Asia-Pacific Economic Cooperation

APEC PERU 2016

2016 APEC BUSINESS ETHICS FOR SMES FORUM

LIMA, PERU | 5-6 SEPTEMBER 2016

Biopharmaceutical Sector Workshop

Asia-Pacific Economic Cooperation

Business Ethics for APEC SMEs
Biopharmaceutical Sector

Opening Session, 8:30 – 9:30

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Introductory Remarks

Ms. Lynn Costa
Project Overseer, Business Ethics for APEC SMEs Initiative,
U.S. Department of Commerce

Participant Introductions and Status Updates by Associations

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Business Ethics for APEC SMEs
Biopharmaceutical Sector

Opening Session, 8:30 – 9:30

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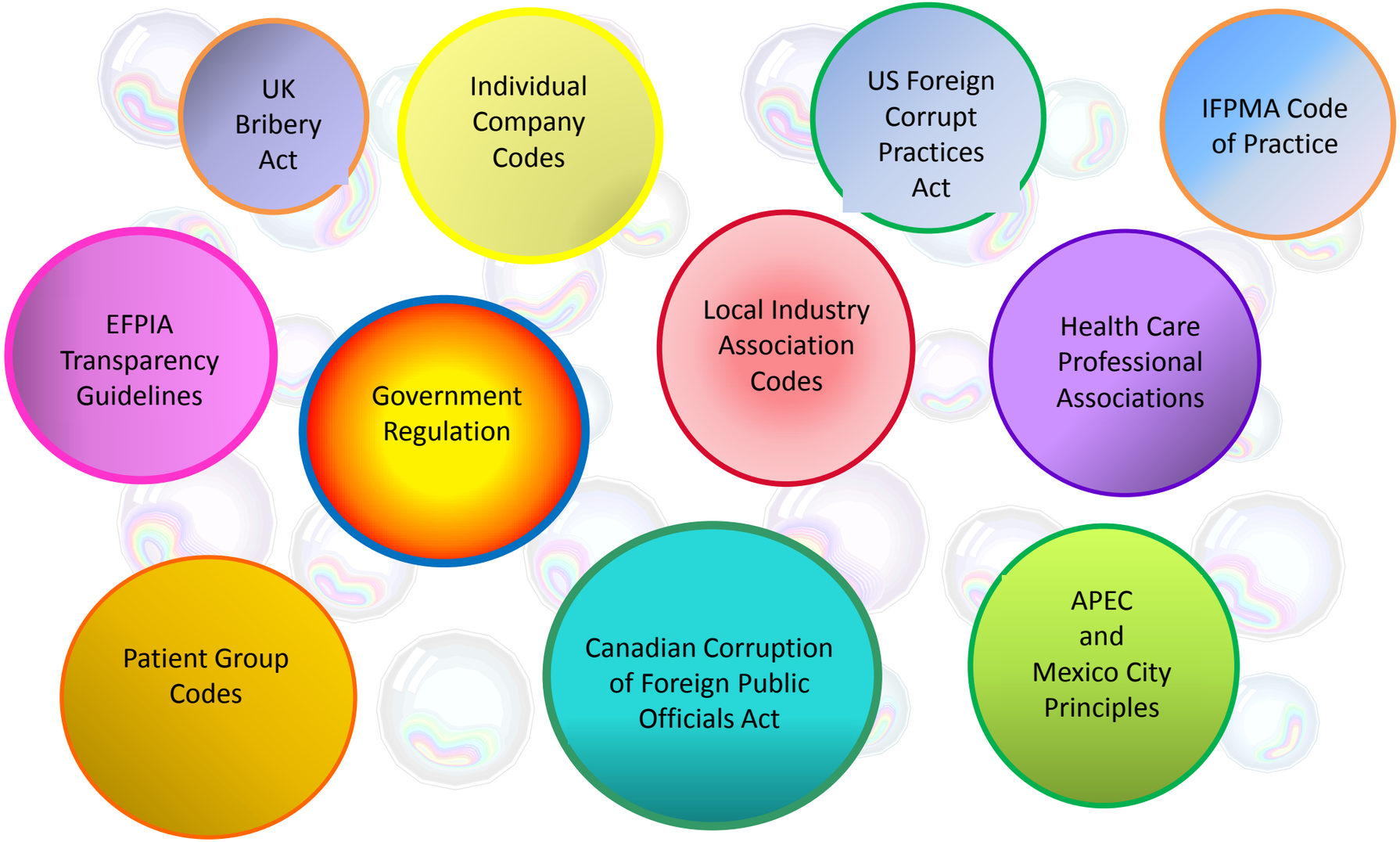
Progress and Emerging Trends in Ethical Business Practices

Mr. Russell Williams
Industry Co-Chair, APEC Biopharmaceutical Working Group on Ethics

Complex Environment



Process

- The first part of the exercise would require that each economy(Industry, Governments and Stakeholders) identify on the matrix where it believes the Biopharmaceutical Industry exists on the matrix in relation to self-regulation.
- The second exercise would ask “Where the Economy would like to see the Biopharmaceutical Industry exist on the matrix in relation to self-regulation?”.
- All stakeholders in the room would be asked to participate and make their own evaluations of where they see their economy.

