Asia-Pacific Economic Cooperation

APEC CHILE 2019

2019 APEC Business Ethics for SMEs Forum

SANTIAGO DE CHILE | 9-10 SEPTEMBER

DISTRIBUTORS PORTAL SESSION

OPENING SESSION

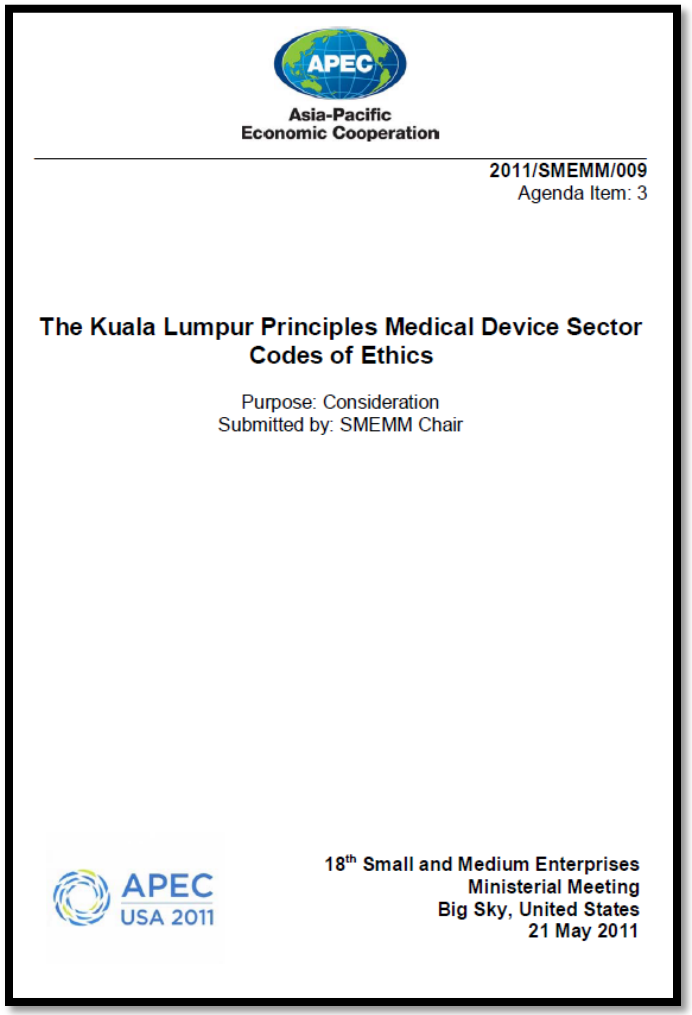
Ms. Tricia Van Orden
Overseer
Business Ethics for APEC SMEs Initiative

DISTRIBUTORS PORTAL SESSION

A DECADE IN REVIEW: MEDICAL DEVICE SECTOR AND ETHICAL BUSINESS CONDUCT

Ms. Nancy Travis, Vice President, International Compliance and Governance, The Advanced Medical Technology Association (AdvaMed)

A Remarkable 10 Year Journey (2010-2011)



Asia-Pacific Economic Cooperation

2011/SMEMM/009
Agenda Item: 3

The Kuala Lumpur Principles Medical Device Sector Codes of Ethics

Purpose: Consideration
Submitted by: SMEMM Chair

APEC USA 2011

18th Small and Medium Enterprises Ministerial Meeting
Big Sky, United States
21 May 2011

http://klprinciples.apec.org

A Remarkable 10 Year Journey (2011-2012)

