

Regulatory Workshop Series
Discussion Forum on Proposed Framework for Statutory Regulatory of Medical Devices

規管工作坊系列：醫療儀器規管架構建議研討會

14 September 2010 (Tuesday) 二零一零年九月十四日 (星期二)

Background 簡介

The Department of Health (DoH) of the HKSAR Government established the Medical Device Control Office (MDCO) in 2004 with the goal of ensuring medical devices are safe, efficacious, and perform as intended. In furthering such goals, MDCO has adopted a risk-based regulatory approach under the current operating Medical Device Administrative Control System (MDACS). MDACS is a voluntary system under which Importers, Local Manufacturers, Local Responsible Person and medical devices are registered and listed. After 6 years of ongoing consultations, the DoH is planning to submit to the Legislative Council a statutory framework for the medical devices regulation.

The Hong Kong Medical and Healthcare Device Industries Association (HKMHDIA), being the only medical device sector specific association in Hong Kong, has taken up the role to understand, monitor and communicate to our members the regulatory approach of the HKSAR Government. In the past, HKMHDIA have responded to MDCO's consultation papers on various components of MDACS and its Regulatory Impact Assessment.

Regulatory Workshop Series aim to create a platform by which HKMHDIA discusses Regulatory and Compliance issues among our members, interested parties and the HKSAR Government. **In this workshop, we have invited representatives from MDCO to introduce the "Proposed Framework for Statutory Regulatory of Medical Devices" (Proposal) which was published on 29th August, 2010.** We are also going to meet with the key staff of MDCO and have better understanding about their daily operations. The purpose of this workshop is to providing networking opportunities and to discuss among our industries and collect comments on the Proposal.

香港特別行政區政府衛生署在 2004 年成立醫療儀器管制辦公室 (MDCO)，確保本港市民可以用到安全、具成效並按原擬設計運作的醫療儀器。MDCO 在現時的醫療儀器行政管理制 (MDACS) 下採取了風險評級的監管辦法。MDACS 是一項自願性的制度。進口商、本地製造商、本地負責人及醫療設備都可申請表例上市。經過 6 年的持續諮詢後，衛生署現正準備向立法會提交建議，成立法定架構以便規管醫療儀器。

香港醫療及保健器材行業協會 (HKMHDIA)，作為香港醫療器材行業唯一代表，擔當著瞭解、監測及向香港特別行政區政府傳遞會員對規管看法的角色。過去，我們曾多次對 MDACS、MDCO 的諮詢文件及其規管影響評估的諮詢作出回應。

規管工作坊的目的是為香港醫療及保健器材行業協會 (HKMHDIA) 會員、相關的團體以及醫療儀器管制辦公室 (MDCO)，提供一個討論醫療器材監管問題的平臺。**本會十分榮幸能夠邀請 MDCO 之代表，向會員介紹最近於 2010 年 8 月 29 日公佈的 "醫療儀器規管架構建議"**。參加者將會與 MDCO 的各關鍵人員會面，討論相關議題並瞭解 MDCO 的日常工作，並希望能透過是次研討會收集各位的建議。

Target Participants 適合參加人士

This seminar is suitable for senior executives and regulatory staff of medical and healthcare product industries including importers and manufacturers. Interested parties from supporting industries, such as plastics, metals, electronic components, are also welcome.

此講座適合醫療及保健器材行業及其他如：塑膠、金屬、電子等的高級行政人員和管理人員，包括進口商及製造商參加。

Sender: Hong Kong Medical and Healthcare Device Industries Association, c/o 5/F, MLD, HKPC Building, 78 Tat Chee Avenue, Kowloon Tong, Kowloon, Hong Kong, Tel: (852) 2788-5625.

發送者：香港醫療及保健器材行業協會，香港九龍達之路 78 號生產力大樓 5 樓 電話：(852) 2788-5625。

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Organiser 主辦機構:



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

Co-organiser 協辦機構:



Hong Kong
Productivity Council
香港生產力促進局

Details 詳情

Time 時間

2:00 p.m. – 5:00 p.m.
下午二時至五時

Quota 人數

Limited to 100, on first-come-first-served basis
只限 100 人, 先到先得

Venue 地點

Lecture Theater, 1/F, HKPC Building,
78 Tat Chee Avenue, Kowloon, Hong Kong
香港九龍達之路 78 號生產力大樓一樓演講廳

Enquiry 查詢

Mr. Campbell Ting, 丁金寶先生
Tel: 27885920
Email: campbellting@hkpc.org

Language 語言

Cantonese and English 廣東話 及 英語
No translation provided 不設翻譯

Miss Beverly Cheung, 張倩琪小姐
Tel: 27885625
Email: beverlycheung@hkpc.org

Registration Fee 費用

Free of charge 免費

ENROLLMENT FORM 報名表

Please put a cross (x) in the appropriate box below. 請於下列適當的空格內加上 (x)。

- I am HKMHDIA Member and would like to join the workshop held on 14 September 2010.
本人是 HKMHDIA 會員並想參加 2010 年 9 月 14 日舉行的活動。
- I am NOT HKMHDIA Member but would like to join the workshop held on 14 September 2010
本人不是 HKMHDIA 會員但想參加 2010 年 9 月 14 日舉行的活動。

Attention: Ms. Beverly Cheung. Fax No. 2788-5522 請填妥此報名表並傳真到 2788-5522 張倩琪小姐收。

中文姓名 (先生 / 女士)			
Name in English (Mr / Ms)			
公司名稱 Company Name			
辦公室地址 Business Address			
職位 Position		互聯網址 Webpage	
辦事處電話 Office Tel.		手提電話 Mobile No.	
電郵 E-mail		傳真 Fax	
簽名 Signature		日期 Date	

IMPORTANT 注意

An applicant may, subject to approval from HKMHDIA, nominate a substitute to attend the symposium on his/her behalf.

參加者可提名他人代替其本人出席, 惟事先須得本會同意。

Some of the topics in this programme might be modified without further notice.

此活動的部份內容可能會作出修改而不作另行通知。

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