Supporting Organizations (According to Alphabetical Order)

FITMI | Hong Kong MHDIA 香港醫療及保健器材行業協會 Hong Kong Medical and Healthcare Device Industries Association | HKSTP 香港科技園 | PSHK | Singapore Manufacturing Federation 新加坡制造商总会 since 1932 | 香港中文大學 The Chinese University of Hong Kong

Two-Day Certificate Training Course on

Combination Products Design, Validation, Safety and Risk Management

Date: 22-23 September 2016 **Time:** 9am-5pm daily

Venue: Classroom 120, 1/F, Hong Kong Productivity Council
78 Tat Chee Avenue, Kowloon Tong, Hong Kong SAR

Medium of Language: English

NTTS Application In Progress

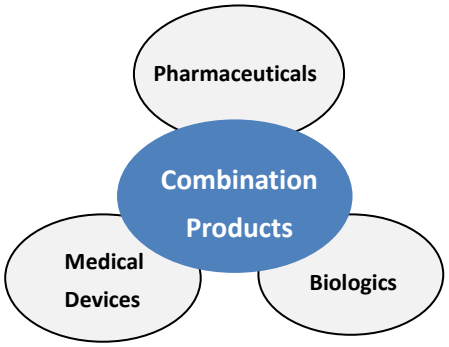
This training course is under the application process of New Technology Training Scheme (NTTS) Funding, once approved, eligible applicants can be reimbursed up to 50% of course fees.

BACKGROUND

Combination products incorporate two or more regulated components with any combinations between a drug, a device and a biological product, providing novel solutions to healthcare problems for better patient outcomes. However this unique combination of technologies faces many challenges in the design and production processes. Special considerations that differ from the existing approaches should be taken to ensure safety of combination products.

COURSE OBJECTIVES

The objective of this 2-day training course is to equip participants with essential knowledge on the **regulatory requirements** & **safety considerations** that should be made during the design and production processes of combination products. Risk management is also a key topic in this course, the methodologies for carrying out a **comprehensive risk analysis** specific to the development of combination products will be discussed.



SPEAKERS' PROFILE

Mr Scott Sardeson

Mr Scott Sardeson has over 20-year experiences on regulatory and quality compliance of combination products, skin and wound care products as well as other medical devices. Mr Sardeson is currently working in 3M Health Care Business Group as the International Regulatory and Quality Compliance Director. Mr Scott provides regulatory and quality guidance to global subsidiaries that import, manufacture, and design medical devices/ pharmaceutical/combination products. He is currently an advisor to Asian Harmonization Working Party (AHWP) Technical Committee, and Convener for ISO TC210 WG1 responsible for ISO 13485 revision.

Mr Jin Jizhong is an expert in the field of regulatory affairs and quality systems audit for medical device/combination products with over 10-year experiences, and is currently responsible for Regulatory Affairs and Quality Compliance as the Leader of Greater China Area at 3M Health Care. Mr Jin is a RABQSA certified ISO13485 lead auditor. He has been providing speech and training on regulatory matters.

Mr Jin Jizhong

HKPC
HKPC Building, 78 Tat Chee Avenue, Kowloon, Hong Kong
香港九龍達之路78號生產力大樓
T 852.2788.5678 F 852.2788.5900
www.hkpc.org

WHO SHOULD ATTEND

Medical device/pharmaceutical/biologics product manufacturers & distributors, regulators in government authorities, quality/compliance/engineers in healthcare facilities, medical technology researchers, engineers and investigators, corporations that intend to expand their business in combination products production and trading, etc.

COURSE FEE

The fee for this 2-day training course is **HK$8,500.- / US$1,100.-** per person, in which the fees for training materials and lunch gathering for technical discussions are included. This training course is under the application process of New Technology Training Scheme (NTTS) Funding, once approved, eligible applicants can be reimbursed up to 50% of course fees.

COURSE OUTLINE

Part A Overview

- Definition of combination product and its constituents: device, drug , biological product
- Methodology in determining the nature of combination products: Primary Mode of Action (PMOA)

Part B Regulatory Requirements

- Risk based classification of combination products
- Global regulatory requirements for pre-market submission and latest trends
- Related guidance/standards

Part C Design & Production Controls

- Consideration in materials selection for combination products
- Chemical reactions of materials within a single combination product / Between raw materials and manufacturing equipment / residuals
- Packaging of combination products
- Appropriate sterilization/cleaning procedures and environments
- Highlighted quality system requirements
- Key elements for inspection
- Potential risk factors
- Methodologies of risk management
- Case study & Group discussion

Part D Validation on Combination Products

- Considerations procedures and methods for carrying validation on combination products
- Considerations in clinical trial for combination products