APEC USA 2011

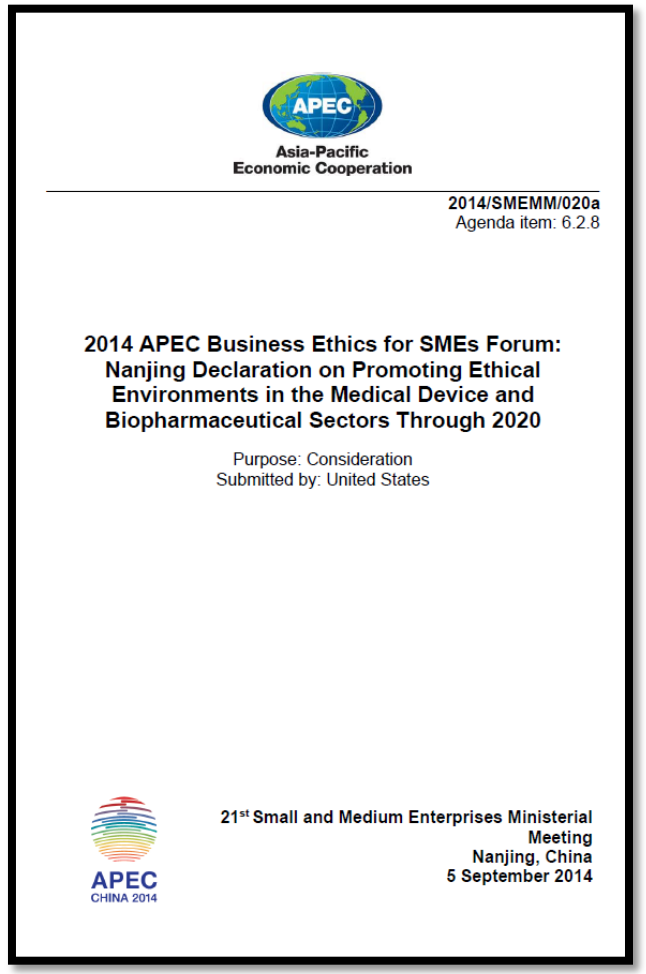
A Remarkable 10 Year Journey (2012)

APEC RUSSIA 2012

We recognize the important role of business and public-private partnerships in promoting the elaboration of codes of conduct in the private sector and measures to fight corruption, especially measures that support the promotion of ethical business practices in interactions between government, business and other stakeholders. We welcome efforts by our SME Ministers, industries and academics to promote voluntary, industry-specific APEC principles that aid in this effort.

http://klprinciples.apec.org

A Remarkable 10 Year Journey (2013-2014)



Asia-Pacific Economic Cooperation

2014/SMEMM/020a
Agenda item: 6.2.8

2014 APEC Business Ethics for SMEs Forum: Nanjing Declaration on Promoting Ethical Environments in the Medical Device and Biopharmaceutical Sectors Through 2020

Purpose: Consideration
Submitted by: United States

APEC CHINA 2014

21st Small and Medium Enterprises Ministerial Meeting
Nanjing, China
5 September 2014