Government Participation

High		
Low		
	Low	High

Industry Self-Regulation

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Business Ethics for APEC SMEs
Biopharmaceutical Sector

Session One, 9:30 – 11:00

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Communicating the Value of High Standard Ethics in Enterprise & Successful Strategies for Low Cost Implementation of your Code of Ethics

Perspectives from Enterprise

Mr. Beau Agana, President, Pharex HealthCorp (The Philippines)

Dr. José Roberto C. Pereira, Business Development and Innovation Director, Biolab, Inc. (Brazil)

Perspectives from Industry Associations

Dr. Xu Ming, Vice President, CCCMHPIE (China)

Dr. Juan Francisco Millán Soberanes, CETIFARMA (México)

Session Facilitator

Karen Eryou, Senior Director , Corporate Compliance (APAC), UCB Pharma (China)

Session Exercise

Rotating Breakout Tables
30 Minutes Per Rotation

APEC Biopharmaceutical Workshop Structure for Session 1

Pre-Workshop

Needs Assessment Survey Results:

Mentors needed in all areas
Identified Areas Tool Kits

Communications

Handling Objections

Government Relations

Reputation

Next Steps for Code Implementation

Workshop

Based on outcome of survey, set up "expert forums" (i.e. 2-3 of our industry mentors) who are expertise on a topic identified in survey (i.e. influencing skills) listen to association/s challenges and troubleshoot, offer advice.

Association completes and "action card" listing 2-3 actions based on expert advice

After 30 minutes, facilitator rings a bell, and association physically move to another table for their next consultation with a new expert forum.

In an hour, an association could rotate through 2 experts forums to seek advice on 2 different challenges.

Output, Challenges, Benefits

Session Output: each association develops 2-3 actions per challenge area that will move them along on the road to code effectiveness once back to their country.

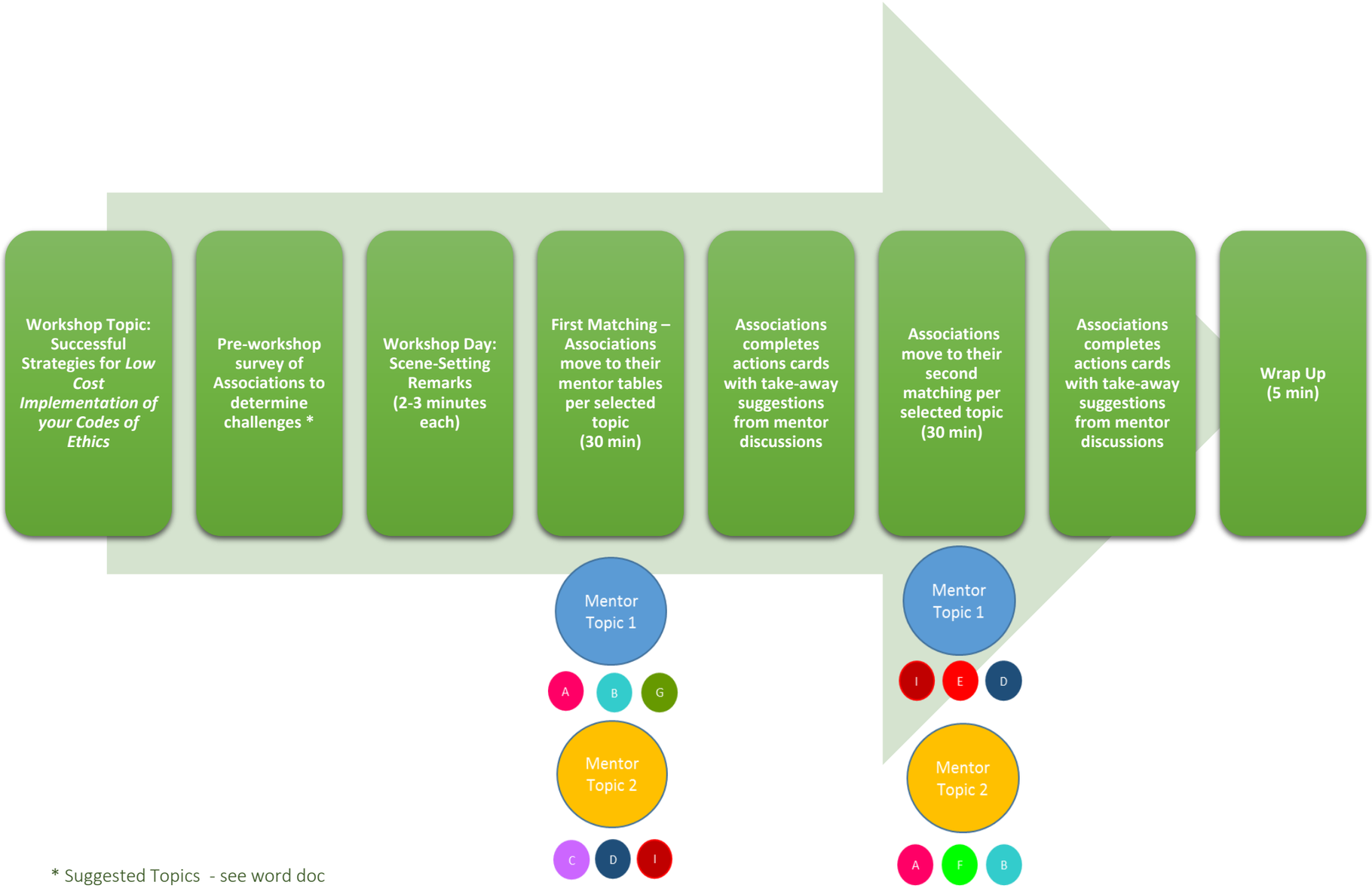
Challenges:

- Clear explanation for Associations on module
- Table cards to identify table topics
- Good classroom organisation and instructions (slides and mentors prepared)

Benefits:

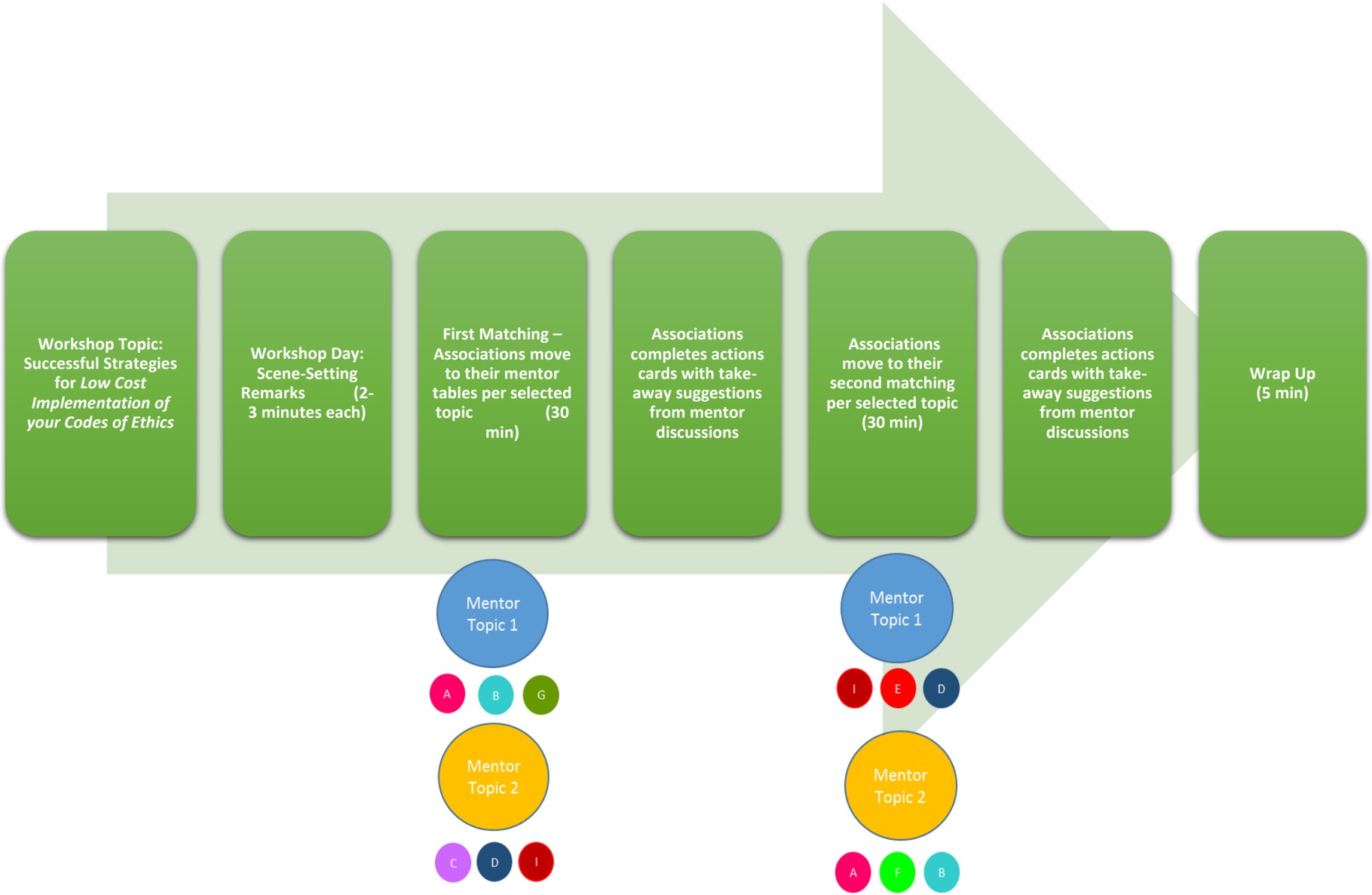
- Attendees moving about and meeting many people in short timeframe
- Will help socialize the group for later conversations

