Organizers:

HKPC DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

V 2.0

自動化 AUTOMATION

Co - Organizing and Supporting Organizations:

Hong Kong MHDIA 香港醫療及保健器材行業協會 Hong Kong Medical and Healthcare Device Industries Association

HKIE THE HONG KONG INSTITUTION OF ENGINEERS 香港工程師學會 Biomedical Division 生物醫學分部

Certificated Training Course

Medical Software Design, Standards and Validation

Date: 20 & 21 March 2014   **Time: 9am—5pm daily**
Venue: Hong Kong Productivity Council, 78 Tat Chee Avenue, Kowloon,   Hong Kong
Medium of Speech: English

Better Design. Ensure Safety and Quality. Prevent Failure.

> **Application of NTTS grant In progress;   Eligible individuals might reimburse up to HK$3,200, subject to final result of NTTS Approval**

Increased cases of recall of medical devices, rising failure rates, cybersecurity, leakage of patient information, hacking of devices, etc. are problems for medical software. There is a need to prevent, minimize the risk level, avoid recurrence of the problems, which give rise to standards, regulations and software development best practices in medical software. The constant evolving of compliance documents or guidance, medical software developers and manufactures have more aspects to consider than ever before, and seek to improve the quality, usability and software lifecycle of their software development.

This course will provide a detailed curriculum on essentials elements for the design, relevant standards and validation considerations of medical software. This course is intended to help attendees designing and validating medical software so that the software can meet the reasonably-set specifications, reduced risk and comply with relevant standards and regulatory requirement that are up-to-date.

Course Outline

> highly interactive training format: situational analyses to actual software design and validation scenarios

Background and Regulatory Requirements on MSW
◊ Definition; MD Software vs non-MD software
◊ Generic types of medical software (e.g. standalone software, embedded software, specialized software, mobile medical Apps, etc.)
◊ Keeping pace with technology: Trends, needs and industry best practices
◊ Software Development Life Cycle

Part A: Regulatory Requirements on Medical Software
◊ Adverse Events and Safety Concerns in Software for medical uses
◊ Current Regulatory Framework & Considerations
◊ Highlighted Regulatory Requirements, Guidance Documents (PRC, Japan, US, EU, t.b.c.)
◊

Part B: Standards related to Medical Software
◊ International Standards related to medical software
◊ Risk Assessment/Management
◊ Good Practices for Medical Software Development and Deployment

Part C: Design Aspects of Medical Software
◊ Principles
◊ Quality Management
◊ Risk Management
◊ Medical Software Development Models
◊ Development Planning and Process
◊ Configuration Management
◊ Case Study

Part D: Medical Software Verification and Validation
◊ Certification / Certified testing process
◊ Procedures and Methods for Validation
◊ Validation Plan
◊ Design & Execution of Validation Protocols
◊ Data Collection & Analysis
◊ Documentation (e.g., Record and Report of Validation Results)
◊ Problem identification and Resolving Process
◊ Case Study

Trainer Profile

The training course will be conducted by experts from Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA).

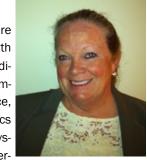Olivier Kagan holds a master degree in Computer Science and has over 10 years of experience designing medical software including PACS, RIS and Cardiology Information Systems. In his career, Olivier directly contributed to all aspects of software design and validation holding various R&D positions such as software developer, software architect and manager of R&D sites in France, Austria, Italy and USA. Olivier is also familiar with generating technical files and 510(k) as well as with ISO audits and FDA inspections. Oliver is currently the Global Process Manager for IT Solution Development and is responsible for the software development process at Agfa HealthCare, United States.

