



GO DE CHILE | 9-10 SEPTEMBER



JOINT SECTOR OPENING CEREMONY PRE-READ / BIOGRAPHIES

8:00-9:00: BADGE COLLECTION, HEADSETS, AND TEA/COFFEE SERVICE

9:00-9:20: OPENING KEYNOTE REMARKS

Biography of the Honorable Gilbert Kaplan:



Gilbert B. Kaplan was confirmed by the U.S. Senate and assumed his position as Under Secretary of Commerce for International Trade in the United States Department of Commerce in March 2018. In this role, he leads a workforce of 2,100 personnel within the International Trade Administration ("ITA"). He oversees three major units at ITA: Global Markets and the Domestic and Foreign Commercial Service, Industry and Analysis, and Enforcement and Compliance. The Global Markets team provides support to tens of

thousands of American exporters, with over 200 offices in the U.S and worldwide. Industry and Analysis is a powerhouse of expertise with an ability to leverage data analytics and implement strategies to strengthen global competitiveness of U.S. Industries. The Enforcement and Compliance staff are charged with enforcing U.S. trade laws, particularly antidumping and countervailing duty law, holding trading partners accountable for their international commitments to ensure a level playing field at home and abroad. Prior to assuming his current position, Mr. Kaplan was a partner at King & Spalding and part of the International Trade Practice Group. He is a graduate of Harvard Law School and Harvard College.

Biography of the Honorable Rodrigo Yáñez Benítez:



Rodrigo Yañez is the vice minister of trade at the General Directorate of International Economic Relations in Chile. During President Piñera's previous administration, from 2010-2014, Rodrigo served as senior advisor on international and regulatory affairs to the Presidency, where among his duties, he developed foreign policy proposals and oversaw the implementation of domestic policy initiatives for different ministries. He previously worked as director of financial advisory services at Deloitte

where he led the Business Intelligence and Anticorruption, Compliance & Regulatory Advisory service lines. He was ranked by Chambers & Partners Latin America 2018 as a Leading Practitioner in the field of Compliance. Yañez was also a member of the Panel on Public Works Concessions (2014–2018), board member of Chile's Public Enterprise System (2013–14), and Intl Cooperation Agency Board (2012–14). Rodrigo holds a JD from Pontificia Universidad Católica de Chile and a MSc in regulation from the London School of Economics and Political Science (LSE).

9:20-9:30: PROGRAM OVERVIEW AND DELEGATE BRIEFING

Biography of Ms. Tricia Van Orden:



Tricia Van Orden serves as the Overseer of the *Business Ethics for APEC SMEs Initiative* and Deputy Director of the Trade Promotion Coordinating Committee (TPCC) Secretariat at the International Trade Administration (ITA) within the U.S. Department of Commerce. In this role, she coordinates trade promotion strategies across 20 federal agencies and among states and localities to better assist and to improve the





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competitiveness of U.S. exporters. With a focus on small business export promotion, Ms. Van Orden also serves as the U.S. delegate to the Asia-Pacific Economic Cooperation (APEC) Forum Small and Medium Enterprises Working Group. Previously, Ms. Van Orden worked at the Inter-American Development Bank, where she led training programs to increase the capacity of small businesses to access capital. She started her career as an aide in the U.S. Senate working on foreign affairs and international trade policies.

BIOPHARMACEUTICAL SESSION PRE-READ / BIOGRAPHIES

9:30-10:00: OPENING SESSION

<u>Description:</u> Following remarks by Mr. Kirwan, participants will provide their name and organizations. Delegates will then come to the front of the room for a group photograph.

Biography of Mr. Patrick Kirwan:



Kirwan is the Director of the Trade Promotion Coordinating Committee Secretariat at the U.S. Department of Commerce. In this capacity, he coordinates a network of 20 government agencies to improve federal trade promotion and finance programs to increase U.S. exports. He has focused specifically on developing commercial strategies for key markets and improving federal/state cooperation on export promotion. Kirwan also serves as U.S. delegate to the APEC SME Working Group. Prior to his current role,

Kirwan has served as Acting Deputy Assistant Secretary for Domestic Operations, where he oversaw the operations of the 105 export assistance offices of the Department of Commerce. He has also spent two years in the White House at the Domestic Policy Council working on a variety of trade-related issues. As part of the Office of the President, Kirwan participated in the development of a number of strategic trade initiatives in areas such as electronic commerce, international standards setting, trade finance, and Asia policy.