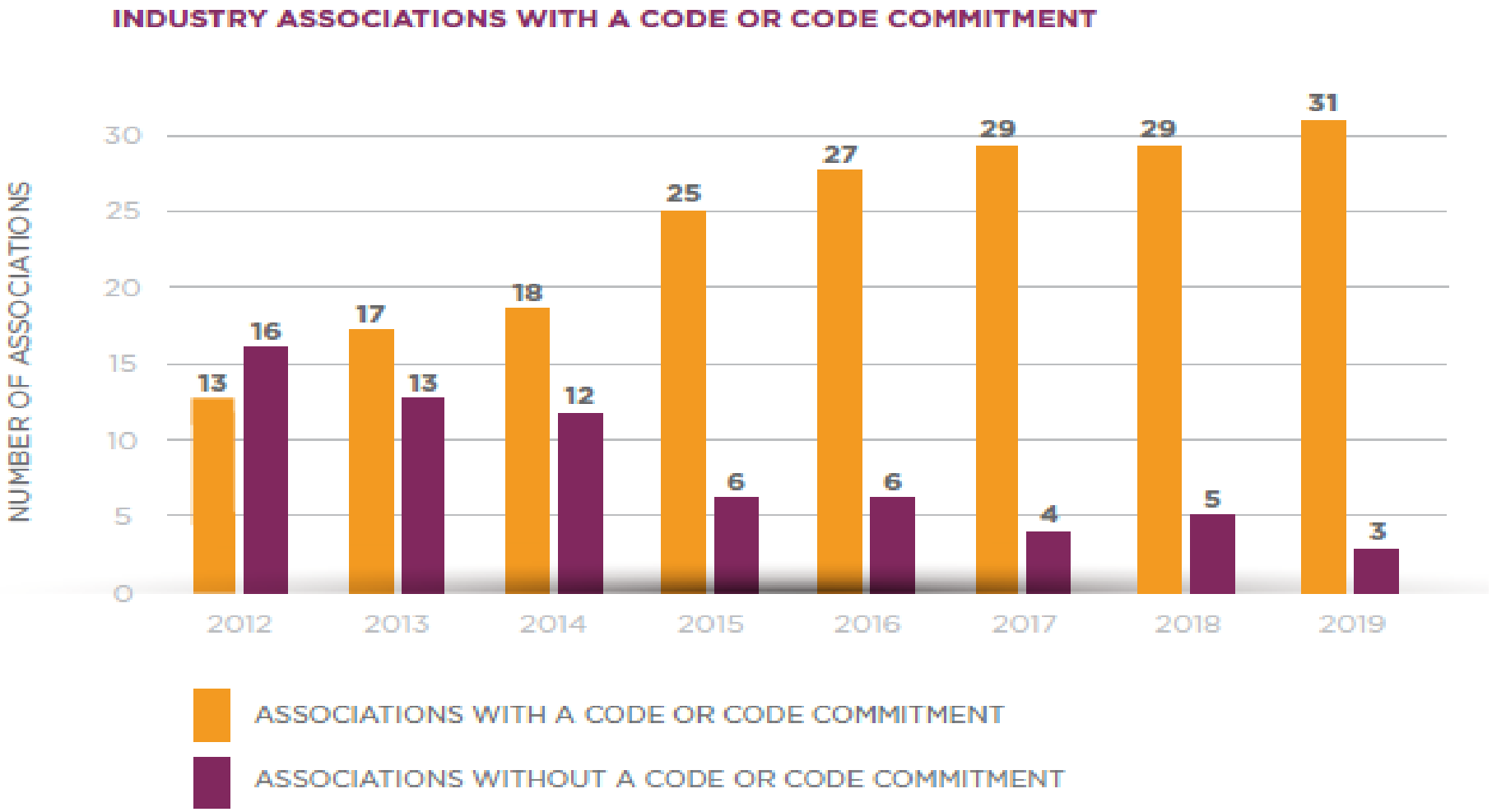
http://klprinciples.apec.org

A Remarkable 10 Year Journey (2015-2017)

A Remarkable 10 Year Journey (2018)

http://klprinciples.apec.org

Rapid Uptake of Medical Device Sector Codes of Ethics



http://klprinciples.apec.org

DISTRIBUTORS PORTAL SESSION

A HISTORY OF STRENGTHENING ETHICAL THIRD PARTY INTERMEDIARY RELATIONSHIPS IN THE MEDICAL DEVICE SECTOR

Ms. Faye Sumner
Chief Executive Officer
Medical Technology Association of New Zealand

THIRD PARTY INTERMEDIARIES AND ETHICS

AdvaMed
Advanced Medical Technology Association

medical technology
ASSOCIATION OF NEW ZEALAND

MedTech Europe
from diagnosis to cure

MTAA Medical Technology
ASSOCIATION OF AUSTRALIA

MEDEC

JOINT GUIDANCE FOR MEDICAL DEVICE AND DIAGNOSTICS COMPANIES ON ETHICAL THIRD PARTY SALES AND MARKETING INTERMEDIARY ["SMI"] RELATIONSHIPS

Version July 10, 2014

- Written Policy and Procedure
- Risk Assessment
- Diligence Programs
- Written Contract
- Training and Education
- Monitor/ Audit
- Appropriate Collective Action

