



Introduction on Essential Elements of ISO13485 Medical Device Quality Management System

– Entry Ticket for the Medical Device Industry

27 – 28 February 2014

NATURE AND OBJECTIVES

This program aims to provide enabling knowledge on the ISO13485 quality management system requirement for the design, manufacturing and distribution of medical devices. It includes case studies and experience sharing in system building, implementation and audit of the documented system for ISO13485 compliance.

TARGET PARTICIPANTS

Top executives of the manufacturing and distribution companies from all industry sectors who are planning to enter the high-value medical devices industry.

Organizer

PRODUCTIVITY
生產力培訓學院 *Training Institute*
Your partner in human capital development

Supporting Organization

HKIE THE HONG KONG
INSTITUTION OF ENGINEERS
香港工程師學會

Biomedical Division
生物醫學分部

PROGRAM OUTLINES

Session 1	<p>Application of ISO13485 Quality Management System and the related Medical Device Regulatory Requirements (27 Feb 2014, 3 hours)</p> <ul style="list-style-type: none"> • Definitions and Classifications of Medical Devices in Hong Kong, EU and USA • Requirements of ISO13485 in GHTF and AHWP for the Design, Manufacturing and Distribution of Medical Devices in the Global Markets
Session 2	<p>ISO13485 Quality Management System Requirement (27 Feb 2014, 3 hours)</p> <ul style="list-style-type: none"> • Principles and Key Elements of ISO13485 QMS • Essential Elements in Medical Devices Technical File
Session 3	<p>Risk Management Requirement for ISO13485 Compliance (28 Feb 2014, 3 hours)</p> <ul style="list-style-type: none"> • Application of Risk Management in Medical Devices • Introduction of ISO14971 Risk Management System and the Implementation Tools
Session 4	<p>Requirement on ISO13485 System Audit and Case Studies (28 Feb 2014, 3 hours)</p> <ul style="list-style-type: none"> • Guidance in Preparation for ISO13485 System Assessment • Sharing of Common Non-Conformities in ISO13485 System Audit • Group Discussion and Case Studies

Duration	27 & 28 Feb 2014 (Thu & Fri)	Venue	Hong Kong Productivity Council, 1/F HKPC Building, 78 Tat Chee Avenue, Kowloon
Time	Session 1 & 3: 9:30 am - 12:30 pm Session 2 & 4: 2:00 pm – 5:00 pm		
Course Fee	HK\$2,200 (Normal Fee) HK\$1,980 (Early Bird Fee for enrollment received on or before 30 January 2014) HK\$1,800 (Group Discount Fee for 3 or more enrollments from the same company or member of supporting organization)		
Medium of Instructions	The course will be conducted in Cantonese and supplemented with English or Chinese materials.		
Award of Certificate	Participants who successfully completed the course will be issued a certificate by the Hong Kong Productivity Council.		
Application	Please complete the enrollment form and send it together with the appropriate fee to Hong Kong Productivity Council at the following address: Hong Kong Productivity Council, 3/F HKPC Building, 78 Tat Chee Avenue, Kowloon. Attn: Ms. Wong, Productivity Training Institute [Cheque should be crossed and made payable to "Hong Kong Productivity Council "]		
Remarks	The application deadline is 13 Feb 2014. If the program is cancelled, applicants will be informed on or before 20 Feb 2014/		
Enquiry	Ms. Wong Tel: (852) 2788 6183 Email: willisw@hkpc.org Fax: (852) 2788 6260 Ms. Li Tel: (852) 2788 6036 Email: joanli@hkpc.org Website: www.hktrainingonline.com		

SPEAKERS

Ir Bryan SO, Senior Consultant of Biomedical Engineering Unit in Hong Kong Productivity Council, with more than 12 years of experience in Advanced Manufacturing Technologies, Product Development Technologies, Medical Device Development and the related Regulatory Affairs and Quality Management System. He is also the current Executive Deputy Secretary General of Asian Harmonization Working Party (AHWP), providing communication channels to regulatory authorities of 23 member economies, as well as obtaining the most updated medical and healthcare device related regulatory information for the local industries. Bryan has been actively involved in the government funded projects in biomedical engineering and medical devices, including projects on medical devices risk management, and Medical Device Good Distribution Practice (MDGDP).

