

#### Asia-Pacific Economic Cooperation

# APEC Leadership in Heightening Ethical Standards



Asia-Pacific Economic Cooperation

# Why APEC launched the "Business Ethics for APEC SMEs Initiative"

# Dato' Hafsah Hashim

Chief Executive Officer of SME Corporation, Malaysia Co-Chair of the Expert Working Group to Draft The Kuala Lumpur Principles

## Why APEC focused on SMEs and Business Ethics

- Small & Medium Enterprises (SMEs) are the engine of economic growth and will continue to serve as a key driver in the APEC region's economic expansion <u>as long as they are able to operate, trade, and</u> <u>innovate in ethical business environments.</u>
- As a result, the *Business Ethics for APEC SMEs* initiative was launched under the APEC SME Working Group in 2010.
- The initiative was co-sponsored by 16 APEC economies (Australia, Brunei Darussalam, Canada, Hong Kong China, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Peru, The Philippines, Singapore, Chinese Taipei, Thailand, and Vietnam), and strongly supported by the APEC Business Advisory Council (ABAC).

## Why APEC focused on SMEs and Business Ethics

#### **Unethical behavior hurts economies**

- Negative impacts on inflation
- Decreased GDP
- Currency depreciation
- Reduced foreign investment
- Undermined health systems
- Inferior and unsafe Infrastructure

Source: Presentation by Dr. Philip Nichols (Professor of Legal Studies and Business Ethics at the Wharton School of Business) at the APEC Business Ethics for APEC SMEs Workshop in Gifu, Japan – September 2010.

#### **Unethical behavior hurts individual businesses**

- Increases the costs of doing business (through bribes and penalties)
- Lowers sales growth and productivity
- Lowers the ability to enter new markets
- Constricts access to capital
- Over the long term undermines a company's financial growth

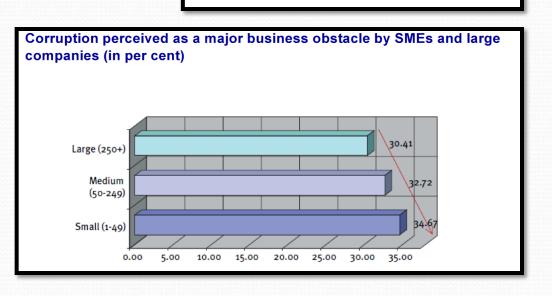
As the Government of Mexico explained at the May 2011 APEC SME Ministerial in Big Sky, Montana (USA), countries with higher perceived corruption tend to have lower real per capita GDP.

Source: World Bank.

# Unethical business environments disproportionately impact SMEs.

- More than 70% of SMEs in transition economies perceive corruption as an impediment to their business.
- One-third of SMEs in transition economies perceive corruption as a major business obstacle.

Source: The Business Environment and Enterprise Performance Survey (BEEPS) - a joint initiative of the European Bank for Reconstruction and Development (EBRD) and the World Bank.



**Relationship between Corruption and Development** 

1 2

(in 97 countries)

15

And more than US\$1 trillion dollars are paid in bribes every year, meaning the cost of corruption is equal to a full THREE PERCENT of world GDP.

Source: World Bank Institute.

# Why APEC developed voluntary codes of ethics

#### Benefits APEC member economies

- Provides a platform for effective industry self-regulation
- Supports government enforcement and anti-corruption efforts

#### Benefits businesses, especially resource-constrained SMEs

- Provides companies with clarity and harmonization in rules and practices
- Allows companies to compete across the region at a reduced cost
- In the case of the biopharmaceutical and medical device sectors, facilitates ongoing innovation

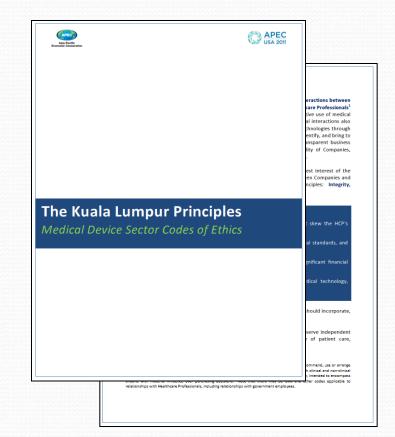
#### Benefits patients

- Fuels advances and promote access to life-saving medicines
- Ensures that decisions are made in the best interest of patients
- Facilitates safe and effective use by ensuring appropriate training