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10:00-10:15: APEC'S JOURNEY IN ETHICAL BUSINESS CONDUCT CAPACITY-BUILDING

<u>Description:</u> From 2012 to 2018, the *Business Ethics for APEC SMEs Initiative* has undertaken numerous train-the-trainer sessions across the APEC region for over 1,500 individuals. These sessions have enabled dozens of biopharmaceutical industry association under undertake code of ethics adoption in accordance with the APEC Mexico City Principles. With an overwhelming majority of the region's industry associations now having a code of ethics in place, the Initiative is placing greater focus on implementation of the APEC Principles by these associations' member companies, an overwhelming majority of which are SMEs. In this session, Thomas Cueni will provide an overview of APEC's capacity-building work to-date and how it continues to evolve to achieve even greater results at the enterprise level.

Biography of Mr. Thomas Cueni:



Thomas Cueni is Director General of IFPMA, the global association of pharmaceutical research companies, based in Geneva and is Secretary of the global Biopharmaceutical CEO Roundtable (BCR). Thomas Cueni serves as Industry Co-Chair of the APEC Biopharmaceutical Working Group on Ethics and Chair of the Business at OECD Health Committee. He also serves on the Board of Directors of the City Cancer Challenge (CCan), an initiative aiming to improve cancer care in major cities in low- and middle-

income economies. Furthermore, he is Chair of the Board of the cross-sectoral AMR Industry Alliance, a group committed to tackling the threat of antimicrobial resistance, which includes more than 100 companies and associations representing Rx pharma, generics, biotech, and diagnostics. Prior to joining IFPMA he was Secretary General of Interpharma, the association of pharmaceutical research companies in Switzerland, and for many years was a member of the Board and Chair of a key committee of the European Federation of Pharmaceutical Industries and Associations. Prior to his appointment with Interpharma, Thomas Cueni had a career as a journalist, inter alia as London correspondent for the "Basler Zeitung" and "Der Bund", and he served as a Swiss career diplomat with postings in Paris (OECD) and Vienna (IAEA, UNIDO). He studied at the University of Basle, the London School of Economics, and the Geneva Graduate Institute for International Studies, and has Master degrees in economics (University of Basel) and politics (London School of Economics, LSE).

10:15-10:45: ESTABLISHING TONE AT THE TOP: INSIGHTS FROM SME LEADERS AND ASSOCIATIONS

<u>Description:</u> This session will spotlight SME leadership perspectives on implementing ethical business practices across diverse economies. The panelists will include company and association leaders who have experience in implementing ethical business practices into their organizations. In a facilitated discussion, panelists will describe the challenges and opportunities they experience as they have led from the top.

Biography of Mr. Le Quoc Khanh:



Le Quoc Khanh is General Director of HADIPHAR, an SME pharmaceutical company based in Viet Nam. HADIFAR manufactures drugs, herbal medicines, and food supplements to supply the Viet Nam market and is a member company of the Vietnam Pharmaceutical Companies Association (VNPCA) which has adopted a code of ethics aligned with the APEC Mexico City Principles. Le Quoc Khanh received his BSc at Hanoi College of Pharmacy and MBA at the Asian Institute of Technology (AIT).





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Biography of Mr. Vicente Astorga:



Vicente Astorga is an Industrial Engineer from the University of Chile, General Manager of Droguería Farmoquímica del Pacífico, and President of Cámara Nacional de Laboratorios, an industry body comprised primarily of SMEs in Chile's biopharmaceutical sector.

Farmoquímica del Pacífico was founded in 1834 in Valparaíso, Chile. His company — Droguería Farmoquímica del Pacífico — is focused on bringing innovation to the Chilean people through three channels, physicians, pharmacies, and direct to patient. Cámara

Nacional de Laboratorios is an association that congregates SME laboratories primarily in Santiago. Most were founded in the nineteenth and twentieth centuries in Chile. Its history has demonstrated the commitment to the health of the people that live in Chile and the main motivation is to consolidate its presence in the pharmaceutical market through improving access of the population to quality medicines at fair value.