Part E Post-market Obligations

- Product changes
- Adverse events

Organizer:

HKPC
Hong Kong Productivity Council
香港生產力促進局

The **Hong Kong Productivity Council (HKPC)** is a multidisciplinary organization established by statute in 1967, a non-profit distributing semi-government organization in Hong Kong. HKPC's mission is to promote productivity excellence through the provision of integrated support across the value chain of Hong Kong firms, in order to achieve a more effective utilization of resources, to enhance the value-added content of products and services, and to increase international competitiveness. With more than 200 professional consultants, HKPC and its subsidiaries provide a multitude of services in technology transfer, consultancy, training and other support services in the areas of manufacturing technology, information technology, environmental technology and management systems, to help the industry move up the value chain. For further details on HKPC, please visit **http://www.hkpc.org**

Certification of Participation:

Certificate of Participation issued by Hong Kong Productivity Council will be given to participants who achieved 75% attendance.

Enquiry:

Biomedical, Optical and Precision Engineering Unit, Automotive and Electronics Division, HKPC
Ms Kaman CHAN, Trainee Consultant [Tel: +852 2788 6028 / Fax: +852 2788 5405 / Email: kamanchan@hkpc.org]
Ms Carol LIU, Consultant [Tel: +852 2788 5550 / Fax:+852 2788 5405 / Email: carolliu@hkpc.org]

Enrolment Form
報名表

請以正楷填寫此表格　Please complete this form in BLOCK LETTERS

課程 Programme：

課程編號 Programme Code：	課程名稱 Programme Title：	學費 Programme Fee:
10004182	Two-Day Certificate Training Course on Combination Products Design, Validation, Safety and Risk Management	☐ HK$8,500.- (Eligible applicants can be reimbursed up to 50% of course fees with NTTS Funding) ☐ US$1,100.-

甲部 (Part A) 申請者資料 Applicant Information：

中文姓名 (先生/小姐/太太/女士*)： Chinese Name (Mr./Miss/Mrs./Ms*)：			
英文姓名： Name in English：	姓 last name	名 first name	(必須與香港身份證/護照相同 Must be the same as shown on ID card/Passport)
公司名稱： Company Name：			
職位： Position：			

最高教育程度 Highest Achieved Education Level (請選擇一項 Please select one only):

☐ 小學 Primary School　☐ 中學 Secondary School　☐ 文憑至副學位 Diploma to Associate Degree　☐ 學位 Degree　☐ 研究院或以上 Postgraduate

辦事處電話： Office Telephone：		手提電話： Mobile No.：		住宅電話： Home Telephone：	
電郵地址： E-mail Address：				傳真： Fax：	
通訊地址： Correspondence Address：					

乙部(Part B) 繳費方法 Method of Payment：

請選擇一項 Please select one only

☐ 信用卡 Credit Card

☐ 現金 Cash

☐ 支票號碼 Cheque No.：_____，(公司 Company / 私人 Private*)。

(支票請劃線，抬頭人為「香港生產力促進局」。The cheque has to be crossed and made payable to the "Hong Kong Productivity Council.")

Is the programme fee sponsored by your employer? 課程費用由僱主贊助？　☐ YES 是　☐ NO 否

*Please delete whichever is inappropriate / 請刪去不適用者

聲明 Declaration：

本人聲明在此報名表格及隨附文件所載的資料，依本人所知均屬完整、真實及準確。本人已**細閱**並**接受**報名表內的所有條款及細則。

I declare that all information provided in this enrolment form and the accompanying documents are, to the best of my knowledge, true, accurate and complete. I have **read** and **accepted** all the terms and conditions of this enrolment form.

☐ 本人反對香港生產力促進局使用本人的個人資料，包括但不限於姓名、年齡、性別、電話號碼、傳真號碼、職位、會員身份、繳費資料包括信人卡資料(如適用)、學術及專業資格、通訊地址及電郵地址（"**個人資料**"）於推介該局最新發展、工業支援服務、顧問服務、培訓課程及相關的活動及其他由生產力局的推廣活動的用途。I object to the proposed use of my personal data including, without limitation, name, age, gender, phone number, fax number, job title, member status, payment details including credit card information (where applicable), academic and professional qualification, correspondence address and email address ("**Personal Data**") for the purpose of sending me information relating to HKPC's latest developments, industry support services, consultancy services, training courses and related events, and other marketing activities as may be organized by HKPC..