Asia-Pacific Economic Cooperation

2017/SMEMM/016
Agenda Item: 3.3

Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

Purpose: Information
Submitted by: United States

APEC VIET NAM 2017

Asia-Pacific Economic Cooperation

2018/SMEWG47/016
Agenda Item: 13.1

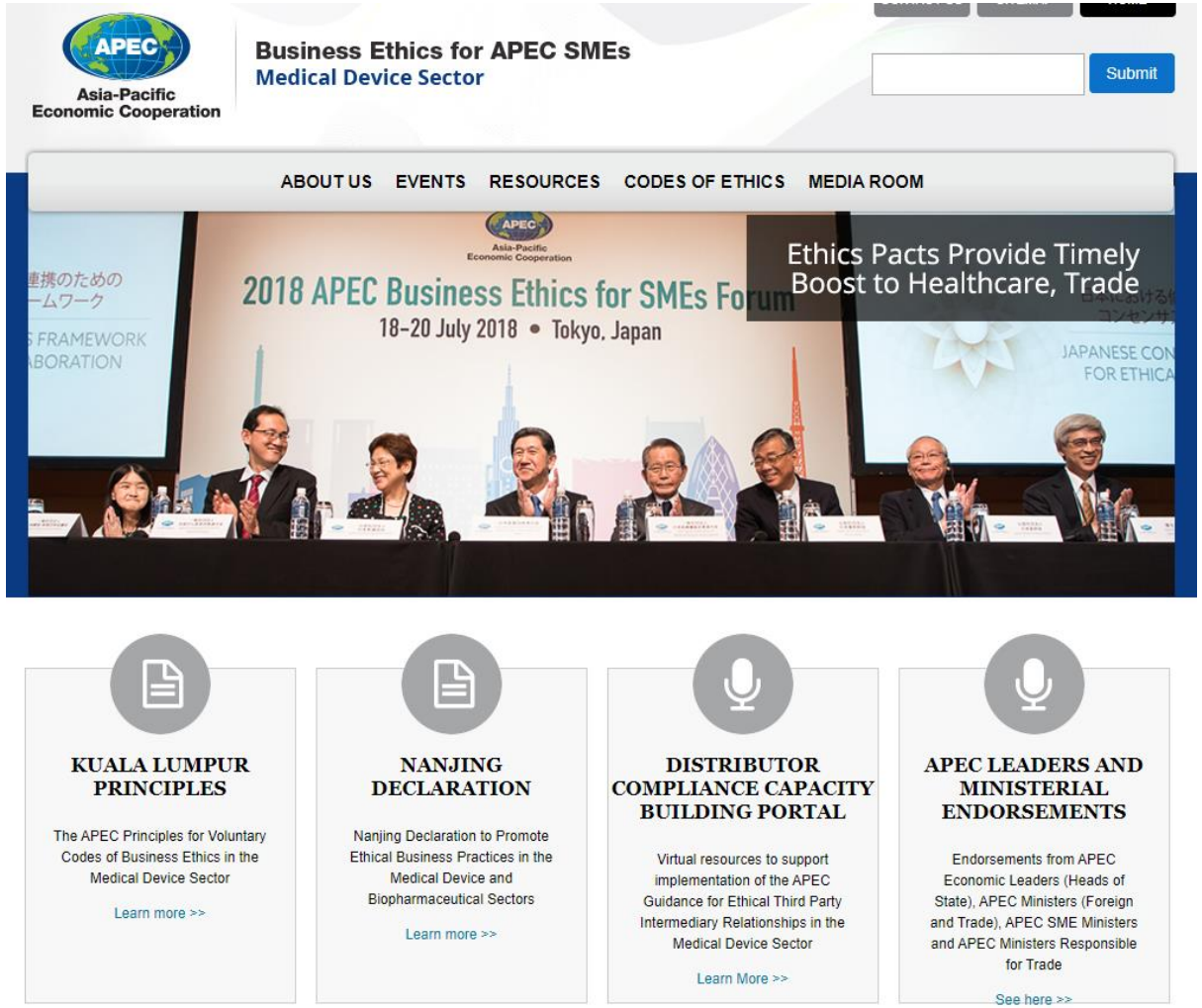
2018 APEC Business Ethics for SMEs Forum - Tokyo Declaration: Promoting Ethical Third Party Intermediary Relationships in the Medical Device Sector Through 2021 (Endorsed)

Purpose: Information
Submitted by: United States

DISTRIBUTORS PORTAL SESSION

WORK PLAN PRESENTATION OF THE MEDICAL DEVICE DISTRIBUTOR'S ETHICAL PORTAL

Ms. Michelle Wagner, Global Lead, Third Party Intermediary and Supply Chain Compliance, Johnson & Johnson



Tokyo, Japan, 20 July 2018

2018 APEC Business Ethics for SMEs Forum

Tokyo Action Plan: Recommendations to Promote Ethical Third Party Intermediary Relationships in the Medical Device Sector through 2021

1. We, representatives from medical device researchers and manufacturers, third party intermediaries (such as distributors, wholesalers, and sales agents), industry and third party intermediaries' associations, healthcare providers and professional organizations, government agencies, health regulatory authorities and patient groups from across the APEC region, convened in Tokyo, Japan from 18-20 July 2018 for the APEC Business Ethics for SMEs Forum.

