

**APEC Business Ethics for SMEs Forum:  
Promoting Ethical Environments in the Medical Device & Biopharmaceutical Sectors**  
Sofitel Nanjing Zhongshan | Nanjing, China | 1-3 September 2014

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**MEDICAL DEVICE SECTOR TRAINING SESSION (DAY ONE) – 1 SEPTEMBER 2014**

*Grand Ballroom A, Sofitel Nanjing Zhongshan  
No.9 Huanling Road Nanjing, Jiangsu, 210042, China*

TIME	PROGRAM
08:30-09:00	Registration
09:00-09:45	<p><b>Achievements since the KL Train-the-Trainer: Reports from associations on adopting and aligning codes with The KL Principles – Key Learnings and Remaining Challenges</b></p> <p><b>Moderator: Ms. Lynn Costa</b>, Senior Trade Development Advisor, U.S. Department of Commerce &amp; Project Overseer, Business Ethics for APEC SMEs Initiative</p> <p><b>Discussants:</b></p> <ul style="list-style-type: none"> <li>• Mexican Association of Innovative Medical Devices Industries (AMID)</li> <li>• Philippine Association of Medical Device Regulatory Affairs Professionals (PAMDRAP)</li> <li>• International Medical Device Manufacturers Association (IMEDA-Russia)</li> <li>• Singapore Manufacturing Federation’s Medical Technology Industry Group (MTIG)</li> <li>• Lima Chamber of Commerce, Committee of Health Products and Related Sciences (COMSALUD-Peru)</li> <li>• Scientific Society of the Medical Devices Industry (SDCM-Chile)</li> <li>• Taiwan Advanced Medical Technology Association (TAMTA)</li> <li>• Others</li> </ul> <p><i>3 Minutes Per Discussant – 20 minutes for other participants to provide reports from their associations and economies</i></p>



<p><b>09:45-10:30</b></p>	<p><b>The Value of Ethics and Compliance in Today's Medical Device Sector for SMEs</b></p> <p><b>Moderator: Dato' Hafsa Hashim, Malaysia SME Corp (Malaysia)</b></p> <p><b>Ms. Jessie Yap, Covidien (Australia)</b> <b>Ms. Andrea Perez Figueroa, AMID (Mexico)</b> <b>Mr. Philippe Bizot, Edwards Lifesciences (Greater China and Korea)</b></p> <p><i>8 Minutes Per Discussant – 20 Minutes for Q&amp;A / Discussion</i></p>
<p><b>10:30-11:30</b></p>	<p><b>Key Trends and Issues in Medical Device Sector Compliance</b></p> <p><b>Moderator: Ms. Jessie Yap, Covidien (Australia)</b></p> <p><b>Breakout tables – Each table to identify top 5 trends and issues and report back to the group</b></p> <p><b>Breakout table leaders:</b> <b><u>Table A (Americas): Mr. Stephen Dibert, MEDEC (Canada)</u></b> <b><u>Table B (Asia ex China) : Ms. Faye Sumner, MTANZ (New Zealand)</u></b> <b><u>Table C (China – Team 1 of 2): Ms. Elise Owen, AdvaMed (United States)</u></b> <b><u>Table D (China – Team 2 of 2): Mr. HSU Chen Tong (Thomas), Edwards Lifesciences</u></b></p> <p><i>40 Minutes for Breakout discussion – 20 Minutes for each table to report findings</i></p>
<p><b>11:30-12:30</b></p>	<p><b>Lunch Break</b></p>
<p><b>12:30-13:30</b></p>	<p><b>Getting Started: Organizing and Executing Local Trainings – Key Learnings and Best Practices</b></p> <p><b>Moderator: Ms. Faye Sumner, MTANZ (New Zealand)</b></p> <p><b>Breakout tables – Each table to identify top learnings and best practices for their assigned topic, and report back to the group</b></p> <p><b>Breakout table leaders:</b> <b><u>Table A: Developing effective training programs – Led by Ms. Michelle Wagner, Johnson &amp; Johnson (Australia)</u></b> <b><u>Table B: Getting organizational buy in – Led by Ms. Andrea Perez, AMID</u></b></p>