APEC Biopharmaceutical Workshop Structure for Session 1
Pre-Survey to Workshop Day



* Suggested Topics - see word doc

APEC Biopharmaceutical Workshop Structure for Session 1 Workshop Day



Mentor Assignments and Tables

Topic	Tables	Mentor	Mentor	Mentor/ Floaters
Handling objections	A, B	Neil (A)	Katsumi (B)	
Government relations	C, D	Isabela (C)	Sabrina Chan (D)	
Next Steps on Code Implementation	E, F	Chrisoula (E)	Ricardo Moreno (F)	
Tool kits	G-H	Ricardo Muza (G)	Silvia (H)	
Communications	I, J	Claudia (I)	Reiner (J)	
Reputation	K, L	Rosina (K)	Sujata (L)	
Additional Support: (in case of extra table or support needed)	M-O	Irina (M)	Laura (N)	Cecilia (O)

30 minutes session and Attendees move to another table
Mentors remain at assigned table

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Business Ethics for APEC SMEs
Biopharmaceutical Sector

Session Two, 11:00 – 12:00

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Leading Multi-Stakeholder Perspectives in Peru

Industry Association Perspectives
Mr. Gabriel Apestegui Castro, Board of Directors, ADIFAN
Ms. Maria Aste, President, ALAFARPE
Mr. Carlos Leigh Vigil, Executive President, ALAFAL

Health Care Professional Perspectives
Dr. Alberto Gayoso Villaflor, President, Medicines Committee, College of Physicians of Peru
Dra. Amelia Villar López, Dean, College of Pharmacists

Patient Perspectives
Ms. Karla Ruiz de Castilla Yabar, Chief Executive Officer, Esperantra
Mr. Julio Cesar Cruz Requenes, President, PROSA

Government Perspectives
Dr. Ruben Espinoza, Director-General, DIGEMID, Ministry of Health

Moderator
Ms. Kathleen Hamann
Partner, Pierce Atwood,
Former International Policy Counsel,
U.S. Department of Justice
The United States

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LUNCH BREAK
NEXT SESSION AT 1:00 PM

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Session Three, 1:00 – 3:30

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Interactive Case Exercises

CASE STUDY ONE (30 Minutes):
Interactions with Healthcare Professionals

Presented by: Mr. Katsumi Kojima, JPMA (Japan)
Ms. Isabella Pires, Eli Lilly (Brazil)

Case Review: 15 Minutes
Case Feedback by Tables: 15 Minutes

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Session Three, 1:00 – 3:30

APEC PERU 2016

Interactive Case Exercises

CASE STUDY TWO (45 Minutes):
Interactive, Multi-Stakeholder Scenario

Presented by: Ms. Laura Giussani, Eli Lilly (United States)
Ms. Sabrina Chan, HKAPI (Hong Kong, China)
Mr. KP Tsang, IAPO (Hong Kong, China)
Dr. Philip Ashok, Malaysian Medical Association (Malaysia)
Ms. Claudia Hernandez Loustalot Laclette, AbbVie (Mexico)
Ms. Silvia Rodriguez, Eli Lilly (Mexico)

Overview

1. In this exercise, you will receive information and sketches framing the case scenario

2. Case questions will be presented and each table will discuss the response

3. We will conclude the case by sharing feedback from each tables and highlighting our key takeaways

Exercise / Scenario

- A small biopharmaceutical company (Farma-Star) in your economy is about to launch a new product.

- Given the nature of the disease this product treats, and how the product works, Farma-Star is not only focused on the patient but also on the caregivers.

- It is important this new product be a commercial success, based on the revenue expectations Farma-Star leaders have expressed to the board and their investors.

Dialogue

- **Patient Organization #1:**
  The new medication is so exciting for all of us!

- **Patient Organization #2:**
  It will be critical to understand the roles of caregivers and also be actively engaged on how the medicine will be priced.

- **Health Care Professional Organization #1:**
  When is the National Congress? It will be an opportunity to continue our medical education and ensure we remain key players. Perhaps the biopharmaceutical company can help.

- **Health Care Professional Organization #2:**
  I am sure the company with this new product will want to invest.

Questions (15 Minutes)

- **What are some possible plans the Patient Organizations, the Medical Associations and Farma-Star could undertake to ethically achieve their goals? Discuss for 5-7 minutes.**

- **What are your thoughts on the proposals below? Each group should pick one and discuss for 5-7 minutes.**

1. **Farma-Star** considers funding and partnering with the Patient Organizations for a disease-awareness fair; says patients' willingness to give testimonials would increase the chance of product success.

2. **Farma-Star** invites the Patient Organizations to a focus group for both patients and caregivers, to better understand their needs; reasonable expenses for participants would be covered by Farma-Star.