2. We note that it may often be considered necessary for medical device researchers and manufacturers ("Companies") to contract with third party sales and marketing intermediaries ("Third Party SMIs") to support their activities, enabling ongoing access for patients and healthcare professionals ("HCPs") to innovative, reliable, and effective medical devices. Third Party SMIs may serve an integral role in the medical device sector, and a majority of them are small and medium-sized enterprises that contribute to employment and commercial activity in the APEC region.

3. We reaffirm the APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector[1] ("the Guidance"), recognized by APEC SME Ministers in Ho Chi Minh City, Viet Nam on 15 September 2017. The Guidance advances ethical business practices for SMEs as called for by the APEC Kuala Lumpur Principles[2] (the "KL Principles"), the APEC Nanjing Declaration[3], and the *Business Ethics for APEC SMEs Initiative* ("the Initiative"). The Guidance states that Companies and Third Party SMIs should develop and adhere to codes and compliance programs that embrace the KL Principles and include the following elements: written anti-bribery policy/procedure; risk assessment; diligence program; written contract; training and education; monitor/audit; and appropriate corrective action.

4. Recognizing our shared commitment to ethical interactions that are in the best interest of patients and to the ability of the region's Third Party SMIs to be able to sustainably grow and trade, we agree on a collective vision to promote ethical third party intermediary relationships in the medical device sector.

5. We declare our intention to APEC SME Ministers, APEC Ministers, and APEC Leaders to work towards achieving the following goals. We call upon APEC economies and stakeholders to consider undertaking the following recommendations, respecting the diversity of healthcare systems:

AdvaMed
Advanced Medical Technology Association

Asia-Pacific Economic Cooperation

Business Ethics for APEC SMEs
Medical Device Sector

MEDICAL DEVICE DISTRIBUTORS ETHICS PORTAL

Phase 1: Code Adoption

Phase 2: Communication Tools

Phase 3: Template Policies

Phase 4: Working with Sub-Distributors

Phase 5: Sophistication of Procedures

Phase 1: Code Adoption

Materials and guidance for the company to create its own code of ethics in alignment with relevant industry association codes while also building the company's own compliance and training program

Phase 2: Communication Tools

Materials and guidance for internal and external communication concerning the adoption process and adherence details of the company's code of ethics

Phase 3: Template Policies

Materials and guidance for creating template policies and contracts concerning consultant agreements, meeting sign-in sheets, payment for booth space forms, and anti-trust disclosure language, among others

Phase 4: Working with Sub-Distributors

Template policies, contracts and guidance geared toward working with sub-distributors

Phase 5: Sophistication of Procedures

Materials and guidance on sophisticated record keeping, expense claims, detailed Code provisions, and other related resources

Distributor Compliance Portal

1. **Phase 1 - Code Adoption**
   - Sample Slide Deck - Working with a Code of Ethics - Key Areas for Distributors - PDF
   - APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector
     - English - PDF
     - Japanese - PDF
     - Chinese - PDF
     - Spanish - PDF
     - Vietnamese - PDF
   - Basic Recordkeeping - PDF
   - Employee Training Attendance Form - PDF
   - Sample Code of Conduct Template - PDF
   - Sample Quiz With Answers from MEDEC - PDF
   - Written Contract Guidance - PDF

2. **Phase 2 - Communication Tools**
   - Sample Code of Ethics Brochure - PDF
   - Form TPS Certification - PDF
   - Sample Postcard - PDF
   - HCP Invitation - PDF
   - Notification to Employer Training - PDF

3. **Phase 3 - Template Policies**
   - Sample Compliance Checklist New Hire - PDF
   - Consultant Contract - PDF
   - Form Request Consultant Services - PDF
   - Payment Booth Fees Form - PDF
   - Grants and Donations Form - PDF
   - Sign in sheet HCPs Training - PDF
   - Template Funding Agreement - PDF
   - Written Contract Guidance - PDF

4. **Phase 4 - Working with SubDistributors**
   - Due Diligence Guide Sub Distributor 21 - PDF
   - Sample Compliance Certification Form - PDF
   - TPS Sponsorship Form - PDF
   - Template Agreement Sub Distributors - PDF
   - Pilot Webinar on the Guidance
     - PowerPoint Presentation - PDF
     - Script Overview - PDF
       Note: Delivered 9 July (Auckland, New Zealand) and 10 July (Toronto, Canada)