## **The KL Principles**

#### for Voluntary Codes of Business Ethics in the Medical Device Sector

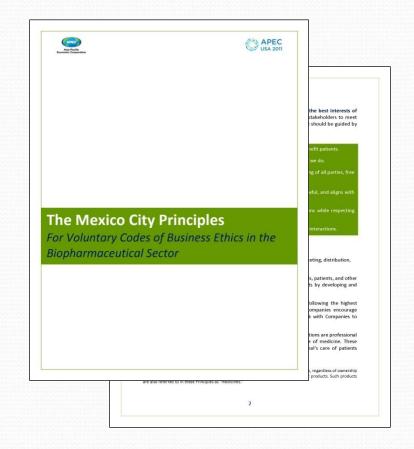
- Recognizes that appropriate and ethical interactions help ensure that medical decisions are made in the best interests of patients
- Assists <u>entire</u> medical device sector and eco-system to align standards for ethical interactions:
  - Companies and industry associations
  - Healthcare professional organizations
  - Industry regulators and/or anti-corruption enforcement authorities



## **The Mexico City Principles**

#### for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector

- Recognizes that appropriate and ethical interactions help ensure that medical decisions are made in the best interests of patients
- Assists <u>entire</u> biopharmaceutical sector <sup>1</sup> and eco-system to align standards for ethical interactions:
  - Companies and industry associations
  - Healthcare professional organizations
  - Industry regulators and/or anti-corruption enforcement authorities



<sup>&</sup>lt;sup>1</sup> For purposes of The Mexico City Principles the term "biopharmaceutical sector" includes companies, regardless of ownership status, that develop, manufacture, market, or distribute pharmaceutical and/or biologic products.



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# **APEC Leadership through Public-Private Partnership**

# Mr. Ivan Ornelas Diaz

Director of International Relation, Ministry of Economy of Mexico Co-Chair of the Expert Working Group to Draft the Mexico City Principles

# **The KL Principles:**

**Developed by Government / Industry / Civil Society - Academia** 

 37 Expert Working Group members representing 18 APEC Member Economies: 21 from Industry, 13 from Government; and 3 from Academia



# **Co-Chaired by Government and Industry**

Dato' Hafsah Hashim Chief Executive Officer of SME Corporation, Malaysia Mr. Chris White Executive Vice President & General Counsel

AdvaMed (United States)



# **The Mexico City Principles:**

### **Developed by Government / Industry / Civil Society - Academia**

 36 Expert Working Group members representing 14 APEC Member Economies: 22 from Industry, 12 from Government; and 2 from Academia



# **Co-Chaired by Government and Industry**

Ivan Ornelas Diaz Ministry of Economy Republic of Mexico Russell Williams President, Rx&D Canada





# Both principles developed and agreed to through collaboration and consensus



The KL & Mexico City Principles: Endorsed by APEC Ministers (Foreign and Trade Ministers) in the U.S. APEC Host Year (2011)



"We applaud the decision of the APEC SME Ministers at Big Sky, Montana in May 2011 to endorse the Kuala Lumpur Principles for Medical Device Sector Codes of Business Ethics. This set of principles for the region's medical devices industry is the first of its kind, and will improve the quality of patient care, encourage innovation, and promote the growth of SMEs that produce medical devices.



We also congratulate the work of the APEC SME Working Group in establishing voluntary sets of ethics principles for the biopharmaceutical sector (the Mexico City Principles) and the construction and engineering sector (the Hanoi Principles). We endorse these three sets of principles and look forward to further APEC efforts to ensure that these principles have a practical impact for small and medium-sized companies."

-- November 2011, Honolulu, Hawaii

The KL & Mexico City Principles: Endorsed by APEC Leaders (Heads of State) in the Russia APEC Host Year (2012)



Corruption is "...a tremendous barrier to economic growth, the safety of citizens, and to the strengthening of economic and investment cooperation among APEC economies...We recognize the important role of business and public-private partnerships in promoting the elaborating of codes of conduct in the private sector and measures to fight corruption, especially measure that support the promoting of ethical business practices in interactions between government, business and other stakeholders."



