external experts, faculty and speakers. They come from national regulatory authorities, noted companies, government agencies and industry associations.

These experts are recognised for their extensive real-world experience and contributions to regulatory and healthcare excellence. As a student, you will have the opportunity to engage with them in workshops, seminars, symposiums and conferences.

**DR MURRAY LUMPKIN**
**Deputy Director**
*Integrated Development Lead & Global Regulatory Systems Initiatives*
*Bill & Melinda Gates Foundation*
**Visiting Expert,** *CoRE*

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**Former Head**
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**Senior Lecturer**
*University of Otago*
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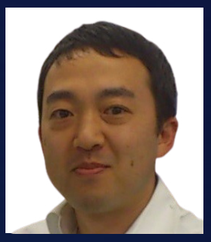

**DR YOSHIAKI MARUYAMA**
**Review Director**
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*Japan*

To read more about our experts, please visit our website.

*Information is accurate as of 26 January 2022*


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