Biography of Mr. Ma Ensheng:



Ensheng has 17 years of experience working as a trade official in the Government of the People's Republic of China, with a focus on trade remedy and WTO affairs. He has served as a Deputy Division Director in the Trade Remedies and Investigation Bureau of the Ministry of Commerce since 2014. Previously, he has been posted to the Bureau of Fair Trade for Imports and Exports at the Ministry of Commerce, to the Economic & Commercial Counsellor's Office of the Chinese Embassy to Canada as Third Secretary, later becoming Deputy Division Director

of Division III of Imports Investigation of the Bureau of Fair Trade (2011-2014). He joined the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCCMHPIE) in 2018 and served as Deputy Director of Department of Legal Affairs and Strategic Planning. CCCMHPIE is one of the largest medical device and biopharmaceutical industry associations in the APEC region with over 1,650 member enterprises, nearly 1,500 of which are SMEs. Ensheng graduated in 2001 from Shenyang University of Technology with a Bachelor's Degree in Law, and in 2016 from Lee Kuan Yew School of Public Policy, National University of Singapore with a Master's Degree in Public Management, which includes spending a semester as a Lee Kuan Yew Fellow at the Harvard Kennedy School of Government.

Biography of Ms. Sabrina Chan (Facilitator):



Sabrina Chan is Senior Executive Director of the Hong Kong Association of the Pharmaceutical Industry (HKAPI) and has been an integral expert in supporting code of ethics development within the *Business Ethics for APEC SMEs Initiative* since 2012. She has provided direct assistance in the launch of new industry codes in Indonesia, the Philippines, and Chinese Taipei, among others, with benefits for thousands of companies. She is a Member of the APEC Biopharmaceutical Working Group on Ethics. Prior to joining the

pharmaceutical industry, she led the External Affairs Department of a telecommunication conglomerate (listed in Hong Kong Stock Exchange) to deal with the company's government relations, regulatory affairs, corporate affairs and communications. She co-founded the Telecommunications Research Project under Centre of Asia Studies of University of Hong Kong (HKU), and was a journalist at various print and electronic media. She holds some advisory positions for the Hong Kong government and academics, including, member of the High Level Steering Committee on Antimicrobial Resistance / Business Facilitation Advisory Committee, and chairs the Advisory Board of Bachelor of Pharmacy of HKU. Sabrina started her tertiary





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education in Communications in Hong Kong, holds graduate degree in Intl Studies from the University of Sheffield (UK) and law degrees from the Chinese University of Hong Kong / University of Tsinghua (China).

10:45-11:00: MORNING TEA/COFFEE BREAK

11:00-11:45: APEC SME LEADERS IN ETHICS AND INTEGRITY PROGRAM (LEIP) – BIOPHARMACEUTICAL SECTOR

<u>Description:</u> The APEC SME Leaders in Ethics and Integrity Program (LEIP) is envisaged as a multi-stage platform to equip SMEs leaders in the biopharmaceutical sector with the right tools to implement an effective ethics and integrity program in alignment with the APEC Principles, while including strong business case and communication components. This interactive session will offer the opportunity for delegates to provide direct input on the design plan as well as to hear from industry associations how they can leverage LEIP in their work. Delegates are encouraged to read the design plan and consider the following questions:

- What does success look like for APEC SME LEIP (i.e., number of leaders who complete the program)?
- What incentives could encourage SME leaders to participate in APEC SME LEIP (i.e., networking or international recognition)?
- What could be the benefits and consequences of offering SME leaders certification or membership a component of APEC SME LEIP?
- Should APEC SME LEIP differ between APEC member economies and, if so, how?
- How should APEC biopharmaceutical industry associations recruit APEC SME LEIP participants?

<u>Table Facilitators:</u> Ms. Connie Cote (Canada), Ms. Karen Eryou (Canada), Ms. Sabrina Chan (Hong Kong, China), Mr. Marco Ivan Escotto Arroyo (Mexico), Ms. Maria Teresa Cantu Reus (Mexico), Mr. Teodoro Padilla (Philippines), Ms. Sofie Melis (Switzerland), Dr. Julien Durand (Switzerland), Ms. Kathleen Hamann (United States)

Related Materials:

- APEC SME LEIP Design Plan: PDF to be Included in Next Version
- SME Guide to the APEC Mexico City Principles: Website Link Here

Biography of Ms. Karen Eryou:



Karen Eryou is the Global Head of Ethics & Compliance Programs for UCB Pharma, where she is responsible for UCB's program on ethical decision-making as well as leading the global compliance operations teams, which includes transparency, third party management, investigations, monitoring & analytics, as well as policies, procedures, training and communication. Originally from Vancouver, Canada, and now living in Amsterdam, Karen has worked internationally for the past 18 years in the biopharmaceutical industry, with the

past 10 years, including 6 years based in Shanghai, focused on ethics and compliance topics, particularly in cross-cultural settings. Karen is a frequent speaker on ethics and compliance practices. She is currently undertaking a coaching program in Design Thinking (user-centered design). Karen is the chair of the IFPMA Ethics & Business Integrity Code Capacity workgroup, and has served as an expert in the Business Ethics for APEC SMEs Initiative for the past five years.





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Biography of Ms. Kathleen Hamann:



Kathleen Hamann (Kate) is a partner in the Washington, DC and Boston offices of Pierce Atwood LLP. Kate is an internationally recognized authority in the field of transnational criminal and compliance law after decades in the field, including 18 years of service to the United States Government. During her tenure as a federal prosecutor, she led the enforcement team that investigated transnational bribery in the medical device industry from 2009 to 2013, led the industry sweep into bribery in pharmaceuticals in 2011. She

has presented on patterns of bribery in the life sciences at the World Bank and the Working Group on Bribery and is also a regular speaker and author on issues including multijurisdictional and international investigations and enforcement, compliance, corruption, data privacy and protection, and conflict of laws. Since 2014, Kate assists enterprises around the globe with internal and external investigations into regulatory and criminal matters; designing and implementing robust, scaled compliance programs; global risk assessments; pre-acquisition due diligence and post-acquisition remediation; and has acted as a monitor. She has a particular focus on life sciences and small and medium sized enterprises (SMEs).

Biography of Ms. Chrisoula Nikidis:



The career of Chrisoula Nikidis is highlighted by creative citizen mobilization, coalition-building and the development of ethical practices on a provincial, national and international level. She has built a world-class understanding of the issues and challenges facing the advancement of ethical policies. As the Head of Ethics and Compliance at Takeda Canada, Chrisoula will be helping to navigate the complex and changing environment in compliance and transparency in the life sciences industry. As Vice President of Ethics, Integrity and

Governance, she built a reputation as a trusted and respected leader of issues involving ethics and integrity both in the private and public sectors. Chrisoula has been very skillful in balancing competing and challenging issues and priorities in a fast-paced, continually changing environment. She successfully coordinated the Canadian Consensus Framework for Ethical Collaboration, including the Canadian medical, nursing, patients and industry organizations. She continues as a senior member of the expert team implementing collaborative ethical partnerships. Her strong legal background helped her lead several rounds of modernization of Canada's innovative pharmaceutical code of ethics. She has played a key role in the advancement of international ethics through leadership at the IFPMA and APEC.

11:45-12:45: LUNCH

12:45-13:00: PRESENTATION OF THE INAUGURAL CHINA INDUSTRY ASSOCIATION SURVEY AND REPORT

<u>Description:</u> Following the launch of the China Consensus Framework in 2018, several of the parties (including CPIA, CCCMHPIE, PhIRDA, and RDPAC) have actively worked to champion ethical business practices across China's biopharmaceutical sector. This included the development and launch of the first detailed survey of biopharmaceutical sector industry associations specific to one economy. This brief presentation will highlight the outcomes of the survey through a consolidated report.

Related Materials:

2019 Report on China Biopharmaceutical Industry Assn Code of Ethics Implementation: <u>PDF HERE</u>





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Biography of Ms. Patricia Wu:



Patricia Wu is the Managing Director at Crowell and Moring International and was instrumental in working with public and private sector stakeholders to launch the *Business Ethics for APEC SMEs Initiative* in 2010. She also served as a major thought leader in the development of the APEC Kuala Lumpur Principles and APEC Mexico City Principles, as well as the formation of the APEC Nanjing Declaration and annual APEC Business Ethics for SMEs Forum. She actively counsels a broad range of the Initiative's goals, including the significant

advances that have and continue to occur in strengthening ethical business practices in China. Patricia also advises a number of strategic initiatives across the Asia-Pacific Economic Cooperation (APEC) forum. Prior to her current role, Patricia held a number of positions in the private sector. At The Estée Lauder Companies, the world's premier prestige beauty company, Patricia launched award-winning products in over 140 markets around the world under the Clinique and Estée Lauder brands. She also launched several global digital and social media marketing programs, many of which were the first of their kind in the industry. Patricia was also with the investment bank of J.P. Morgan in their Global Financial Institutions and Governments group. Patricia holds an MBA from Harvard Business School, where she co-authored several published case studies focused on business strategy as it relates to government. She graduated summa cum laude and Phi Beta Kappa from Tufts University, with a bachelor of arts in international relations and Asian studies. She also holds a degree from the Institut d'Etudes Politiques de Paris and studied at Peking University. She speaks Mandarin Chinese and French. Patricia is a Term Member of the Council of Foreign Relations, serves on the board of The Washington Ballet, is an officer (and former board member) of Women in International Trade and was recognized by Washington Life Magazine as a "Mover and Shaker 40 and Under".

13:00-14:00: PATIENT ORGANIZATIONS AND IMPLEMENTING THE APEC PRINCIPLES

<u>Description</u>: Patients have a strong interest in ensuring ethical business practices are adhered to in the biopharmaceutical sector. Patient organizations across the region have also been instrumental to-date in advocating for high-standard ethical business practices in the sector, including by promoting the adoption of industry codes of ethics and direct engagement in the development and implementation of Consensus Frameworks. Both the APEC Mexico City Principles and APEC Nanjing Declaration reference patient organizations. Building on the outcomes agreed at the 2018 APEC Business Ethics for SMEs Forum in Tokyo – such as the formation of a patient organizations' ethics network – this session will provide participants with an overview of patient organization engagement to-date in the Initiative. This will be followed by an interactive exercise where patient organizations and facilitators will hold breakout discussions to draft recommendations on how patient organizations may support APEC Principles implementation beyond 2020.

<u>Table Facilitators / Rapporteurs:</u> Russell Williams (Canada), Connie Cote (Canada), John Adams (Canada), KP Tsang (Hong Kong, China), Karla Ruiz de Castilla Yábar (Peru), Jo Watson (Australia), Roberto Pagdanganan (Philippines), Chrisoula Nikidis (Canada), Sabrina Chan (Hong Kong, China), Reiner Gloor (Philippines).

Related Materials:

APEC Mexico City Principles: <u>PDF HERE</u>
 APEC Nanjing Declaration: <u>PDF HERE</u>





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Biography of Mr. Russell Williams (Facilitator):



Russell serves as Senior Vice President of Diabetes Canada and Patient Co-Chair of the APEC Biopharmaceutical Working Group on Ethics overseen by the U.S. Department of Commerce under the *Business Ethics for APEC SMEs Initiative*. He served as President of Innovative Medicines Canada (formerly Rx&D). Russell also previously chaired the International Code Compliance Network for the IFPMA and was member of the Council of the IFPMA. From 2011-2015, he served as the primary private sector lead for the biopharmaceutical sector program under this Initiative. Prior to his work in the sector,

Russell had a successful career in the National Assembly of Quebec. He is a well-known champion for many causes which include better patient care, improved emergency services, increased research and development, individual rights, as well as reform for handicapped services. He is Chair of the Canadian Frailty Network, National Chair of the Champions Council for the Canadian Hospice Palliative Care Association, Member of the Board of Life Sciences Ontario and BioCanRx.

14:00-15:00: HEALTHCARE PROFESSIONAL ORGANIZATIONS AND IMPLEMENTING THE APEC PRINCIPLES

<u>Description:</u> Healthcare Professionals (HCPs) feature prominently in the APEC Mexico City Principles and, other than industry and patients, are widely viewed as the most important stakeholder to ensure effective implementation of the Principles' provisions. Despite the significant synergies that exist, many industry and HCP groups across the region are still limited in their collaboration to strengthen ethical business practices. In many economies, there is a trust gap. As Consensus Frameworks continue to expand across the region, this session will include an interactive exercise that draws out specific recommendations from delegates on how to heighten HCP engagement and collaboration in implementing the APEC Mexico City Principles. Patricia Wu will introduce and facilitate the exercise, together with HCP representatives in attendance from Canada, Malaysia, the Philippines, and Thailand, among others. Patricia Wu will collect the recommendations that are made and submit them as a consolidated summary to the Overseer.