Mr Henry FONG, Associate Consultant of Biomedical Engineering Unit in Hong Kong Productivity Council, received his Master of Philosophy degree from The University of Hong Kong in the field of bioengineering. In the past six years, he has worked on various research projects related to the applications of biomaterials and biomechanics. During Henry's services in HKPC, he extended his research and development interest to orthopedic implant fabrication and testing, as well as served as one of the key project members on the implementation of pilot schemes on Medical Device Good Distribution Practice (MDGDP). Besides, Henry has also familiarized himself to ISO13485 via providing consultancy services to medical device design houses and manufacturers in Hong Kong and Southern China.

Ms Carol LIU, Associate Consultant of Biomedical Engineering Unit in Hong Kong Productivity Council, with practical project experiences in ISO13485 compliance audit. She also serves as the secretariat team of Asian Harmonization Working Party (AHWP) to facilitate the global development of the harmonized requirements on Quality Management System (QMS) for medical devices. Carol received her undergraduate degree in Automation Science and Engineering, and later the M.Phil. degree in Biomedical Engineering under Electronic Engineering. She is currently working on the medical device-related R&D projects, capacity building projects for local healthcare related professionals, and consultancy projects on automation of medical device production equipment with compliance to QMS requirements for the industry.

Or other Consultants and Guest Speakers of HKPC

[Hong Kong Productivity Council reserves the right to change the contents and speakers subject to unforeseeable circumstances]

RELATED CONSULTANCY SERVICES

The Automation Service Division of the Hong Kong Productivity Council provides One-Stop Services on Biomedical Engineering, Medical and Healthcare Device Development through:

- Computer-Aided Design (CAD) for new medical devices development (e.g. nebulizer, cervical cell collector, acupuncture healthcare device, etc.)
- Functional prototyping for surgical and medical devices (e.g. lordoplasty surgical device, dental surgical device, etc.)
- Advanced manufacturing support services (e.g. precision machining for medical implant, single point diamond turning for bio-optics development, etc.)
- Automation system fabrication services (e.g. artificial finger joint motion stimulation tester, IVD optical inspection system, etc.)
- Medical devices regulatory affairs and quality management system consultancy (e.g. ISO13485, ISO14971, FDA 510k, GMP, GDP, etc.)
- Biomedical Engineering R&D (e.g. Dental CAD/CAM system, Artificial Finger Joint, Precision Moulding Technology for Liquid Silicone Rubber (LSR), Bio-Optics Development for Melanoma, etc.)

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:

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):			
<input type="checkbox"/> 小學 Primary School	<input type="checkbox"/> 中學 Secondary School	<input type="checkbox"/> 文憑至副學位 Diploma to Associate Degree	<input type="checkbox"/> 學位 Degree
<input type="checkbox"/> 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	
<input type="checkbox"/> 現金 Cash	
<input type="checkbox"/> 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? <input type="checkbox"/> YES 是 <input type="checkbox"/> 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、繳費資料包括信用卡資料 (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生產力培訓學院 (請於信封面註明報讀課程名稱及編號。)

條款及細則:

- 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。
- 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。
- 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。
- 除非本局於以下限期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。
- 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。
- 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。
- 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。
- 颱風及暴雨警告: 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。
- 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.

Mailing Address: Productivity Training Institute, Hong Kong Productivity Council, HKPC Building, 78 Tat Chee Avenue, Kowloon. (Please mark the programme title and programme code on the envelope.)

Terms and Conditions:

- Course fee must be accompanied with this form (or photocopy) before course commencement, otherwise enrolment will be rejected.
- 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.
- 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.
- 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.
- 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.
- 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.
- HKPC reserves the right to replace the speaker and/or change the contents, venue and/or time as may be necessary.
- 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.
- 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.