Organizer: **Co-organizer:** **Supporting Organizations: (in alphabetical order)**

Pre-approval of NTTS grant **confirmed**; Eligible individuals could reimburse up to **HK$2,000.-**

Certificated Training Course: Enabling Knowledge and Advanced Technologies on Medical Software Design, Validation and Standards

Date: 12 & 13 January 2017 **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.

Increased cases of recall of medical devices, cybersecurity vulnerability, rising failure rates, 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. With the constant evolving of compliance documents or guidance, medical software developers and manufacturers 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 essential elements for the design, relevant standards and validation considerations of medical software. Updates on the requirements related to medical software validation in ISO 13485:2016 will be discussed. This course will also cover the topics including cybersecurity vulnerability, mobile apps medical software validation, and risk-based computer and software validation, etc. This course is intended to help attendees design and validate medical software so that the software can meet the reasonably-set specifications, reduce risk and comply with relevant standards and regulatory requirement that are up-to-date.

Highly interactive training format: Situational analyses to actual software design and validation scenarios

Course Outline

Background and Regulatory Requirements on MSV
- ◊ Definition; MD Software vs Non-MD Software
- ◊ Generic Types of Medical Software (e.g. Standalone Software, Embedded Software, Specialized Software, etc.)
- ◊ Keeping Pace with Technology: Trends, Needs and Industry Best Practices (e.g., Cybersecurity Vulnerability, Mobile Medical Apps)
- ◊ 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
- ◊ New Requirements on Medical Software Validation in ISO 13485:2016
- ◊ 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 (e.g., Risk-based Computer & Software 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 nominated by DITTA.

Olivier Kagan

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 Managing Consultant to deliver business optimized compliance solution to industry by synchronizing business goals with compliance needs at NSF Avarent, United States.

Peter Linders

Peter Linders holds a doctorate degree in Biomedical Physics and has over 28 years experiences in research and innovations for diagnostic imaging and healthcare IT, and global advisory experiences in the development of relevant standards. In his career, Peter has over 24 years involvement in standards development in IEC and ISO. Furthermore, he is also one of the advisors in Asian Harmonization Working Party (AHWP) Technical Committee. Peter is also the Chair of Quality Management and Corresponding General Aspects for Medical Devices (ISO/TC 210). Peter is currently the Director of Standards & Regulations of Philips Healthcare, Netherlands.

Training Fee

The fee for this 2-day training course is **HKD 7,500.- (USD 970.-) per person**, which the fee for training materials is included. Supporting Organization's member can enjoy 10% off of the training fee. Training fee is **HKD 6,750.- (USD 875.-) per person** after the discount. 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: 17 December 2016

NTTS funding has been applied for this course. With the success application, each eligible trainee may grant up to **HKD 3,750.- (USD 490.-)** funding support. The application result is subject to the final decision of the funding agency. Please refer to **http://ntts.vtc.edu.hk** for the detailed application guideline.

Registration and Enquiry

Please contact the Hong Kong Productivity Council:
Ms Carol LIU, Consultant, Automotive and Electronics Division (Tel: +852 2788 5550; Email: carolliu@hkpc.org)
Mr Kyle LIU, Cadet Engineer, Automotive and Electronics Division (Tel: +852 2788 5682; Email: kyleliu@hkpc.org)
Mr Edmund LIU, Assistant Project Officer, Automotive and Electronics Division (Tel: +852 2788 5799; Email: edmundliu@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**.

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

Training Co-organizer

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

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**.

Organizer: HKPC

Co-organizer: DITTA

Supporting Organizations: (in alphabetical order) FHKI, HONG KONG BAPTIST UNIVERSITY, FITMI, INFORMATION SECURITY GROUP HONG KONG, HKSTP, WTIA

Enrollment Form 報名表

Certificated Training Course:
Enabling Knowledge and Advanced Technologies on Medical Software Design, Validation and Standards

Date: 12 & 13 January 2017 **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: ☐ HKD 7,500.- (USD 970.-) ☐ HKD 6,750.- (USD 875.-)

Please specify the name of supporting organization and the membership number to enjoy 10% off.

Method of Payment (Please Tick One Only)

1) ☐ By Cheque
   Cheque No.: _____ Bank: _____
   i. Crossed cheque HKD 7,500.- / HKD 6,750.- payable to "Hong Kong Productivity Council"
   ii. Send to HKPC at AED, 5/F, HKPC Building, 78 Tat Chee Avenue, Kowloon, Hong Kong (Attn: Mr. Kyle LIU) 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 would be charged.
   ii. "Credit Card Authorization Form" attached is required 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 choose "Remitter to pay all charges" for the "Fund Transfer Charges" choice
   ii. Telegraphic Transfer form/receipt needed to be handed in together with this enrolment form.
   iii. Registrants should transfer HKD7,500.- (USD 970.-) 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 **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: _____

Terms and Conditions:

1. Programme fee must be submitted together with this form (or photocopy of this form) before programme 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 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.
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.
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 programme commencement for training program run by **local speaker**
- **at least 15 working days** before the programme 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 around 4%** of the enrolment fee will be imposed.
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.
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.
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 (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.
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.

HOW TO APPLY:

Please complete the enrolment form and email to stephaniewun@hkpc.org together with the enrolment fee on or before 17 December 2016.

ENQUIRY:

Please contact Ms Carol LIU/Mr Kyle LIU/Mr Edmund LIU at
Tel: (852) 2788 5550/2788 5682/2788 5799
E-mail: carolliu@hkpc.org/kyleliu@hkpc.org/edmundliu@hkpc.org

Hong Kong Productivity Council
香港生產力促進局

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:** Enabling Knowledge and Advanced Technologies on Medical Software Design, Validation and Standards		
Project Code 課程/活動編號:		Duration 課程/活動日期:	**12 & 13 January 2017**

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

Total Payment Amount 支付總金額: ☐ HKD 7,725.- (USD 1000.-) ☐ HKD 6,952.50- (USD 900.-)
(3% service charge included 已包含 3%服務費)

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: _____