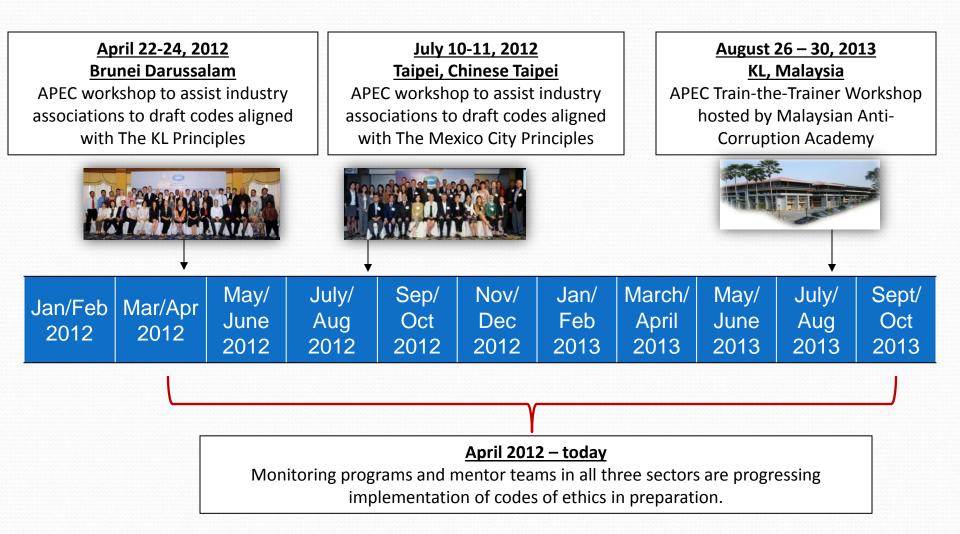
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# Implementation, Implementation, Implementation

## **Mr. Chris White**

Executive Vice President & General Counsel, AdvaMed (United States) Co-Chair of the Expert Working Group to Draft the Kuala Lumpur Principles

## **Capacity building to implement The KL and Mexico City Principles**



## **KL Train-the-Trainer Workshop Objectives**

- A. Build common, region wide:
  - Awareness of anti corruption trends applicable to the industry; and
  - Understanding of device sector's top compliance challenges.

B. Build technical compliance skills necessary to organize, manage and drive effective device company compliance programs.

## KL Train-the-Trainer Workshop Objectives (continued)

C. Develop economy-specific action plans to increase Code adoption among industry members, and to increase awareness among HCPs, including

Conducting at least two local trainings before August 2014 (with at least one held in 2013), to expand the number of ethics practitioners

D. Form APEC's largest network of ethics compliance practitioners and champions, committed to regular best practices exchange, code harmonization and compliance excellence

