

FUNDAMENTALS OF VACCINE REGULATION

ONLINE COURSE

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QUALITY • COMPLIANCE • METHODOLOGY

“

Online learning provides individuals the ability to learn with flexibility and convenience while gaining world-class expertise.

Supported by the Duke-NUS learning infrastructure, CoRE's online learning courses have been designed for optimal learning via a digital medium and brings insights on key topics to learners at their convenience.

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Professor John Lim

Executive Director
Centre of Regulatory Excellence (CoRE)



Duration

Approximately 8 hours



Start Date

Immediately upon enrolment



Format

Fully online at your own pace



Mode of Study

Voice Annotated Videos and
Multiple Choice Questions



Certification

Duke-NUS Certificate



Accreditation

Accredited by the Singapore
Pharmacy Council for 8 CPE Points



About Vaccine



Course Objectives



Course Highlights



Register Now

YOU DON'T HAVE TO BE A DUKE-NUS STUDENT TO HAVE ACCESS TO A DUKE-NUS EDUCATION

FOUR REASONS TO CHOOSE A DUKE-NUS CORE ONLINE COURSE

1

Contemporary Topics



Our online courses delve into contemporary topics, offering insights from leading industry and regulatory experts.

You will explore key areas of regulatory decision-making, and global health issues, gaining insights that are not only relevant, but that empower you to drive meaningful solutions.

2

Immediate Impact



Our online courses feature comprehensive modules and assessments that effectively close knowledge gaps.

The courses will equip you with practical skills that can be applied immediately in professional settings.

3

Flexible Learning



Whether you are working full-time or navigating a busy schedule, you can learn anytime, anywhere.

Access course content at your convenience, pause and resume as needed, all while experiencing the quality of a Duke-NUS education.

4

Get Certified



Upon course completion, you will receive a verified digital certificate from Duke-NUS Medical School.

Showcase your achievement to employers, colleagues, or institutions as a testament to your commitment to continuous learning.



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ABOUT FUNDAMENTALS OF VACCINE REGULATION

The COVID-19 pandemic has underscored the critical role of vaccines, driving unprecedented investments in research, manufacturing, and workforce expansion across the life sciences sector. With public health preparedness now a global priority, there is a growing need for skilled professionals equipped with strong regulatory expertise to navigate the complexities of vaccine development and ensure their safe, effective, and equitable use.

To address this growing need, CoRE presents a self-paced online course that delves into the principles and processes of vaccine regulation. Designed in collaboration with industry and regulatory experts, this course empowers participants to understand vaccine development from inception to market approval. It aims to prepare professionals to make meaningful contributions in pandemic preparedness, vaccine accessibility, and global health initiatives.

WHAT WILL THIS COURSE DO FOR YOU?

This course will:

- Highlight key differences between vaccines and conventional therapeutics in lifecycle management processes
- Summarise the efficacy and safety studies in the nonclinical and clinical development of vaccines
- Explain the fundamental principles of vaccine manufacturing and critical attributes for quality evaluation
- List the regulatory considerations for performing the clinical evaluation for marketing authorisation of vaccines
- Identify stakeholder roles and strategies for successful and effective vaccine pharmacovigilance systems
- Discuss pandemic preparedness plans and ensuring equitable vaccine access globally in public health emergencies

TARGET AUDIENCE

This course is designed to suit a wide audience within the healthcare industry including healthcare and regulatory professionals, physicians, pharmaceutical executives and researchers, who are interested in gaining insights on the regulatory management of vaccines.

TYPICAL ROLES



Healthcare Professionals



Regulatory Professionals



Physician



Pharmaceutical Executives



Researchers



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MODULE 1 INTRODUCTION TO VACCINE SCIENCE
This module explores the significance of immunisation, the components that trigger immune responses, the characteristics and influencing factors of vaccine protection, various technology platforms, and future challenges in vaccine development.

MODULE 2 OVERVIEW OF VACCINE DEVELOPMENT
The comprehensive stages involved in vaccine development process are explained, which include lifecycle stages, non-clinical and clinical evaluations, human challenge trials, and ongoing safety monitoring to ensure vaccine effectiveness and reliability.

MODULE 3 REGULATION OF VACCINES
Detailing the global regulatory landscape for vaccines, this module delves into lifecycle regulation, detailing essential regulatory features, and World Health Organisation’s (WHO) mechanisms such as prequalification (PQ) and emergency use listing (EUL) that support global access and distribution.

MODULE 4 NON-CLINICAL EVALUATION OF VACCINES
This module covers nonclinical evaluation of vaccines, including foundational studies, pharmacological and toxicological assessments, and their inputs to the design of first-in-human trials.

MODULE 5 CLINICAL EVALUATION OF VACCINES
Focusing on the clinical testing phase, this module addresses how vaccines are assessed for immune response, effectiveness, and safety, with an emphasis on trial designs and data collected across different phases.

MODULE 6 PHARMACOVIGILANCE FOR VACCINES
This module focuses on vaccine pharmacovigilance, including post-licensure monitoring, surveillance systems, and vaccine adverse event reporting based on international regulatory guidelines, standards, and best practices.

MODULE 7 MANUFACTURING, CHANGES & LOT-RELEASE OF VACCINES
Insights are provided into the production and purification processes of vaccines, along with international standards for packaging, shipping, lot-release protocols, and lifecycle oversight of manufacturing changes.

MODULE 8 QUALITY EVALUATION OF VACCINES
Outlining the standards and guidelines used to maintain vaccine quality, this module references WHO, International Council for Harmonisation (ICH) guidelines, and US Pharmacopeia (USP) standards, and addresses how manufacturing changes are evaluated in the post-approval phase.

MODULE 9 PANDEMIC PREPAREDNESS AND ACCESS TO VACCINES
Exploring strategies for responding to pandemics, this module emphasises the roles of key organizations in vaccine development & production during health emergencies, regulatory approaches for expedited approvals, and frameworks for ensuring equitable access to vaccines.

6 SIMPLE STEPS TO SELF-DIRECTED LEARNING

1

Login

2

Select a Module

3

Start 1st Module

4

Learn, pause, repeat as needed

5

Answer Multiple Choice Questions

6

Move to next Module



About Vaccine



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Course Highlights



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DUKE-NUS CERTIFICATE

Upon successful completion of the course, participants will be awarded a verifiable digital certificate by Duke-NUS Medical School.



This certificate is awarded to

Jane Smith

for successfully completing the

Fundamentals of Vaccine Regulation

on
[DDMMYYYY]

Professor Silke Vogel

Senior Associate Dean, Graduate Studies
Deputy Director, Centre of Regulatory Excellence
Duke-NUS Medical School

Professor John Lim

Executive Director
Centre of Regulatory Excellence
Duke-NUS Medical School

Transforming Medicine, Improving Lives



About Vaccine



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ABOUT CoRE

The Centre of Regulatory Excellence (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.

ABOUT DUKE-NUS

Duke-NUS is Singapore's flagship graduate entry medical school, established in 2005 with a strategic, government-led partnership between two world-class institutions: Duke University School of Medicine and the National University of Singapore (NUS).

[Read more](#)

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CPE points are available for this online course for registered Singaporean pharmacists.

Upon completion of this course you may email SPC@spb.gov.sg with your certificates of completion to claim 8 CPE points.

Refund Policy

There will be no refunds for online courses.
Kindly e-mail CoRE_online@duke-nus.edu.sg for more information.

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