Olivier Kagan

Cathy Bahr was Director of Software Regulatory Strategy at GE Healthcare before her retirement in 2014. She has over 35 years of global experience working with GE with over 15 years assuring that healthcare software products in both medical and non-medical device areas are designed, distributed and serviced in compliance with global regulations. Cathy has served as the Chair of DITTA Medical Software Task Force, and as the Vice Chair of the Medical Imaging & Technology Alliance (MITA) Medical Imaging Informatics Committee. Cathy was a contributor to AAMI publication on the application of quality management system to medical device data systems (MDDS) ANSI/AAMI SW87:2012 and the Medical Device Interoperability White Paper developed by the AAMI Ad Hoc Group on Health Information Technology and Interoperability (HITI). She is currently a member of the IMDRF Medical Software Working Group. Cathy received a Bachelor's degree in finance from the University of Pennsylvania's Wharton School. She is also certified as a Master Black Belt.

Catherine Bahr

Training Fee

The fee for this 2-day training course is **HKD 6,400 (~USD 820) per person**, which the fee for training materials is included. Reprints of DITTA published articles, book chapters, policies, procedures, forms, and case studies will be provided along with resource lists directing course attendees to other sources of related information from competent authorities and agencies. Registration Deadline: 10 March 2014

Registration and Enquiry

Please contact the Hong Kong Productivity Council:
Ir Bryan SO, Senior Consultant, Automation Service Division (Tel: +852 2788 5548; Email: bryanso@hkpc.org)
Ms Carol LIU, Associate Consultant, Automation Service Division (Tel: +852 2788 5550; Email: carolliu@hkpc.org)
Ms Miranda KWOK, Assistant Project Officer, Automation Service Division (Tel: +852 2788 5547; Email: mirandakwok@hkpc.org)

Training Organizer

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

Training Co-organizer

DITTA (the Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association) is a global association that represents medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers. DITTA acts as the global voice for diagnostic imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers to better communicate, coordinate and collaborate on matters of common interest between participating associations and member companies. DITTA enables participating associations and their member companies to work more effectively with international policymakers, organizations, professional associations and stakeholders. For further details on DITTA, please visit **http://globalditta.org**

Sender: Hong Kong Productivity Council, HKPC Bldg, 78 Tat Chee Avenue, Kowloon   Tel: 852 2788 5550.
發送者：香港生產力促進局 九龍塘達之路78 號生產力大樓 電話: 852 2788 5550。
If you do not wish to receive further information from HKPC, please inform us via email to : unsubscribe@hkpc.org with "unsubscribe" as the subject.
若閣下不欲再接收香港生產力促進局信息，請發電郵至: unsubscribe@hkpc.org ，並在主旨欄填上「拒絕接收」

Enrollment Form
報名表

Certificated Training Course:
Medical Software Design, Standards and Validation

Date: 20 & 21 March 2014 **Time: 9am—5pm daily**
Venue: *Hong Kong Productivity Council, 78 Tat Chee Avenue, Kowloon, Hong Kong*

Please complete this form in BLOCK LETTERS.

Applicant Information

Name in English: (Ir / Prof / Dr / Mr / Miss / Ms / Mrs)*

First Name   Last Name

Organization:

Position:

Member from Supporting Organizations: (Yes/No)*

Please specify Name of Supporting Organization: _____

Mobile No.:	Email:
Office Phone No.:	Fax No.:

Address:

Prior Knowledge Survey (For the better preparation of the course, please advice by ticking the boxes)

	Beginner		Intermediate		Advanced
quality management systems	☐	☐	☐	☐	☐
risk management	☐	☐	☐	☐	☐
medical device software standards (e.g. ISO/IEC62304)	☐	☐	☐	☐	☐

Fee: HKD6,400

Method of Payment (Please Tick One Only)

1) By Cheque
   Cheque No.: _____ Bank: _____
i. Crossed cheque HKD6,400 payable to "Hong Kong Productivity Council"
ii. Send to HKPC at ASD, 5/F, HKPC Building, 78 Tat Chee Avenue, Kowloon, Hong Kong (Attn: Ms Miranda KWOK) together with this enrolment form
iii. Training Course name written down at the back of the cheque.