# Make Tools Available to Facilitate Code Adoption & Best Practices

		Codes of Ethics - APEC-EWG ×
	C → D - A = C × A A A C-EWG     File Edit View Favorites Tools Help	File Edt View Feveretes Tools Hep  Asia-Pacific Economic Cooperation
ि https://sites.google.com/s/legit.skramed.org/spec-eng/code-of-er P = क्षे डि C X ाि Outrach & Eductional Re Edit. View Favorites Tools Help	Asia-Pacific Economic Cooperation	APEC Train-The-Trainer Workshop Codes of Ethics Outreach & Educational Resources Medical Device Codes of Ethics (by Country & Association)
Asia-Pacific Economic Cooperation	Kuala Lumpur, Malaysia: 26-30 August 2013	Approved and finalized codes of ethics for the medical device sector by country and association.  Australia MTAA Medical Technology Industry Code of Practice; Published
APEC Train-The-Trainer Workshop Codes of Ethics Outreach & Educational Resources	Apec Train-the-Trainer Workshop for Voluntary Codes of Business Ethics in the Medical Device, Biopharmaceutical, and Construction & Engineering Sectors. The Malaysia Anti-Corruption Academy (MACA) & Malaysian Institute of Integrity (IIM)	(MTAA)         December 2012 (8th Edition).           PDF         Canada         MEDEC Code of Conduct on Interactions with Healthcare           (MEDEC)         Professionals; Published October 2012.           PDF         PDF
uutreach & Educational Resources eipful sample materials. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Fusce dignissim tin pero, eu scelerisque nisi pulvitaria ut. Morbi dignissim, est eget pellentesque feuglar, libero orci temp	Program Program Agenda for the Medical Device Sector Workshop. DOC	Hong Kong, China HKMHDIA Medical Device marketing Practice Guideline; (HKMHDIA) Published November 2011. PDF
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rtor id sodales pretium, nunc nibh molestie lectus, quis tempor ligula mi vel tortor. Sunshine Brochure for physicians detailing the Physician <u>PDF</u>	Shuttle Schedule of police escorted shuttle service for conference DOC Schedule attendees.	(JFMDA) Published March 2005. HTML Korea KMDIA Fair Competition Code of Transactions of Medical
Brochure for Payments Sunshine Act. Physicians	Key Documents The Kuala Lumpur (KL) Brindiales for Medical Davides DDE	(KMDIA) Devices; Published December 2011. PDE
Sunshine Brochure for teaching hospitals detailing the EDE Brochure for Physician Payments Sunshine Act. Hospitals	The Kuala Lumpur Principles (The KL Principles) The Kuala Lumpur (KL) Principles for Medical Device PDE (The KL Principles) Sector Codes of Business Ethics.	Malaysia AMMI Codes of Ethics; Published June 2013 (Version 1). (AMM1) <u>PDE</u>
AdvaMed Code of thics Brochure         Brouchure to help explain the AdvaMed Code of Ethics on Interactions with Healthcare Professionals	Sample Code of the Sample code of Ethical Conduct based on the KL DOC KL Principles Principles.	Mexico         AHID Code of Interactions with Healthcare Professionals;           (AMID)         Published February 2013.           DDE         DDE
IdvaMed Code         Overview of the revised AdvaMed Code of Ethics on PDE           reining Sildes         Interactions with Health Care Professionals	Comparison of Gift Provisions of APEC Economies Comparison document of the gift provisions within the DOC various code of ethics of various countries/associations.	New Zealand         MTANIZ Code of Practice; Published July 2013 (6th Edition).           (MTANZ)         EDE
ATAA Code A brochure of the Medical Technology Industry EDE Code of Practice license	Compendium for Ethical Codes of APEC         Compendium spreadsheet that compares the APEC         XLS           Medical Device         Medical Device Associations Code of Ethics.         Medical Device Associations	
MTAA Code A postcard that summarizes the Medical Technology <u>PDF</u> Postcard Industry Code of Practice		
MTAA Company A templated slide deck for MTAA member EDE Training Slide companies to conduct introductory training on the Deck Template code of foractice		