5. **Phase 5 - Sophistication of Procedures**
   - Accounts Payable Red Flags - PDF
   - 5 Steps to Monitor a Compliance Program24 - PDF
   - Expenses Form - PDF
   - Sample Quick Reference Common Interactions - PDF
   - Policy Template - PDF

6. **Other Documents**
   - Tokyo Action Plan Recommendations to Promote Ethical Third Party Intermediary Relationships
   - Sample Illustrative Code Flow Charts - PDF
   - Sample Info Notice - PDF
   - Sample Business Conduct Reminders - PDF
   - Speaker Agreement - PDF
   - Speaker Agreement - PDF
   - Notification to Employer Consulting - PDF
   - FCPA FAQs - PDF
   - UK Bribery Act Guidance - PDF
   - UK Bribery Act Quick Start - PDF

CONSIDERATIONS

- **Does this approach make sense? Are the five phases of the resources appropriately segmented? Would you make any adjustments or expand upon the kinds of materials that are already indicated?**
- **Who are the right users within SME distributors and third party intermediaries for these resources?**
- **What approaches should be considered in order for industry associations to routinely utilize this resource for the benefit of their member companies? What do associations need to make it work?**
- **The Tokyo Action Agenda calls for a third party intermediary certification model by 2021. How can this be achieved together?**

DISTRIBUTORS PORTAL SESSION

MORNING TEA / COFFEE BREAK

10:45 – 11:15

DISTRIBUTORS PORTAL SESSION

DISTRIBUTOR PERSPECTIVES AND CHALLENGES

Facilitator:

Ms. Michelle Wagner
AUSTRALIA

Roundtable Discussants:

Mr. Eduardo Del Solar
CHILE

Mr. Ma Ensheng
CHINA

Mr. Omar Neyra
PERU

Mr. Bruno Boldrin
BRAZIL

DISTRIBUTORS PORTAL SESSION

NON-INDUSTRY PERSPECTIVES ON DISTRIBUTORS

Ms. Bronwen Taylor
UNITED STATES

Mr. Adrian Cosenza
AUSTRALIA

Ms. Jo Watson
AUSTRALIA

DELEGATES NETWORKING LUNCH (SAN CRISTOBAL A) 13:00 – 14:00

Asia-Pacific Economic Cooperation

APEC CHILE 2019

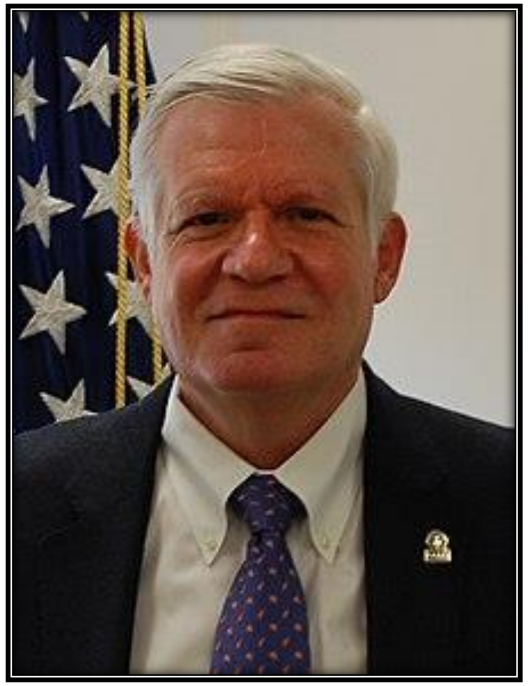
2019 APEC Business Ethics for SMEs Forum

SANTIAGO DE CHILE | 9-10 SEPTEMBER

Coalición Interamericana de Ética Empresarial
SECTOR DE TECNOLOGÍA MÉDICA

Coalização Interamericana de Ética Empresarial
SETOR DE TECNOLOGIA MÉDICA

Inter-American Coalition for Business Ethics
MEDICAL TECHNOLOGY SECTOR



WELCOMING REMARKS AND CODE OF ETHICS LAUNCH BY ASOCIACIÓN DE DISPOSITIVOS MÉDICOS DE CHILE (ADIMECH)

The Honorable Gilbert Kaplan
Under Secretary for International Trade
U.S. Department of Commerce

