3rd APEC Blood Supply Chain Policy Forum

"Accelerating Regional Implementation of Good Manufacturing Practices in Blood Establishments"

8-9 December 2016| National Institute of Hematology and Blood Transfusion, Hanoi, Vietnam

OVERVIEW

The APEC Blood Supply Chain 2020 Roadmap, welcomed by APEC Ministers and Leaders in 2015, calls on APEC Economies to develop and implement domestic policies and plans on Good Manufacturing Practices (GMP) throughout the blood supply chain - from selecting qualified donors, collecting and processing donations, testing of donor and patient samples, issuing compatible blood, to transfusing the patient. GMP is an integral part of quality assurance which ensures that blood products are consistently produced and controlled to quality standards. According to the World Health Organization (WHO), establishing reliable quality assurance systems covering the blood supply chain is critical to improving the global availability of blood and blood products that meet internationally standards.

GMP compliance varies widely across the APEC region as many APEC Economies struggle to implement GMP into their daily practice. The quality and safety of the blood supply can only be ensured if APEC Economies implement and enforce appropriate international GMP standards. Once GMP compliance is achieved, blood centers in the APEC region will be prepared to address opportunities to further improve their blood systems through centralization and regionalization, implementing advanced testing strategies, and manufacturing plasma.

The 3rd APEC Blood Supply Chain Policy Forum will convene APEC Economy representatives to share experiences and best practices for achieving GMP compliance in blood establishments. The Policy Forum will also examine the economic benefits of GMP compliance, including the return on investment in GMP certification. APEC ministries of health, national regulatory authorities, blood services leadership, as well as representatives of the Pharmaceutical Inspection Cooperation Scheme (PICS), the World Health Organization, ASEAN, academia, private sector, and civil society are invited to attend.

DRAFT AGENDA

Thursday, 8 December

08:00 – 09:00		**Registration**	
09:00 – 09:20		**Welcome**	**Prof. Nguyen Anh TRI, MD., PhD.** Director - National Institute of Hematology and Blood Transfusion, Viet Nam **Maureen M. Goodenow, Ph.D.** Chair, APEC Life Sciences Innovation Forum Planning Group and Associate Director for AIDS Research and Director of the Office of AIDS Research National Institutes of Health, United States
09:20 – 09:35		**Keynote Speaker**	**Minister of Health, Viet Nam (to be invited)**
9:35 – 10:30		**The current blood safety landscape in the APEC region – challenges and opportunities** Topics to be addressed: - the cost of inaction	**Dr Cheuk-Kwong Lee,** Chief Executive Officer of the Hong Kong Red Cross Blood Transfusion Service (HKRCBTS) and Chair, Asia Pacific Blood Network (to be invited)

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		- addressing patient needs (bleeding disorders)	**World Federation of Hemophilia**
10:30 – 10:50		**Coffee Break**	
10:50 – 11:30		**The Case for Implementation of GMP in the APEC Region**	**Christian Schärer, Ph.D.,** Head Inspectorate, Swissmedic, Swiss Agency for Therapeutic Products and Chairman, WHO Blood Regulators Network (invited) **Discussant and Moderator:** **Sushil G. Devare, PhD** Distinguished Research Fellow and Director, Diagnostics Research, Strategic & Emerging Markets Initiatives, Abbott Diagnostics (to be invited)
11:30 – 12:30		**The Returns on Investment in GMP in Blood Establishments** Topics to be addressed: - economics of plasma fractionation - economic returns of GMP, attracting investment, etc - WHO Requirements for Plasma regarding Contract and Domestic Fractionation Programmes	**Patrick Robert,** Marketing Research Bureau (MRB) (invited) **Sia Chong Hock,** Director of Quality Assurance and Senior Consultant of Audit and Licensing, Health Products Regulation Group, Health Sciences Authority, Singapore (invited)
12:30 – 14:00		**Lunch**	
14:00 – 15:30		**GMP Implementation Strategies – Experiences of APEC Economies** Topics to be addressed: - Presentation of pre-workshop survey results	**Prof. Dr. Liu Zhong,** Vice President, Institute of Blood Transfusion, CAMS; Vice Director, Department of Blood Transfusion, PUMC, Editor in Chief, Chinese Journal of Blood Transfusion, People's Republic of China (invited) **Dr. Yuyun Soedarmono,** Director, Directorate of Basic Health Care, Ministry of Health, Indonesia (invited) **Dr. Noryati Abu Amin,** Director, National Blood Centre, Ministry of Health, Malaysia (invited) **Dr. Soisaang Phikulsod, M.D.,** Director, National Blood Center, Thai Red Cross Society, Thailand (invited) **Discussant and Moderator:** **Jerry A. Holmberg, PhD,** Director, Scientific Business Development, Grifols Diagnostic Solutions Inc. (invited)
15:30 – 17:00		**Addressing Patient Needs in the APEC Region**	**World Federation of Hemophilia (invited)** **Mr Bruce Lim, IPOPI Board Member, Malaysia**