3. **The Medical Associations** ask Farma-Star to sponsor its directors (HCPs) to the National Congress; in the request letter they mention the HCPs can have a key role in government formulary decisions.

4. **The Patient Organization** reach out to Farma-Star for a grant to create educational materials on disease awareness.

GAME CHANGER!

- **Development #1**: A reputable newspaper has released an expose on how HCPs are being given special privileges by biopharmaceutical companies to speak well about new products.

- **Development #2**: The Patient Organizations mention they would prefer not to disclose grant funding from Farma-Star to avoid the impression of undue influence in their activities.

Do these developments impact the plans your group has suggested or the proposals you have discussed? If yes, what alternatives can you offer to help the parties ethically achieve their goals?

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Business Ethics for APEC SMEs
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Session Three, 1:00 – 3:30

APEC PERU 2016

Interactive Case Exercises

EXERCISE THREE (45 Minutes):
Role of Government in Facilitating Voluntary Ethical Practices

Presented by: Mr. Russell Williams, Co-Chair, APEC Biopharm WG on Ethics
Ms. Chrisoula Nikidis, Innovative Medicines Canada

Objective of Exercise Three

- The objective of the exercise is to carry out a discussion on self-regulation and the role governments may play in supporting this process.
- The discussion will focus on the values and challenges around self –regulation and, recognizing that in some instances pure self-regulation is not always an option.
- The relationship of government and stakeholders in industry self-regulations in the Biopharmaceutical sector area varies.
- Industry has the responsibility to earn the respect and trust required for self-regulation.

Process

- The first part of the exercise would require that each economy(Industry, Governments and Stakeholders) identify on the matrix where it believes the Biopharmaceutical Industry exists on the matrix in relation to self-regulation.
- The second exercise would ask “Where the Economy would like to see the Biopharmaceutical Industry exist on the matrix in relation to self-regulation?”.
- All stakeholders in the room would be asked to participate and make their own evaluations of where they see their economy.

Mexico City Principles

APEC Economies should:

- Develop and make known clear, distinctive, accountable and comprehensive policies on procurement processes and procedures.
- Encourage industry regulators and/or anti-corruption enforcement authorities to endorse and support the above Principles and national and local industry codes of ethics, where appropriate.
- Encourage Companies to adhere to the above Principles and national and local industry codes of ethics.
- Formulate and promote clear laws and regulations that are objectively applied.
- Work to advance ethical collaborations consistent with the above Principles regionally, through regular communication, joint policies, joint capacity building activities, and other forms of collaboration.

Nusa Dua Statement

The Nusa Dua Statement issued on 3 September 2013 established that each stakeholder has a unique and important role to promote ethical healthcare environments, including:

- ***Health Ministries and Health Regulatory Agencies*** should recognize the value of industry codes of ethics and encourage all stakeholders to support ethical principles, such as the APEC principles, and national and local industry codes of ethics.

Nanjing Declaration

- **For Governments**: Support and endorse local partnerships in APEC economies between relevant government ministries/ agencies and the medical device and biopharmaceutical industries to advance industry's voluntary efforts to strengthen ethical business practices.

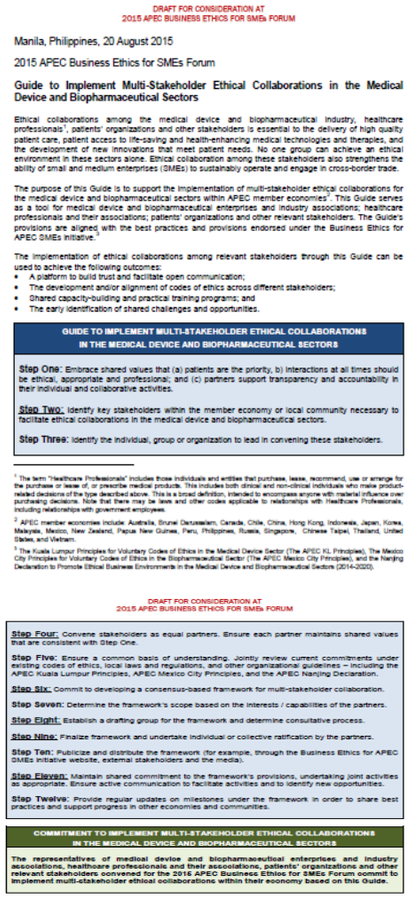
Self-Regulation

- Self-regulation is a privilege and not a right;
- The private sector relies on self-regulation to address a range of issues, from establishing industry standards, to developing and applying codes of professional ethics, to ensuring consumer confidence.;
- Despite its widespread use, some policymakers are skeptical of the efficacy and credibility of self-regulation;
- Regulatory styles vary considerably from country to country and industry to industry.