	<p>(Mexico) <b>Table C: Making it cost-efficient, especially for SMEs – Led by Ms. Chew Yee Ling (Stephanie), Medtronic (China)</b></p> <p><i>40 Minutes for Breakout table discussion – 20 Minutes for each table to report findings</i></p>
<b>13:30-14:30</b>	<p><b>How Do I Know It's Working? Key Performance Indicators, Metrics and More</b></p> <p><b>Moderator: Mr. Stephen Dibert, MEDEC (Canada)</b></p> <p><b>Mr. Ronald Goon, Johnson &amp; Johnson (Singapore)</b> <b>Mr. Katsumi Kojima, Edwards Lifesciences (Singapore)</b> <b>Mr. Fay LI, BD (Singapore)</b></p> <p><i>10 Minutes Per Discussant – 30 Minutes for Q&amp;A / Discussion</i></p>
<b>14:30-15:00</b>	<b>Networking Break</b>
<b>15:00-16:00</b>	<p><b>Best Practices for Ethical Compliance with Physicians</b></p> <p><b>Moderator: Dr. Andreas Loeffler, Australian Orthopaedic Association</b></p> <p><b>Breakout tables – Each table to identify top 5 best practices and report back to the group</b></p> <p><b>Breakout table leaders:</b> <b>Table A: Ms. Chew Yee Ling (Stephanie), Medtronic (China)</b> <b>Table B: Ms. Minah Cho, Korea Medical Devices Industry Association (KMDIA)</b> <b>Table C: Ms. Michelle Wagner, Johnson &amp; Johnson (Australia)</b></p> <p><i>40 Minutes for Breakout table discussion – 20 Minutes for each table to report findings</i></p>
<b>16:00-16:45</b>	<p><b>2015 Action Plans: Turning Learnings into Concrete Actions</b></p> <p><b>Moderator: Dato' Hafsa Hashim, Malaysia SME Corp (Malaysia)</b></p> <p><b>Associations to begin drafting a 2015 Action Plan.</b></p>



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<b>16:45 – 17:00</b>	<b>Unveiling of online training modules by Dr. Kavita Mehrotra, UL EduNeering (United States)</b>
<b>17:00 – 17:45</b>	<b>Discussion with regulatory leaders from the region on their views on proactive industry leadership to build ethical business environments</b>  <b>Moderator: Ms. Jessie Yap, Covidien (Australia)</b>  <b>Ms. Kathleen HAMANN, Partner, White and Case – Formerly with the U.S. Department of Justice (United States)</b> <b>Dr. Kenneth HARTIGAN-GO, Acting Director-General, Food and Drug Administration (Philippines)</b> <b>Dr. Pamela MILLA, Head, Agencia Nacional de Medicamentos (ANAMED), Instituto de Salud Publica de Chile</b> <b>Datuk Mustafar Ali, Deputy Chief Commissioner (Prevention), Malaysian Anti-Corruption Commission</b>  <i>5 Minutes for discussant – 20 Minutes for Q&amp;A and discussion</i>
<b>17:45-18:00</b>	<b>Closing Remarks</b>  <b>Ms. Patricia Wu, Business Ethics for APEC SMEs Initiative</b>
<b>18:00-20:00</b>	<b>Welcome Reception</b>  Outside Terrace (First Floor – Beside Western Restaurant)



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**MEDICAL DEVICE SECTOR TRAINING SESSION (DAY THREE) – 3 SEPTEMBER 2014**

*Grand Ballroom A, Sofitel Nanjing Zhongshan  
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**Promote Ethical Interactions with Third Party Sales and Marketing Intermediaries**

*Third party sales and marketing intermediaries are a vital component of the APEC region’s medical device sector. They account for thousands of small and medium enterprises, including distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commissionary commercial agents and independent sales representatives. These enterprises benefit from and are necessary to the facilitation of high-standard ethical business practices. The Kuala Lumpur Principles for Voluntary Codes of Business Ethics in the Medical Device calls for the following:*

