



HKUSPACE

香港大學專業進修學院
HKU School of Professional and Continuing Education

Certificate in Drug Safety and Pharmacovigilance 藥物安全與藥物警戒學證書 Programme Code: HS143A

Application Code: 1470-HS143A

INTRODUCTION

The pharmaceutical industry suffered from the oversight of drug safety over the past few years. Although some well-prescribed drugs had been marketed for several years, they were withdrawn from the market due to a variety of serious, unexpected and/or adverse drug reactions found in patients.

In 2009, the Government set up the Review Committee on Regulation of Pharmaceutical Products to review the existing drug regulatory regime and to find out long-term measures to deal with the drug safety crisis, after a series of drug safety incidents found in Hong Kong¹. The Review Committee then made a total of 75 recommendations² to strengthen the pharmacovigilance and drug safety mechanisms in Hong Kong by using existing resources and soliciting new resources from the Government. One recommendation is to enhance the current GMP licensing standards in pharmaceutical production to more stringent Pharmaceutical Inspection Co-operation Scheme (PIC/S) standards. Besides, the Pharmacovigilance and Risk Management Division is also established under the auspices of the Drug office of the Department of Health.

In view of the Review Committee's recommendations and the raising of ADR reporting awareness, there is an urgent need to equip staff in the pharmaceutical industry with up-to-date knowledge on drug safety and pharmacovigilance in order to cope with the most stringent requirements and regulations which set by both local and international regulatory authorities.

COURSE AIMS AND OBJECTIVES

The programme is intended to be a beginner to intermediate-level programme in the field of drug safety and pharmacovigilance for learners who are working in but not limited to the following sectors: pharmaceutical production, import/export of pharmaceuticals, retailing and wholesaling of pharmaceuticals, procurement and supply of pharmaceutical products, regulatory affairs, risk communication and education.

It is the first ever award-bearing pharmacovigilance programme to be offered by tertiary institution in Hong Kong.

¹Chan T. Y. K (2014) Pharmacovigilance in Hong Kong. In: *Mann's Pharmacovigilance, 3rd ed. John Wiley & Sons Ltd.*

²*Review Committee on Regulation of Pharmaceutical Products in Hong Kong. (2009). Report of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong, Food and Health Bureau, Hong Kong.*

COURSE CONTENTS

Module 1: Principles of Drug Safety and Pharmacovigilance (50 Hours)

- Introduction to Pharmacovigilance
- Introduction to Adverse Drug Reactions
- Classification of Drugs and Diseases
- Current Pharmacovigilance Scenarios in HK and in the World
- Pharmacovigilance Terminologies and Coding
- Pharmacovigilance Programme in Different Settings
- Adverse Drug Reaction Reporting Systems
- Risk Assessment and Risk Management
- Seriousness Assessment Criteria
- Drug Informatics
- Pharmacovigilance Tools
- Pharmacoepidemiology and Pharmacovigilance
- Pharmacovigilance Communications
- Pharmacogenomics and the Genetic Basis of ADRs

Module 2: Pharmacovigilance Regulatory Affairs (50 hours)

- Safety Monitoring in Different Phases of Drugs' Life Cycle
- Drug Safety in Vulnerable Groups: Children, Pregnant Women and Elderly People
- ICH Guidelines
- PIC/S and Pharmacovigilance
- Pharmacovigilance Organizations in Other Countries and Their Regulations
- Case Reporting Skills and Requirements
- Pharmacovigilance Quality Assurance, Inspection and Audit
- Handling of Legal Cases
- Pharmacovigilance and the Public Relations
- Case Studies

Lecturers are registered pharmacists in HK and/or holders of doctoral degrees with many years of experience in the pharmaceutical industry.

MEDIUM OF INSTRUCTION

The medium of instruction is English and supplemented with Cantonese where necessary.

ENTRY REQUIREMENTS

Applicants shall have attained:

- 1) an Ordinary Certificate in a related discipline; OR
- 2) HKDSE Level 2 or above in five subjects including English Language and one of the following science subjects: Biology, Chemistry, Physics, Combined Science, or Integrated Science; OR
- 3) HKCEE Level 2 / Grade E or above in English Language and FOUR passes in other subjects including one of the following science subjects: Biology, Chemistry, Physics, or Science and Technology; OR
- 4) equivalent qualifications.

Applicants who hold other qualifications but are aged 21 or above and have relevant work experience will be considered on an individual basis.

AWARD OF CERTIFICATE

The Certificate in Drug Safety and Pharmacovigilance will be awarded to students who have:

1. passed the written examinations and coursework in both modules,
2. attended at least 70% of the meetings in both subjects.