Governments may play a positive role in voluntary self-regulation by

- Encouraging self-regulatory action, by urging businesses to develop self-regulatory schemes;
- Providing advice, by contributing to the development of guidance on how certain issues may best be addressed,
- Supporting compliance, by encouraging adherence
- Authorizing the programs, to ensure their suitability and/or compliance with laws and regulations,
- Monitoring the effectiveness and impact of schemes,
- Promoting multi-stakeholder dialogue, to take part in the development and/or monitoring of schemes and
- Publicly endorse successful self-regulatory efforts

Multi-Stakeholder Ethical Collaborations



DRAFT FOR CONSIDERATION AT
2015 APEC BUSINESS ETHICS FOR SMEs FORUM

Manila, Philippines, 20 August 2015

2015 APEC Business Ethics for SMEs Forum

Guide to Implement Multi-Stakeholder Ethical Collaborations in the Medical Device and Biopharmaceutical Sectors

Ethical collaborations among the medical device and biopharmaceutical industry, healthcare professionals[1], patients' organizations and other stakeholders is essential to the delivery of high quality patient care, patient access to life-saving and health-enhancing medical technologies and therapies, and the development of new innovations that meet patient needs. No one group can achieve an ethical environment in these sectors alone. Ethical collaboration among these stakeholders also strengthens the ability of small and medium enterprises (SMEs) to sustainably operate and engage in cross-border trade.

The purpose of this Guide is to support the implementation of multi-stakeholder ethical collaborations for the medical device and biopharmaceutical sectors within APEC member economies[2]. This Guide serves as a tool for medical device and biopharmaceutical enterprises and industry associations; healthcare professionals and their associations; patients' organizations and other relevant stakeholders. The Guide's provisions are aligned with the best practices and provisions endorsed under the Business Ethics for APEC SMEs Initiative.[3]

The implementation of ethical collaborations among relevant stakeholders through this Guide can be used to achieve the following outcomes:

- A platform to build trust and facilitate open communication;
- The development and/or alignment of codes of ethics across different stakeholders;
- Shared capacity-building and practical training programs; and
- The early identification of shared challenges and opportunities.

GUIDE TO IMPLEMENT MULTI-STAKEHOLDER ETHICAL COLLABORATIONS IN THE MEDICAL DEVICE AND BIOPHARMACEUTICAL SECTORS

Step One: Embrace shared values that (a) patients are the priority, b) interactions at all times should be ethical, appropriate and professional; and (c) partners support transparency and accountability in their individual and collaborative activities.

Step Two: Identify key stakeholders within the member economy or local community necessary to facilitate ethical collaborations in the medical device and biopharmaceutical sectors.

Step Three: Identify the individual, group or organization to lead in convening these stakeholders.

[1] The term "Healthcare Professionals" includes those individuals and entities that purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe medical products. This includes both clinical and non-clinical individuals who make product-related decisions of the type described above. This is a broad definition, intended to encompass anyone with material influence over purchasing decisions. Note that there may be laws and other codes applicable to relationships with Healthcare Professionals, including relationships with government employees.

[2] APEC member economies include: Australia, Brunei Darussalam, Canada, Chile, China, Hong Kong, Indonesia, Japan, Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, Philippines, Russia, Singapore, Chinese Taipei, Thailand, United States, and Vietnam.

[3] The Kuala Lumpur Principles for Voluntary Codes of Ethics in the Medical Device Sector (The APEC KL Principles), The Mexico City Principles for Voluntary Codes of Ethics in the Biopharmaceutical Sector (The APEC Mexico City Principles), and the Nanjing Declaration to Promote Ethical Business Environments in the Medical Device and Biopharmaceutical Sectors (2014-2020).

DRAFT FOR CONSIDERATION AT
2015 APEC BUSINESS ETHICS FOR SMEs FORUM

Step Four: Convene stakeholders as equal partners. Ensure each partner maintains shared values that are consistent with Step One.

Step Five: Ensure a common basis of understanding. Jointly review current commitments under existing codes of ethics, local laws and regulations, and other organizational guidelines – including the APEC Kuala Lumpur Principles, APEC Mexico City Principles, and the APEC Nanjing Declaration.

Step Six: Commit to developing a consensus-based framework for multi-stakeholder collaboration.

Step Seven: Determine the framework's scope based on the interests / capabilities of the partners.

Step Eight: Establish a drafting group for the framework and determine consultative process.

Step Nine: Finalize framework and undertake individual or collective ratification by the partners.

Step Ten: Publicize and distribute the framework (for example, through the Business Ethics for APEC SMEs initiative website, external stakeholders and the media).

Step Eleven: Maintain shared commitment to the framework's provisions, undertaking joint activities as appropriate. Ensure active communication to facilitate activities and to identify new opportunities.

Step Twelve: Provide regular updates on milestones under the framework in order to share best practices and support progress in other economies and communities.