# Make Tools Available to Facilitate Code Adoption

Donations and Research and Education Grant

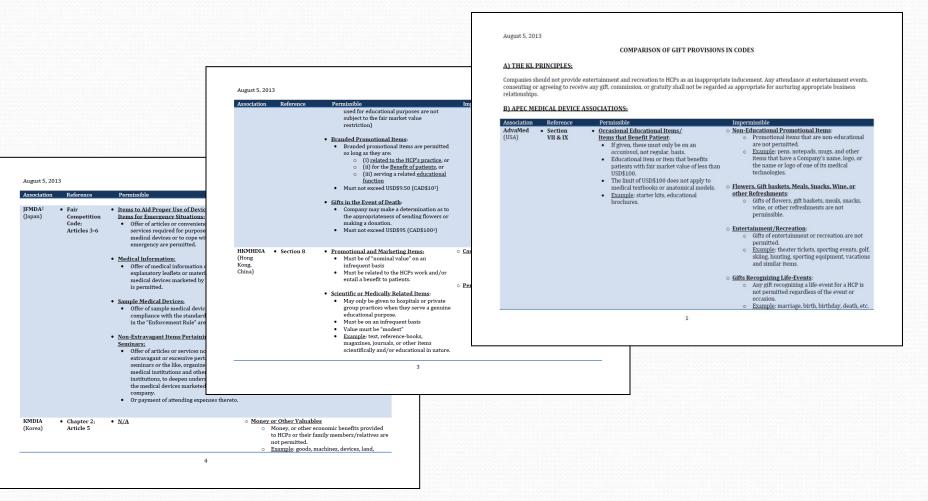
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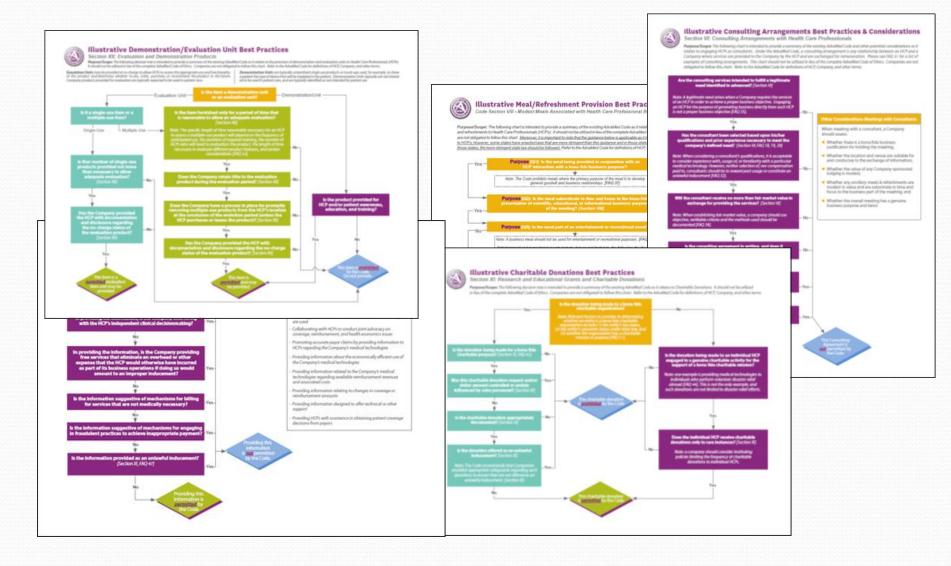
Country	Association	Version	Purpose of Code & General Provisions				Third Party Educational Programs	Company- Organized Education and Training	Sales and Promotional Meetings	Educational Items	
Australia		Approved	x	x	_		x	x		x	1
	No Association				n Ensuring						
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	CAMDI				Impleme	entation					4
	CAME		-		×						4
Chinese Taipei											4
Hong Kong, China			x		x						4
	GAKESLAB	Approved	x				x	x		x	4
	JFMDA	Approved						x	x		+
	KMDIA	Approved	x	x			x	x	x	x	+
Malaysia	MMDA	Draft	x	x			x	x	x		4
Malaysia	AMMI	Approved	x	x			x	x	x	x	+
Mexico	AMID	Approved	x	x	x	K .	x	x	x	x	t
New Zealand	MTANZ	Approved	x	x			x	x	*	x	+
Papua NG	No Association				x	к					t
Peru	COMSALUD	Approved	x	x	x	ĸ	x	x	x	x	Ŧ
Philippines	PAMDRAP				x	ĸ	-		-	-	t
	IMEDA	Approved	x	x			x	x	x	x	Ť
Singapore		Final	x	x	x	ĸ	x	x	x	x	1
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United States	ADVAMED	Approved	x	x			×	x	x	x	1

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# Make Tools to Benchmark Regional Practices: Gift/Entertainment Code Provisions