Related Materials:

APEC Mexico City Principles: <u>PDF HERE</u>
 APEC Nanjing Declaration: <u>PDF HERE</u>

15:00-15:30: AFTERNOON TEA/COFFEE BREAK

15:30-17:30: APEC BIOPHARMACEUTICAL WORKING GROUP ON ETHICS – FORMAL SESSION

<u>Description</u>: Facilitated by Tricia Van Orden with support from Patrica Wu, the APEC Biopharmaceutical Working Group on Ethics will hold its first in-person session in Santiago. Attendance and participation in this meeting is open to all Forum delegates, with Working Group Co-Chairs and Members (indicated below) asked to provide the first set of recommendations on each scheduled topic. The Working Group is an ad hoc body of organizations who are committed to supporting the Overseer achieve implementation of the Nanjing Declaration's goals from a multi-stakeholder perspective. The three topics designated for this Session include: (1) measuring the positive impact of ethical business practices in the biopharmaceutical sector, (2) expanding the sustainability of resources for the Initiative, and (3) supporting the success of APEC LEIP as a major focus in capacity-building over the years ahead. The meeting will conclude with a clear set of recommendations for the Overseer's consideration.





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Proposed Agenda:

- 5 Minutes: Roll Call of Working Group Members (Patricia Wu)
- 5 Minutes: Welcome Remarks / Summation of 2019 Working Group Meetings To-Date (Tricia Van Orden)
- 30 Minutes: Measuring the Positive Impact of Ethical Business Practices
 - Overseer Summary
 - Working Group Member Perspectives
 - Perspective from Forum Delegates / Open Floor
- 40 Minutes: Expanding the Sustainability of Resources for the Business Ethics for APEC SMEs Initiative
 - Overseer Summary
 - Working Group Member Perspectives
 - Perspective from Forum Delegates / Open Floor
- 30 Minutes: Supporting the Success of the APEC SME Leaders in Ethics and Integrity Program (LEIP)
 - Overseer Summary
 - Working Group Member Perspectives
 - Perspective from Forum Delegates / Open Floor
- 5 Minutes: Working Group Membership (Government / HCP Co-Chair Spots + Standard Member Spots)
- 5 Minutes: Closing Remarks (Tricia Van Orden) / Summation of Recommendations (Patricia Wu)

Working Group Members in Santiago:

- Overseer: Ms. Tricia Van Orden, Overseer, U.S. Department of Commerce
- Industry Co-Chair: Mr. Thomas Cueni, International Federation of Pharmaceutical Manufacturers and Associations (Switzerland)
- Patient Co-Chair: Mr. Russell Williams, Diabetes Canada
- Member: Mr. Ma Ensheng, China Chamber of Commerce for Import and Export of Medicines and Health Products
- Member: Ms. Sabrina Chan, Hong Kong Association of the Pharmaceutical Industry
- Member: Mr. Darodjatun Sanusi, GP Farmasi Indonesia
- Member: Dr. Chairat Shayakul, Rational Drug Use Subcommittee, Thailand
- Member: Mr. Marco Arroyo Escotto, Consejo de Ética y Transparencia de la Industria Farmacéutica en México
- Member: Ms. Marta Diez, La Cámara de la Innovación Farmacéutica (Chile)
- Member: Mr. Jose Luis Cardenas, Asociación de Productores Locales de Medicamentos (Chile)
- Member: Mr. Takeshi Matsumura, Japan Pharmaceutical Manufacturers Association
- Member: Mr. Tokuo Tanaka, Japan Pharmaceutical Manufacturers Association

Related Materials:

- APEC Nanjing Declaration: PDF HERE
- Strategic Assessment of the Business Ethics for APEC SMEs Initiative: <u>PDF HERE</u>
- Working Group Terms of Reference: <u>PDF HERE</u>
- APEC Mexico City Principles: <u>PDF HERE</u>

17:30-18:15: SCHEDULE BREAK

18:15-19:00: DEPART SHERATON LOBBY FOR RECEPTION AT U.S. AMBASSADOR'S RESIDENCE (SANTIAGO)

19:00-21:00: WELCOME RECEPTION (TRANSPORTATION PROVIDED)