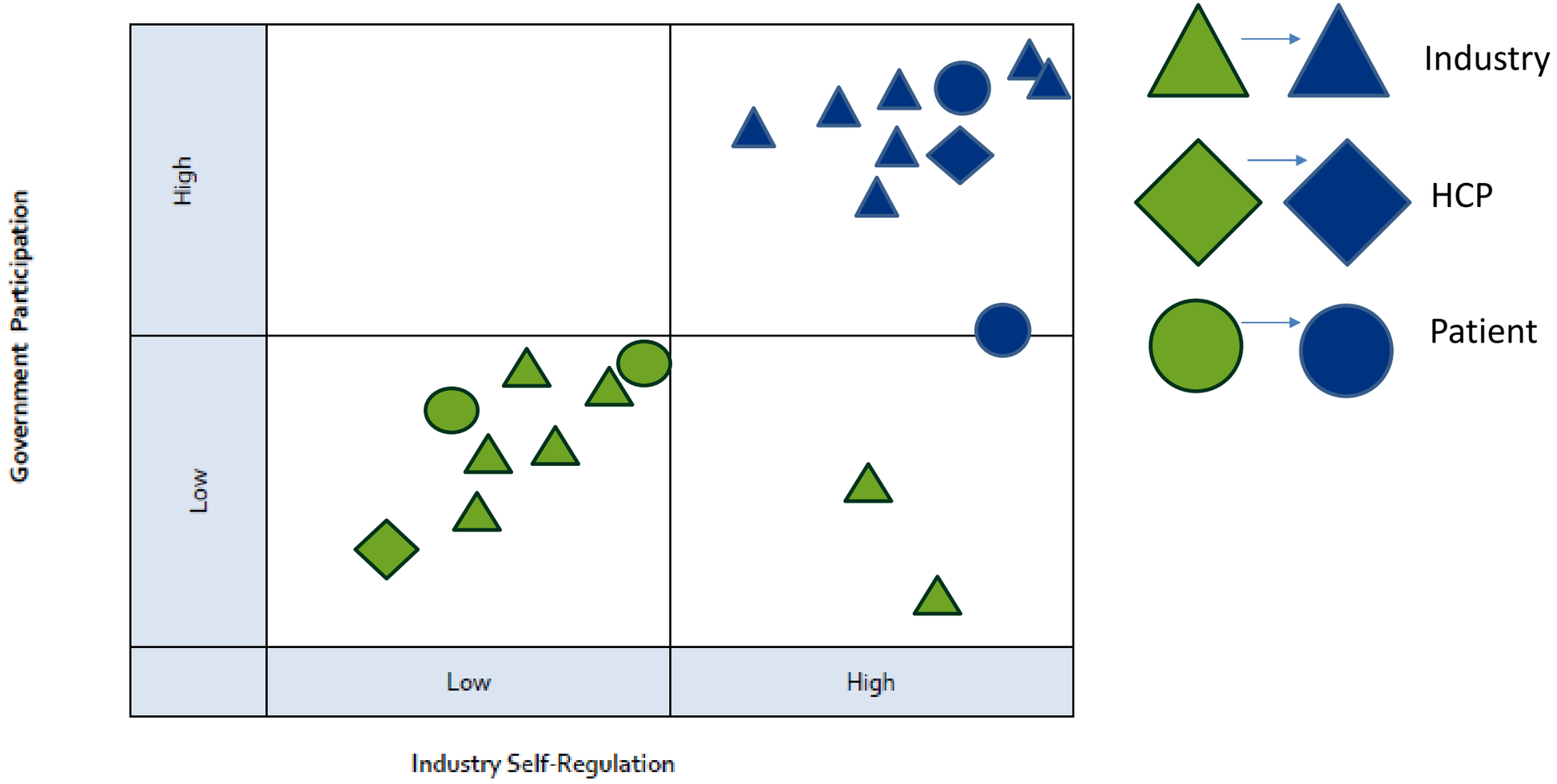
COMMITMENT TO IMPLEMENT MULTI-STAKEHOLDER ETHICAL COLLABORATIONS IN THE MEDICAL DEVICE AND BIOPHARMACEUTICAL SECTORS

The representatives of medical device and biopharmaceutical enterprises and industry associations, healthcare professionals and their associations, patients' organizations and other relevant stakeholders convened for the 2015 APEC Business Ethics for SMEs Forum commit to implement multi-stakeholder ethical collaborations within their economy based on this Guide.