*“To ensure Industry Codes are effective, they should encourage adherence to the following elements that are relevant to a Company’s business: Companies to communicate company policies consistent with the Industry Code to their third party intermediaries with the expectation that the intermediaries will comply with the Industry Code.”*

*This workshop will serve as an important first step in assessing what has and can be done to strengthen ethical interactions in the region’s medical device sector for this stakeholder.*

TIME	PROGRAM
08:30-09:00	Registration
09:00-09:10	<p><b>The Future of the KL Principles – Keeping the KL Principles Relevant for SMEs</b></p> <p><b>Dato' Hafsah Hashim</b>, CEO, Malaysia SME Corporation &amp; Co-Chair of the Expert Working Group, APEC Kuala Lumpur Principles</p>
09:10-10:00	<p><b>Defining the Challenge: Third Party Risk and Compliance Management</b></p> <p><b>Ms. Kathleen Hamann</b>, Partner, White and Case – Formerly with the U.S. Department of Justice (United States)</p> <p><i>25 Minute Presentation – 25 Minutes for Q&amp;A / Discussion</i></p>



<b>10:00-11:00</b>	<b>Understanding Local Challenges for Medical Device Companies with Respect to Third Party Sales and Marketing Intermediaries</b>  <b>Moderator: Ms. Faye Sumner, MTANZ (New Zealand)</b>  <b>Ms. Andrea Perez Figueroa, Baxter (Mexico)</b> <b>Mr. Ronald Goon, Johnson &amp; Johnson (Singapore)</b> <b>Mr. HSU Chen Tong (Thomas), Edwards Lifesciences (China)</b> <b>Ms. Chew Yee Ling (Stephanie), Medtronic (China)</b>  <i>7 Minutes Per Discussant – 30 Minutes for Q&amp;A / Discussion</i>
<b>11:00-11:30</b>	<b>Official Photo &amp; Networking Break</b>
<b>11:30-12:30</b>	<b>Company Best Practices</b>  <b>Moderator: Ms. Jessie Yap, Covidien (Australia)</b>  <b>-- SAME PANELISTS AS IN PREVIOUS SESSION --</b>  <i>7 Minutes Per Discussant – 30 Minutes for Q&amp;A / Discussion</i>
<b>13:00-14:00</b>	<b>Lunch Break</b>
<b>14:00-15:00</b>	<b>Association Efforts to Address the Challenge: Joint Guidance Developed by Associations</b>  <b>Moderator: Ms. Lynn Costa, Senior Trade Development Advisor, U.S. Dept. of Commerce &amp; Project Overseer, Business Ethics for APEC SMEs Initiative</b>  <b>Ms. Elise Owen, AdvaMed (United States)</b> <b>Ms. Faye Sumner, MTANZ (New Zealand)</b> <b>Mr. Stephen Dibert, MEDEC (Canada)</b>  <i>10 Minutes Per Discussant – 30 Minutes for Q&amp;A / Discussion</i>
<b>15:00-15:30</b>	<b>Coffee &amp; Networking Break</b>



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<p><b>15:30-16:00</b></p>	<p><b><u>Beyond The Kuala Lumpur Principles: How can the APEC Business Ethics for SMEs Initiative help to address Third Party Risk and Compliance Management?</u></b></p> <p><b>Ms. Lynn Costa</b>, Senior Trade Development Advisor, U.S. Department of Commerce &amp; Project Overseer, Business Ethics for APEC SMEs Initiative</p> <p><i>30 Minutes Open Discussion</i></p>
<p><b>16:00-16:15</b></p>	<p><b>Closing Remarks</b></p> <p><b>Ms. Lynn Costa</b>, Senior Trade Development Advisor, U.S. Department of Commerce &amp; Project Overseer, Business Ethics for APEC SMEs Initiative</p>