

# Workshop on Medical Device Regulation & Regulatory Harmonization

Ver5F

## International Experts' Sharing on Updates of Medical Device Regulations and Requirements!



The life cycle of medical devices, which includes product development, manufacturing process, quality and risk management, pre-market procedures, post-market surveillance, etc., complies to different regulations and standards in various countries.

This training course offers golden opportunity for various stakeholders related to medical and healthcare device industries to keep abreast of the latest regulatory requirements, as well as to make better strategy and business planning.

**Date: 3 March 2017****Time: 13:30 to 17:30****Registration Fee: HKD500.-****Medium of Speech: English****(Supporting Organization's member can enjoy 10% off of the training fee)****Venue: Theatre 1, HKPC Building, 78 Tat Chee Avenue, Kowloon, Hong Kong**

**Deadline of Application: 24 Feb 2017**  
**First come First Served !!**

## PROGRAMME & SPEAKERS

### ◆ Opening Speech by AHWP Chair

Director General, Medical Device Evaluation Department, MFDS, Republic of Korea

- Dr Hee-Kyo Jeong



### ◆ HKPC One-stop Service in Biomedical Engineering

Principal Consultant, Biomedical, Optical & Precision Engineering, HKPC, HKSAR

- Ir Bryan So



### ◆ Updates on Standards for Software as a Medical Device

Director, Standards & Regulations Global Quality & Regulatory, Philips Healthcare, Netherlands

- Ir Dr Peter Linders



### ◆ Updates on ISO 13485:2016

Convener, Medical Device Working Group for ISO 13485, International Accreditation Forum

- Mr Grant Ramaley



### ◆ Updates by APACMed on Medical Device Regulatory Harmonization

Vice President, Regulatory Affairs, APACMed, Singapore

- Ms Tran Quan



### ◆ Regulatory Updates on Medical Device in EU

Senior Director International Regulatory, Quality & Labeling, Abbott, Germany

- Dr Petra Kaars-Wiele



### ◆ Regulatory Updates on Medical Device in China

Vice Secretary-General, Shenzhen Association of Medical Devices (SAMD), the PRC

- Ms Huang Jin



### ◆ Regulatory Updates on Medical Device in Hong Kong

Senior Electronics Engineer, Medical Device Control Office, Department of Health, HKSAR

- Ir Jennifer Mak



### ◆ Regulatory Updates on Medical Device in Kingdom of Saudi Arabia

Executive Director, Medical Device Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia

- Mr Ali M. Al-Dalaan



### ◆ Regulatory Requirements on Clinical Investigation for Medical Device in Korea

Deputy Director, Cardiovascular Devices Division, MFDS, Republic of Korea

- Mr Seung Hwan Jung



### ◆ Updates on ASEAN Medical Device Directive

Regional Director, Government Affairs/HME, Samsung Electronics, Singapore

- Mr Alfred Kwek



### ◆ Panel Discussion

(Programme is subject to change without prior notice)

#### WHO SHOULD ATTEND:

QA/RA managers & officers, managers, manufacturers related to / interested in medical device industries, engineers for design and development of medical and healthcare devices, personnel for clinical trial planning & conduction, etc.

#### ENQUIRY:

Mr Bill YEUNG Tel: 2788 5869 Email: billyeung@hkpc.org

Mr Kyle LIU Tel: 2788 5682 Email: kyleliu@hkpc.org

Ms Carol LIU Tel: 2788 5550 Email: carolliu@hkpc.org



**Enrollment Form** **報名表**

**Training Course**  
**Workshop on Medical Device Regulation & Regulatory Harmonization**  
**Date: 3 March 2017**  
**Time: 13:30 to 17:30**  
**Venue: Theatre 1, HKPC Building, 78 Tat Chee Avenue, Kowloon, Hong Kong**

Please complete this form in BLOCK LETTERS.