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MEDICAL TECHNOLOGY SECTOR

WELCOMING REMARKS AND CODE OF ETHICS LAUNCH BY ASOCIACIÓN DE DISPOSITIVOS MÉDICOS DE CHILE (ADIMECH)

Mr. Tulio Oliveira, President, ADIMECH

Regional Vice President – Latin America South
Johnson and Johnson

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COALITION PHOTO WITH THE HONORABLE GILBERT KAPLAN

2019 APEC Business Ethics for SMEs Forum

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MEDICAL TECHNOLOGY SECTOR

CHILEAN MULTI-STAKEHOLDER PERSPECTIVES ON STRENGTHENING ETHICAL BUSINESS PRACTICES

Facilitator:

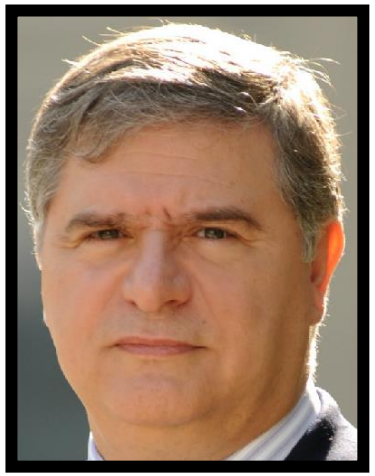
Mr. Alberto Martinez

Roundtable Discussants:

Hon. Javier Macaya Danus

Ms. Cecilia Rodriguez

Dr. Eghon Guzmán



Mr. Jorge Jaraquemada Roblero

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AFTERNOON TEA / COFFEE BREAK

15:30 – 16:00

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COALITION MEETING READOUT FROM BUENOS AIRES (24 JULY 2019)

Mr. Sergio Pinto
Chair, Latin America Compliance Committee,
The Advanced Medical Technology Association

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MEDICAL TECHNOLOGY SECTOR

BEST PRACTICES SESSION ON "EXTERNAL STAKEHOLDER ENGAGEMENT ON THE CODE" BY MEDICAL DEVICE ASSOCIATIONS

Ms. Diane Biagianti
Chief Responsibility Officer
Edwards Lifesciences

WHY should medical device industry associations care about external stakeholder engagement?

- ✓ Because your **members** have committed to follow the code and the association is their collective voice.
- ✓ Because external stakeholders can be an **ally in promoting** ethical business practices.
- ✓ Because external stakeholders may want to **align** there own ethical business practices with yours.
- ✓ Because it may be the only way to address the **"non-member dilemma"**

Inter-American Coalition for Business Ethics
MEDICAL TECHNOLOGY SECTOR

57% Distributed the code beyond the association's members

29% Making code trainings open to non-members

36% Building code awareness through multi-stakeholder initiatives

71% Keen to heighten external stakeholder engagement

HOW should medical device industry associations care about external stakeholder engagement?

- ✓ **Prioritize** as a core activity in effective code implementation
- ✓ Set **measurable commitments** in external engagement on the code
- ✓ Make strong effort to **invite non-member companies** to the association code trainings
- ✓ Meet with peak **healthcare professional organizations and government agencies** at least once per year on the code AND **ask for their views/input** – build genuine collaboration
- ✓ Take the **non-member dilemma** seriously and take action.

DISCUSSION ON WHY AND HOW

- ✓ Do you see other reasons why an association should prioritize external engagement on the code?
- ✓ Do you see other ways in which an association can undertake external engagement on the code?

I LOOK FORWARD TO YOUR IDEAS!

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MEDICAL TECHNOLOGY SECTOR

PUBLIC-PRIVATE PERSPECTIVES ON ETHICAL COLLABORATION FROM THE COMPTROLLER GENERAL OF THE UNION AND THE HEALTH ETHICS INSTITUTE (BRAZIL)

Mr. Alexandre Krügner Constantino
Comptroller General of the Union

Mr. Carlos Gouvea, Etica Saude

Coalición Interamericana de Ética Empresarial
SECTOR DE TECNOLOGÍA MÉDICA

Coalização Interamericana de Ética Empresarial
SETOR DE TECNOLOGIA MÉDICA

Inter-American Coalition for Business Ethics
MEDICAL TECHNOLOGY SECTOR

SUMMARY OF CONCLUSIONS
PREVIEW OF PLENARY

BRING YOUR ID'S TO RECEPTION!

Mr. Andrew Blasi, Director
Crowell & Moring International