

Medical Device Standards Seminar



The seminar was highly successful, with full-house attendance by medical and healthcare industry professionals

SMF-SDO together with the Health Sciences Authority (HSA) and Japan's Pharmaceutical and Medical Device Agency (PMDA), jointly organised a seminar on The Use Of Standards In Medical Device Industry on 24 February 2016. The event was attended by 186 participants from over 100 local and international organisations.

The seminar underlines the importance of standards in the global medical device industry. Participants were able to gain a better understanding on the need for a conformity assessment system in facilitating the conduct of international trade, through the implementation of relevant standards to bring forth both increased market opportunities as well as improved risk management.

"In order to stand out amongst the rest in today's highly competitive medical device industry, organisations will need to



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comply with the relevant standards - from product development, to manufacturing and finally, putting the finished product into the market." Ms Jacqueline Monteiro, advisor to SMF-SDO's Biomedical Standards Committee.

The highlights of the seminar included a series of presentations by ten speakers, who touched upon a wide range of topics. Dr Madoka Murakami, Unit Chief of PMDA's Division of Regulatory Cooperation, invoked an in-depth discussion on the Japanese medical device regulatory framework. On the local front, Dr Sethuraman Rama, HSA Deputy Director, Medical Devices Branch, provided updates on Singapore's medical device regulatory. There were also crucial updates on the recent developments from the first ASEAN Medical Device Committee Meeting by Ms Low Lai Peng, HSA Senior Regulatory Specialist, Medical Device Branch.



SMF-SDO staff with the speakers at the end of the seminar

Educating Tertiary Students on the Importance of Standards

Imagine going to a hardware store to buy a replacement light bulb for your lamp, only to find out that there are several different socket sizes, some of which fit into the lamp while others don't – it would certainly cause a lot of confusion and inconvenience. The fact that all ordinary light bulbs and sockets fit together, regardless of manufacturer, is a testament of standards at work.



SMF-SDO and its industry partners believes in nurturing the next generation the importance of standards

Most people may not even be aware how important standards are to their everyday lives. Nearly everything we touch on a daily basis is impacted by the application of standards – from the food we consume to the mattresses we sleep on, they were all shaped by standards.

Hence, SMF-SDO strongly believes that awareness of industry standards should be integrated in one's education. With this aim in mind, SMF-SDO initiated its first Standards Outreach Programme of the year on 13 January 2016, whereby it collaborated with Singapore Polytechnic to engage students who are pursuing a diploma for Perfumery and Cosmetic Science.

Ms Tan Shiu Ming, SMF-SDO General Manager and two experts from the cosmetic industry were invited to share the importance of standards in the cosmetic industry. The session started with an introduction on the different types of standards, their development processes, and the National Standardisation Programme. Following the presentation, Dr Khoo Keng Meng, Head of Regulatory Assurance (Asia Pacific) for Lonza Specialty Ingredients, shared with the students on the application of standards as a tool to address risks in cosmetics. Ms Stephanie Chan, secretariat for the Cosmetic Toiletry Fragrance Association of Singapore, concluded the session with an insightful presentation on the cosmetic regulations in Singapore. Tapping on her rich experience from leading projects that have pioneered the growth of the local cosmetic industry, Ms Chan included multiple interesting case studies in her discussion.

Riding on the success of the first session, SMF-SDO soon organised a second Standards Outreach Programme – this time with Singapore Polytechnic School of Life Sciences, on 20 January 2016. This session focused on introducing the biomedical standards to the polytechnic students. The audience had the opportunity to hear from Dr Margam Chandrasekaran, Chief Scientist and Chief Executive Officer of Bio Scaffold International, who presented the different type of standards that are critical for medical devices industry. There was also a case study presentation by Ms Heidi Goh, Senior Quality Director at Edwards Lifesciences (Singapore) Private Limited, who shared useful knowledge of complying with the dynamic international regulatory landscape of medical product manufacturing.