<b>Applicant Information</b>		<b>Terms and Conditions:</b>	
Name in English: (Ir / Prof / Dr / Mr / Miss / Ms / Mrs )*		1. Programme fee must be submitted together with this form (or photocopy of this form) before programme commencement, otherwise enrolment will be rejected.	
First Name	Last Name	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 programmes. Personal Data will be treated in strict confidence. Unless otherwise agreed by you, HKPC will not transfer Personal Data 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.	
Organization:		3. You may make payment by credit cards, EPS or cheques. Amount received will be imprinted on the official receipt. Only receipt printed with receipt printers at HKPC is valid. Receipt of cheque payment is subject to bank clearance.	
Position:		4. Enrolment fee (in full or in part) is not refundable except if HKPC is notified in writing of your withdrawal: - <b>at least 5 working days</b> before the programme commencement for training program run by <b>local speaker</b> - <b>at least 15 working days</b> before the programme commencement for training program run by <b>overseas speaker</b>	
Member from Supporting Organizations: (Yes/No)*		A handling charge of <b>HK\$200</b> will be levied. For payment made by credit card, an additional <b>bank charge of around 4%</b> of the enrolment fee will be imposed.	
Please specify Name of Supporting Organization: _____		5. You may, subject to the prior approval of HKPC, nominate a person to attend the programme on your behalf. Programme switching request will not be accepted.	
Mobile No.:	Email:	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. To be accepted for any application, you are required to fulfill the admission requirements.	
Office Phone No.:	Fax No.:	7. HKPC reserves the right to replace the speaker and/ or change the contents, venue and/or time as may be necessary.	
Address:		8. Classes in the morning (09:00-13:00), afternoon (14:00-17:00) or evening (18:30-22:00) will be cancelled if: (1) Tropical Cyclone Signal No.8 or above OR Black Rainstorm Warning remains hoisted after 6:00 a.m., 11:00 a.m. and 4:00 p.m. respectively; OR (2) Tropical Cyclone Signal No.8 or above OR Black Rainstorm Warning 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.	
<b>Fee: HKD500.-</b> Please specify the name of supporting organization and the membership number to enjoy 10% off.		9. These terms and conditions are subject to revisions as may be set out in the programme pamphlets and the latest updates in the Institute's website.	
Method of Payment (Please Tick One Only)		<b>HOW TO APPLY:</b> Please complete the enrolment form and email to <a href="mailto:billyeung@hkpc.org">billyeung@hkpc.org</a> together with the enrolment fee on or before 10 February 2017.	
1) <input type="checkbox"/> By Cheque Cheque No.: _____ Bank: _____		<b>ENQUIRY:</b> Please contact Mr. Bill YEUNG/Mr. Kyle LIU/Ms. Carol LIU at Tel: (852) 2788 5869/2788 5682/2788 5550 Fax: (852) 2788 5405 E-mail: <a href="mailto:billyeung@hkpc.org">billyeung@hkpc.org</a> / <a href="mailto:kyleliu@hkpc.org">kyleliu@hkpc.org</a> / <a href="mailto:carolliu@hkpc.org">carolliu@hkpc.org</a>	
i. Crossed cheque HKD500.- payable to "Hong Kong Productivity Council"			
ii. Send to HKPC at AED, 4/F, HKPC Building, 78 Tat Chee Avenue, Kowloon, Hong Kong (Attn: Mr Bill Yeung) together with this enrolment form.			
iii. Training Course name written down at the back of the cheque.			
2) <input type="checkbox"/> By Credit Card			
i. "Credit Card Authorization Form" with your credit card information is required to be handed in together with this enrolment form.			
ii. Send to HKPC at AED, 4/F, HKPC Building, 78 Tat Chee Avenue, Kowloon, Hong Kong (Attn: Mr Bill Yeung) together with this enrolment form.			
3) <input type="checkbox"/> By Telegraphic Transfer			
i. Please note that service charge would be bore by registrants; you are reminded to <u>choose "Remitter to pay all charges" for the "Fund Transfer Charges" choice.</u>			
ii. Telegraphic Transfer form/receipt needed to be handed in together with this enrolment form.			
iii. Registrants should transfer HKD500 to bank account with details as follows: Bank Name: Standard Chartered Bank (Hong Kong) Limited Bank Address: 4-4A Des Voeux Road Central, Hong Kong Account Name: Hong Kong Productivity Council Account Address: HKPC Building, 78 Tat Chee Avenue, Kowloon, Hong Kong Account No: 447-107-1900-3 Bank Code: 003 Branch Code: 447 Bank Branch: Hong Kong Office Swift Code: SCBLHKHH			
*Please delete as appropriate			
NOTE: 1. I declare that all the information provided in this enrolment form and the attached documents are, to the best of my knowledge, accurate and complete. I have <b>read and accepted</b> all the terms and conditions of the "Important Note" in this enrolment form.			
2. Consent Statement Personal data (including your name, phone number, fax number, correspondence address and email address) provided by you will be used for the purpose of the administration, evaluation and management of your registration. You have the right to request access to, and amend your personal data in relation to your application. If you wish to exercise these rights, please send email to: <a href="mailto:edm@hkpc.org">edm@hkpc.org</a> . HKPC intends to use the personal data (including your name, phone number, fax number, correspondence address and email address) that you have provided to promote the latest development, consultancy services, events and training courses of HKPC. Should you find such use of your personal data not acceptable, please indicate your objection by ticking the box below. <input type="checkbox"/> I object to the proposed use of my personal data in any marketing activities arranged by HKPC. Transfer of Personal Data The personal data that you have provided may be transferred to the partner (s) involving in this event for marketing activities. We shall not use your personal data for this purpose unless we have obtained your written consent. Should you find such use of your personal data not acceptable, please indicate your objection by ticking the box below. <input type="checkbox"/> I object to the proposed transfer of my personal data to HKPC's partner (s) involving in this event for any marketing activities.			
Applicant's Signature: _____		Date: _____	



**Credit Card Authorization Form 信用卡付款授權書**

**To: Hong Kong Productivity Council 香港生產力促進局**

Program Name: : Workshop on Medical Device Regulation & Regulatory Harmonization  
Program Date : 3 March 2017  
Enrolment Deadline : 24 February 2017  
Applicant's Name : \_\_\_\_\_

I hereby authorize Hong Kong Productivity Council to charge my credit card account for payment of training fee.  
本人授權香港生產力促進局，從本人下述之信用卡賬戶支付以上之課程費用。

Visa /  Master (Please tick as appropriate 請選擇其一)

Total Payment Amount 支付總金額	HK\$500.-
Cardholder's Name 持卡人姓名	_____ (Note: Must be the same as shown on credit card. 註：必須與信用卡相同。)
Card Number 信用卡號碼	_____-_____-_____-_____-
Expiry Date (MM/YYYY) 有效日期(月/年)	_____/_____ (Note: The expiry date should be later than the course end date. 有效日期應在課程完結之後。)
Cardholder's Signature 持卡人簽署	_____
Date 日期	_____