FEES

Application Fee: **HK\$150** (non-refundable)
Course Fee: **HK\$12,000**

DATE OF COMMENCEMENT

Late-February 2017

TIME AND VENUE

Friday, 7:00 – 10:00 p.m., from late-February to mid-November 2017, HKUSPACE Learning Centre

APPLICATION

Each application must be accompanied by:

- (i) Completed application form;
- (ii) An application fee;
- (iii) Certified photo copies of academic certificates and transcripts

These should reach Pharmaceutical Studies, HKU SPACE, 13/F, Fortress Tower, 250 King's Road, North Point, Hong Kong ***not later than Friday 13 January 2017.***

(Ref: Certificate in Drug Safety and Pharmacovigilance)

PAYMENT METHODS (in person or by post)

1. **Cash or EPS** - Course fees can be paid by cash or EPS at any HKU SPACE enrolment counters.
2. **Cheque or Bank Draft** - Course fees can also be paid by crossed cheque or bank draft made payable to "HKU SPACE". Please specify the programme title(s) for application, student's name, student number.
3. **VISA/MasterCard** - Course fees can also be paid by VISA or MasterCard, including 'HKU SPACE MasterCard', at any HKU SPACE enrolment centres. Cardholders of HKU SPACE MasterCard can enjoy a 10-month interest-free instalment period for courses with a tuition fee worth a minimum of HK\$2,000. The cardholder has to be the course applicant himself/herself. For enquiries, please contact our staff at any of the HKU SPACE enrolment centres.

DO NOT send cash. HKU SPACE will not be responsible for any loss of payment sent by mail.

Enrolment Counters

HKU Campus Tel.: 2975 5680 Fax: 2546 3538
3/F, T.T. Tsui Building, The University of Hong Kong, Pokfulam Road, Hong Kong.
(Exit A2, HKU MTR Station)
Opening Hours: Monday to Friday 8:30 am - 6:00 pm Saturday Closed

Admiralty Learning Centre Tel.: 3761 1111 Fax: 2559 4666
3/F, Admiralty Centre, 18 Harcourt Road, Hong Kong.
(access via the shopping arcade escalators through Exit A, Admiralty MTR Station)
Opening Hours: Monday to Friday 8:30 am - 7:30 pm Saturday 8:30 am - 5:30 pm

HKU SPACE Po Leung Kuk Stanley Ho Community College (HPSHCC) Campus Tel.: 3923 7171 Fax: 3923 7188
66 Leighton Road, Causeway Bay, Hong Kong
Opening Hours: Monday to Friday 9:00 am - 5:30 pm Saturday Closed

Fortress Tower Learning Centre Tel.: 3762 0888 Fax: 2508 9349
Room 108, 1/F, Fortress Tower, 250 King' s Road, North Point, Hong Kong.
(Exit B, Fortress Hill MTR Station)
Opening Hours: Monday to Friday 8:30 am - 7:30 pm Saturday Closed

Island East Campus Tel.: 3762 0000 Fax: 2214 9493
2/F, 494 King's Road, North Point, Hong Kong. (Exit B3, North Point MTR Station)
Opening Hours: Monday to Friday 8:30 am - 7:30 pm Saturday 8:30 am - 5:30 pm

Kowloon East Campus Tel.: 3762 2222 Fax: 2305 5070
1/F, 28 Wang Hoi Road, Kowloon Bay, Kowloon. (Exit B, Kowloon Bay MTR Station)
Opening Hours: Monday to Friday 8:30 am - 7:30 pm Saturday 8:30 am - 5:30 pm

Kowloon West Campus Tel.: 3762 4000 Fax: 2302 1609
G/F, 38-46, Nassau Street, Mei Foo Sun Chuen, Kowloon (Exit B, Mei Foo MTR Station)
Opening Hours: Monday to Friday 8:30 am - 7:30 pm Saturday 8:30 am - 5:30 pm

FINANCING YOUR STUDIES

You may wish to consider the following options which could help to finance your studies:

Extended Non-Means-Tested Loan Scheme (ENLS)

The ENLS is administered by the Student Finance Office (SFO). You can obtain a loan for the total tuition fees payable to HKU SPACE in the 2016/2017 academic year. Details can be obtained from the SFAA website at <http://www.wfsfaa.gov.hk/sfo/en/index.htm> or call 2150 6223.

HKU SPACE MasterCard

Holders of HKU SPACE Master Card can enjoy a 10-month interest-free instalment for payment of course fees at HK\$2,000 or above. Application form for the HKU SPACE Master Card is available at HKU SPACE enrolment centres, all branches of the Bank of East Asia or visit the HKU SPACE website at <http://www.hku.hk/space/>



Officially Certified Documents

Copies of your original documents (certificates, transcripts) must be certified by the issuing authority concerned, or a notary public. The name, status, and position of the person certifying the copies must be clearly stated.

If you are in Hong Kong, you may call at our Enrolment Centres during office hours bringing with you the application form together with the original of the documents for our verification. **Please *DO NOT* send your original documents by post. HKU SPACE is not responsible for any documents lost in the post.**