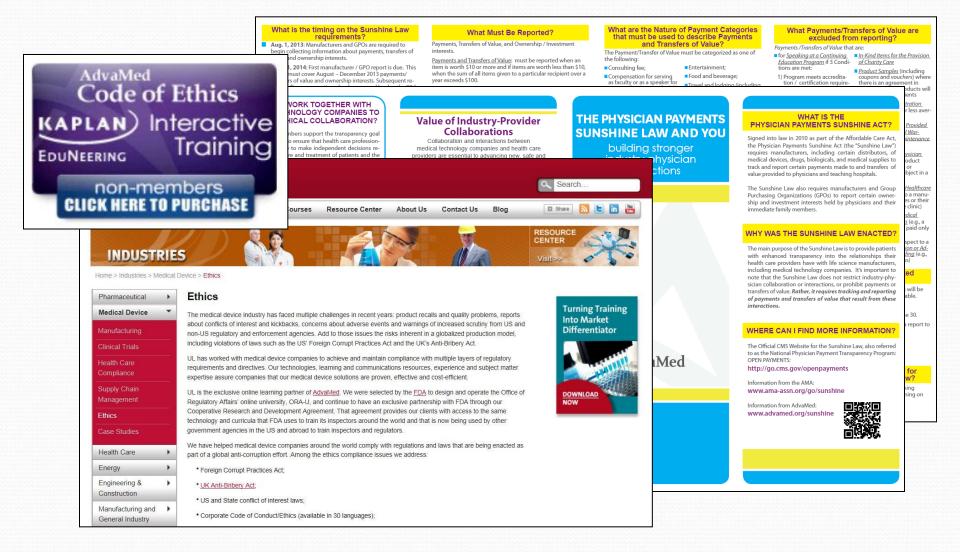
# Make Tools Available to Communicate Best Practices



## Make Tools Available to Address Emerging Risks: Managing Third Party Distributor Risk



# Make Tools Available to Train and Educate



# **Make Tools Available to Implement Good**

## Governance

			XII. NEXT MEETING	2333	
Medical Device Industry Association Governance Toolkit Draft Governance Checklist		XIII. ADJOURNMENT			
CHECKLIST OF KEY GOVERNANCE DOCUMENTS, POLICIES, AND PRINCIPLES		AIII. ADJOURNMENT	1		
GOVERNANCE DOCUMENTS				10000	
Articles of Incorporation			AGENDA FOR INAUGURAL BOARD MEETING		
Bylaws			OF		
All Amendments to Articles and Bylaws			[ORGANIZATION]		
Code of Ethics				1000	
GOVERNANCE POLICIES			[Date, Location]	0000	
SOVER MERCE FOR CHES					
Conflict of Interest			I. WELCOME		
Antitrust/Open Competition			II. ELECTION OF BOARD MEMBERS		
Dues			Resolution: Approving Board Members and Specified Terms		
Membership			III. ELECTION OF INITIAL OFFICERS	1993	
GOVERNANCE PRINCIPLES			Resolution: Approving Initial Officers		
Conducting Meetings Based Upon Agendas Circulated in Advance	_		IV. DISCUSSION AND APPROVAL OF MISSION STATEMENT		
			Resolution: Approving Mission Statement of [Organization]		
Keeping Minutes of Board and Committee Meetings			V. APPROVAL OF BYLAWS	1993	
Transparent Decisionmaking			Resolution: Approving Bylaws of [Organization]		
Board Approval of Key Initiatives and Material Expenses			VI. APPROVAL OF CONFLICT OF INTEREST POLICY		
Board Consideration and Approval of Annual Budget			Resolution: Approving Conflict of Interest Policy	1999	
Annual Audits by Third Party				1999	
Confidentiality on Association Matters			VII. APPROVAL OF POLICY AGAINST RESTRICTING COMPETITION		
Purchasing Insurance for Directors and Staff			Resolution: Approving Policy Against Restricting Competition		
-			VIII. MEMBERSHIP DEFINITIONS AND RECRUITING		
			IX. FUNDRAISING		
			A. Discussion and Approval of Dues Policy	2003	
			Resolution: Approving Dues Policy	2363	
AdvaMed	Medical Technology		B. Discussion of other Fundraising Methods		
Advanced Medical Technology Association Medical technology	ASSOCIATION OF AUSTRALIA		X. COMMITTEE ASSIGNMENTS		
			XI. NEW BUSINESS		



#### Asia-Pacific Economic Cooperation

# What's next?

# **Mr. Russell Williams**

President, Rx&D (Canada) Co-Chair of the Expert Working Group to Draft the Mexico City Principles

# Involving ALL stakeholders in order to promote an ethical health care environment

### Today, we look forward to ...

- Building one another's awareness of APEC and economyspecific initiatives to foster ethical environments in the medical device and biopharmaceutical sectors
- Discussing how we can work more closely together to promote an ethical health care environment in our economies and in the APEC region.
- Better understanding each of our unique and important roles in promoting ethical health care environments.
- Identifying challenges to -- and uncovering opportunities for -strengthening ethical interactions