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			(invited) **Mr Geoffrey Yu, Vice-Chair of IPOPI's National Member Organisation, Hong Kong, China** (invited) **Dr. Bạch Quoc KHANH, MD, PhD.** Deputy Director, National Institue of Hematology and Blood Transfusion (invited) **Dr. Nguyen Thi Mai** Vietnamese Haemophilia Society (invited) **Discussant and Moderator:** **René Buechel,** Shire (invited)
17:00 – 17:15		**Day 1 Wrap-up**	
19:00 – 21:00		**Gala Dinner**	

Friday, 9 December

09:00 – 09:05		**Day 2 Welcome**	**Maureen M. Goodenow, Ph.D.** Chair, APEC Life Sciences Innovation Forum Planning Group and Associate Director for AIDS Research and Director of the Office of AIDS Research National Institutes of Health, United States
09:05 – 09:30		**Keynote Speaker: Viet Nam's Vision for Achieving GMP in the Blood Supply Chain**	**Dr. Pham Tuan Duong** Deputy Director, National Institute of Hematology and Blood Transfusion, Viet Nam
9:30 – 12:30 (Coffee Break 10:30-10:50am)		**Breakout Sessions on GMP Implementation – Groups will spend 45 minutes on Each Topic** **1. Policies** • **Breakout Lead: Ms. Vee Armstrong,** Quality & Regulatory Consultant, Australia (invited) **2. Organization and Personnel** • **Breakout Lead: Ms. Christine Bales,** Vice President, Consulting and Global Services, AABB (invited) **3. Processes** • **Breakout Lead: Ms. Susan Best**, Director, NRL, Australia (invited)	
12:30 – 14:00		**Lunch**	
14:00 – 14:30		**Breakout Session Report Outs**	

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14:30 – 16:00		**Role of National Regulatory Authorities in Promoting GMP-compliant Blood Management Practices**	**Ying-Hua (Ellen) Chen**, Section Chief, GMP Inspectorate, Chinese Taipei Food and Drug Administration, Chinese Taipei **Lutfia Nurhalim,** S.Farm, Apt., Directorate of Production Control of Therapeutic Product and Household Medical Supplies, Badan POM/National Agency of Drug and Production Control (NADFC), Indonesia **Discussant:** **Dr Diana Teo**, Chairman, HSA Professional Board and Senior Consultant, Blood Services Group, Health Sciences Authority, Singapore
16:00 – 16:15		**Coffee Break**	
16:15 – 17:00		**REVIEW OF OUTCOME DOCUMENTS** - Hanoi Principles of Good Manufacturing Practices for Blood and Blood Products - Hanoi Recommendations on Improving Access to Blood Disorder Treatments in APEC Economies	**Dr. Pham Tuan Duong** Deputy Director, National Institute of Hematology and Blood Transfusion, Viet Nam
17:00 – 17:30		**Closing Session**	**Prof. Nguyen Anh TRI, MD., PhD.** Director - National Institute of Hematology and Blood Transfusion, Viet Nam **Maureen M. Goodenow, Ph.D.** Chair, APEC Life Sciences Innovation Forum Planning Group and Associate Director for AIDS Research and Director of the Office of AIDS Research National Institutes of Health, United States