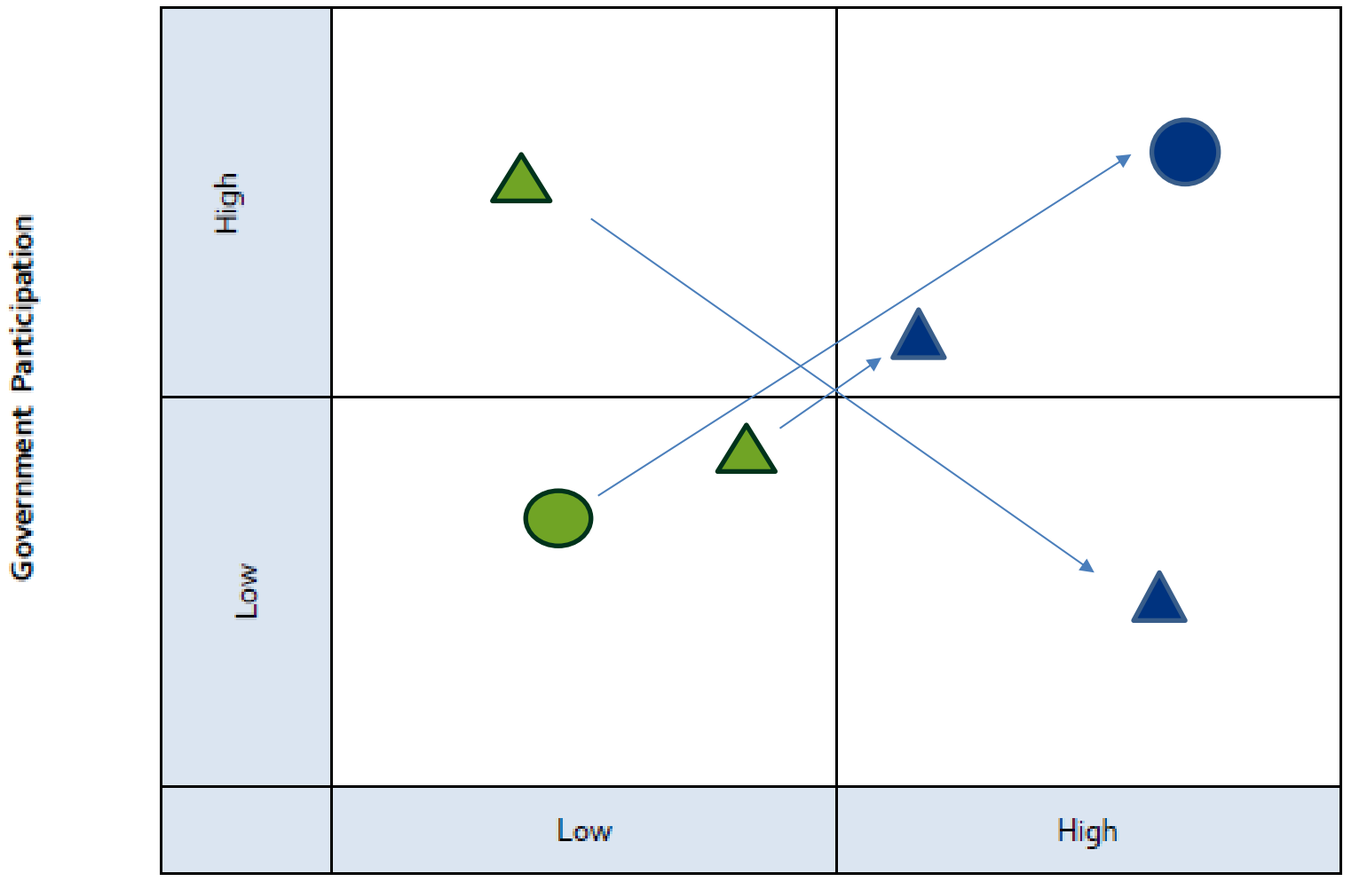
- Ethical collaborations among the medical device and biopharmaceutical industry, healthcare professionals, patients' organizations and other stakeholders is essential to the delivery of high quality patient care, patient access to life-saving and health-enhancing medical technologies and therapies, and the development of new innovations that meet patient needs.

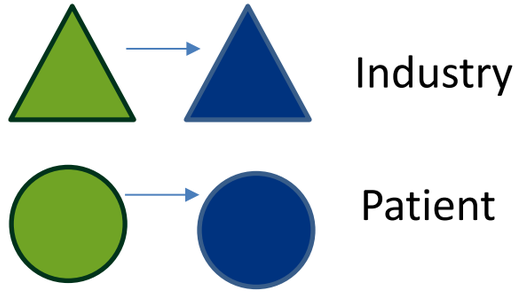
- No one group can achieve an ethical environment in these sectors alone.

PERU


Government Participation
High
Low
Low
High
Industry Self-Regulation
Industry
HCP
Patient

THE PHILIPPINES





Government Participation

High		
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Industry Self-Regulation

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COFFEE BREAK

NEXT SESSION AT 4:00 PM

Asia-Pacific Economic Cooperation

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Session Four, 4:00 – 5:00

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Breakout Sessions

MENTORS AT EACH TABLE TO PROVIDE GUIDANCE ON BEST PRACTICES, CODES OF ETHICS, & HEIGHTENING ETHICAL COLLABORATIONS

Asia-Pacific Economic Cooperation

Business Ethics for APEC SMEs
Biopharmaceutical Sector

Closing Session, 5:00 – 5:30

APEC PERU 2016

Closing Remarks:

Mr. Alejandro Torrendell, Regional General Counsel, LatAm, Merck KGaA

Guidance for Plenary Session (Tuesday, 6 September)

Workshop Group Photograph