申請者簽名 Applicant's Signature： _____　**日期 Date：** _____

報名程序：

請於 2016 年 9 月 7 日或之前填妥報名表、連同相關課程需要的文件及費用，親身或以郵遞方式遞交。

郵寄地址：九龍達之路 78 號生產力大樓香港生產力促進局 4 樓汽車及電子部(陳嘉雯小姐收) (請於信封面註明報讀課程名稱及編號。)

條款及細則:

1. 報名表（可用影印本）必須連同學費於開課前一併繳交，否則報名無效。
2. 所收集的個人資料將會作入學申請、登記、學術、行政、研究、統計及市場分析及用於推介本局最新發展、工業支援服務、顧問服務、活動和培訓課程的用途。個人資料會嚴格保密處理。除非獲得閣下的同意，本局不會將個人資料轉移予第三者。本局已制定收集、使用及保留個人資料的政策，於報名處供索閱，閣下亦可向本局個人資料管理主任查詢。
3. 閣下可以信用咭、易辦事或支票繳交學費。學費收據以本局機印方為有效，支票收妥作實。
4. 除非本局於以下期限前收到申請者書面通知退學，否則已繳學費（不論全費或部份）概不退還：
   - 由本地講師教授的課程，**最少於開課前五個工作天**通知
   - 由外地講師教授的課程，**最少於開課前十五個工作天**通知

   閣下申請退還學費需繳交手續費**二百元正**。如申請者以信用卡繳交學費，則需額外支付學費之 **3%作銀行手續費用**。
5. 閣下可提名他人代替其本人出席課程，惟事先須得本局同意。閣下不可轉換其他課程。
6. 生產力局保留在任何情況下及以任何原因拒絕任何入學申請的權利。閣下繳付學費後，仍須符合入學的所有條件，其申請方可獲得接納。
7. 生產力局保留在有需要的情況下更改講師及/或課程內容、授課地點、日期及/或時間的權利。
8. 颱風及黑雨警告：如課堂時間是在早上(09:00-13:00)、下午(14:00-17:00)或晚間(6:30-10:00)，將在下列情況下取消：(一)八號或以上颱風訊號或黑色暴雨警告訊號在早上 6:00、11:00 或下午 4:00 仍然懸掛；或(二)香港天文台在早上 6:00、11:00 或下午 4:00 或之後，宣佈將懸掛八號或以上颱風訊號或黑色暴雨警告訊號。本局將盡早通知閣下補課的日期及時間。
9. 以上 "條款及細則" 內容均以本院課程單張及網頁公佈之最後更新版本為依歸。

ENROLMENT PROCEDURE:

Please complete and send this enrolment form with requisite documents and fee to the Institute in person or by mail on or before 7 Sep 2016.

Mailing Address: Automotive and Electronics Division, 4/F, Hong Kong Productivity Council, HKPC Building, 78 Tat Chee Avenue, Kowloon. (Attend to Ms Kaman CHAN) (Please mark the programme title and programme code on the envelope.)

Terms and Conditions:

1. Course fee must be accompanied with this form (or photocopy) before course commencement, otherwise enrolment will be rejected.
2. Personal Data collected will be used for processing your application for admission, registration, academic, administrative, research and statistical purposes and will also be used for marketing purposes, specifically for the purpose of sending you information relating to HKPC's latest developments, industry support services, consultancy services, events and training courses. Personal Data will be treated in strict confidence. Unless otherwise agreed by you, Personal Data will not be transferred to any third parties. HKPC implements a policy governing the collection, use and retention of Personal Data, which is made available at the enrolment counter. You may also contact Personal Data Controlling Officer of HKPC for further details.
3. You may make payment by credit cards, EPS or cheques. Amount received will be imprinted on the official receipt. Cheques are subject to bank clearance.
4. Enrolment fee (in full or in part) is not refundable except if HKPC is notified in writing of your withdrawal:
   - **at least 5 working days** before the course commencement for training program run by **local speaker**
   - **at least 15 working days** before the course commencement for training program run by **overseas speaker**

   A handling charge of **HK$200** will be levied. For payment made by credit card, an additional **bank charge of 3%** of the enrolment fee will be imposed.
5. You may, subject to the prior approval of HKPC, nominate a person to attend the course on your behalf. Course switching request will not be accepted.
6. HKPC reserves the right to reject any application in any circumstances and for whatever reasons. Payment of fees should only be construed as conditional acceptance of application.
7. HKPC reserves the right to replace the speaker and/or change the contents, venue and/or time as may be necessary.
8. Classes in the morning, afternoon or evening will be cancelled if typhoon signal No. 8 or above OR black rainstorm warning remains hoisted after (or is announced by the Hong Kong Observatory to be hoisted at/after) 6:00 a.m., 11:00 a.m. and 4:00 p.m. respectively. You will be notified of the re-scheduling arrangement as soon as possible.
9. These terms and conditions are subject to revisions as may be set out in the course pamphlets and the latest updates in the Institute's website.