2) By Credit Card
i. Please note that 3% service fee (HKD198) would be charged. Therefore, registrants should pay HKD6,598
ii. "Credit Card Authorization Form" attached needed to be handed in together with this enrolment form.

3) 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"</u> choice
ii. Telegraphic Transfer form/receipt needed to be handed in together with this enrolment form.
iii. Registrants should transfer HKD6,400 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

IMPORTANT NOTE:

1. Enrolment fee must accompany this form (or its photocopy), otherwise enrolment may be rejected.
2. Cheques, credit card payment and telegraphic transfer remittance are subject to bank clearance.
3. Enrolment fee is <u>not refundable</u>.
4. The information provided will be used for the process of enrolment application, statistical purposes and other related matters. It may be provided to persons authorized to process the information for purpose relating to the course.
5. An applicant may, subject to approval from HKPC, nominate a person to attend the course on his/her behalf
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 change the contents, venue and/ or time as necessary.
8. Classes in the morning, afternoon or evening will be cancelled if typhoon signal No. 8 or above OR black rainstorm warning is still hoisted after (<u>or is announced by the Hong Kong Observatory to be hoisted at/after</u>) 6:00 a.m., 11:00 a.m. and 4:00 p.m. respectively. Participants will be notified when the class will be made up as soon as possible.
9. The above "Important Note" is subject to revisions in the course pamphlets.

HOW TO APPLY:

Please complete the enrolment form and email to mirandakwok@hkpc.org or fax to (852) 2788 6338 together <u>with the enrolment fee</u>.on or before <u>10 Mar. 2014</u>

ENQUIRY:

Please contact Ir Bryan SO/ Ms Carol LIU/ Ms Miranda KWOK at
Tel: (852) 2788 5548 / 2788 5550/ 2788 5547
Fax: (852) 2788 5002
E-mail: carolliu@hkpc.org/ mirandakwok@hkpc.org

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* 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 **read** and **accepted** all the terms and conditions of the "Important Note" in this enrolment form.
2. Personal Information Collection Statement (PICS)
Personal data (including your name, contact details and other information) provided by you will be used for the purpose of the administration, evaluation and management of your registration. You have a right to request access to, and to request correction of, your personal data in relation to your application. If you wish to exercise these rights, please send email to: edm@hkpc.org.
HKPC intends to use the personal data (i.e. your name, company name, phone number and email address) that you have provided to promote the latest development, consultancy services, events and training courses of HKPC and our business partner(s) organizing this event. The personal data that we have collected may be transferred to our business partner(s) for the above mentioned purposes for which the personal data are to be used. We may not so use your personal data unless we have received your written consent. Should you find such use of your personal data not acceptable, please indicate your objection by ticking the box(es) below.
☐ I object to the proposed use of my personal data in any marketing activities arranged by HKPC.
☐ I object to the proposed transfer of my personal data to HKPC's business partner(s) of this event in any marketing activities.

Applicant's Signature: _____   Date: _____

Credit Card Authorization Form 信用卡付款授權書

(Important Note: Your information will be kept confidential. 重要通知:您的個人資料絕對保密)

I hereby authorize **Hong Kong Productivity Council** to charge my credit card account for payment of enrolment fee:

本人授權 **香港生產力促進局**，從下述之信用卡賬戶支付以下課程/活動費用:

Program Name 課程/活動名稱:	**Certificated Training Course: Medical Software Design, Standards and Validation**		
Project Code 課程/活動編號:	**10000245**	Duration 課程/活動日期:	**20-21 March, 2014**

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

Total Payment Amount 支付總金額: **HK$6,598**

Cardholder's Name 持卡人姓名: ＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

(Must be the same as shown on credit card. 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): ＿＿＿＿＿＿/＿＿＿＿＿＿

(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: ＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

Participant's Signature 學員簽署:＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

Participant's Name 學員姓名: ＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