



Asia Pacific Economies Drive Quality

Industry's Response

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March 3, 2017



GRIFOLS

Agenda

What is APEC?

- Why is blood sustainability incorporated into APEC?
- World Health Assemblies resolution for blood safety
- Blood Products and the essential medicinal list
- Development of a Blood Safety Roadmap

Why economies drive quality in blood/plasma products?

APEC Blood Initiatives

Hanoi implementation recommendations of Good Manufacturing Practices (GMP)

Summary

Asia Pacific Economic Cooperative (APEC) Overview

Launched in 1989

Australia
Brunei Darussalam
Canada
Chile
China
Hong Kong
Indonesia
Japan
Republic of Korea
Malaysia
Mexico



New Zealand
Papua NG
Peru
The Philippines
Russia
Singapore
Chinese Taipei
Thailand
USA
Vietnam

“Member economies are stepping up action to promotes growth to improve social mobility and living standards for people on both sides of the Pacific”

Asia Pacific Economic Cooperation is 60% of World GDP

APEC is committed to making it easier to do business in the Asia-Pacific region

APEC started in 1989 with 12 Asia-Pacific economies and stopped accepting new members in 1997.

Meetings are scheduled in a new host country economy annually:

2014	China	Beijing
2015	Philippines	Manila
2016	Peru	Lima
2017	Vietnam	TBA
2018	Papua NG	TBA

Australia	Japan	Philippines
Brunei	South Korea	Russia
Canada	Malaysia	Singapore
Chile	Mexico	Taiwan
China	New Zealand	Thailand
Hong Kong	PNG	USA
Indonesia	Peru	Vietnam



Life Science Innovation Forum

United Nations Millennium Development Goals

Focus on economies' blood supply to achieve Millennium Development Goals which now have been rolled into the Sustainable Development Goals (2015)

4 Reduce Child Mortality



#6 Combat HIV/AIDS, Malaria and other Diseases

#5 Improve Maternal Health

LSIF Blood Safety Workshop - Manila September 2014

Icon by Agnieszka Murphy | Dreamstime.com

WHA 63.12 Availability, Safety and Quality of Blood Products

2010 World Health Assembly

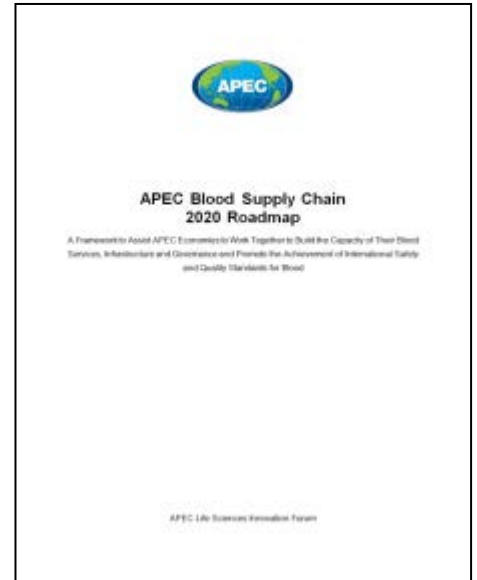
URGES Member States:

- (1) to take all the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the **aim of achieving self-sufficiency**, unless special circumstances preclude it;
- (2) to take all the necessary steps to update their national regulations on donor assessment and deferral, the collection, testing, processing, storage, transportation and use of blood products, and operation of regulatory authorities in order **to ensure that regulatory control in the area of quality and safety of blood products across the entire transfusion chain meets internationally recognized standards**;
- (3) **to establish quality systems, for the processing of whole blood and blood components, good manufacturing practices for the production of plasma-derived medicinal products and appropriate regulatory control, including the use of diagnostic devices to prevent transfusion transmissible diseases with highest sensitivity and specificity**;

APEC LSIF Blood Supply Chain Roadmap

Mission:

APEC economies to improve the safety and sustainability of their blood supply by working through cross-sectoral, multi-disciplinary, coordinated and collaborative approaches to optimize their blood processing, testing, and distribution systems



http://mddb.apec.org/Documents/2015/MM/HLM-HE/15_hlm-he_011.pdf

APEC Blood Supply Chain 2020 Roadmap

Goals of the blood supply roadmap

- **Strengthen quality systems as** an essential foundational element for creating a viable National Blood System or Service that requires full government commitment for long-term success
- **Increase government awareness** that economies of scale are best achieved through centralization and regionalization to provide quality services at the local level
- **Increase government focus on blood testing strategies** based on the disease burden in the APEC developing economy's populations

APEC Blood Supply Chain 2020 Roadmap

Goals of the blood supply roadmap

- **Incorporate models such as public-private partnerships** and partnerships with non-profit organizations to access resources and expertise and identify advocates for advancing blood safety
- **Provide evidence to decision-makers** on the value of blood safety policies that facilitate data-based decisions for public health
- **Adopt patient blood management (PBM)** a standard of care used to optimize the use of a patient's own blood, thereby avoiding unnecessary blood transfusions

APEC Blood Supply Chain 2020 Roadmap

Accomplishments

- Roadmap endorsed by all the APEC economies (2014-15)
- Political awareness of blood safety and pathway to obtain endorsement by Ministries
- Recognized as a supporter of the economic growth of the region
- Networking of Key Opinion Leaders
- Momentum building
 - Peru (November -December 2015)
 - Viet Nam (November -December 2016)
- Industry coalition
- Recommendation for implementation of GMP

Takes commitment from government to move forward;
not a free ride but a partnership

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Quality is Important to APEC

Why economies should invest in Quality?

4 Reduce Child Mortality



#6 Combat HIV/AIDS, Malaria and other Diseases

#5 Improve Maternal Health

- Growing economies demand improved health care
- Aging populations are a reality in highly developed economies
- Millennium Development Goals (#4,5,6) are now Global Sustainable Goals (#4 combined)
- Supports WHA 63.12 of 2010

Plasma is a Strategic Resource

Strengers and Klein, Transfusion (2016, doi:10.1111/trf.13913)

COMMENTARY

Plasma is a strategic resource

Strengers^{1,2} and Harvey G. Klein³

“Plasma collection should be increased outside the United States, including in low- and middle-income countries. The need for capacity building in these countries is an essential part to strengthen quality plasma collection. This will require changes in national and regional policies. We advocate the need for the restoration of an equitable balance of the international plasma supply to reduce the risk of supply shortages worldwide.”

A Quality Blood Supply Provides a Level of Safety

Donors and patients count on testing for pure, potent, and efficacious products



Designing and implementing meaningful levels of blood safety

Quality Systems

Purity & Safety (GMP)

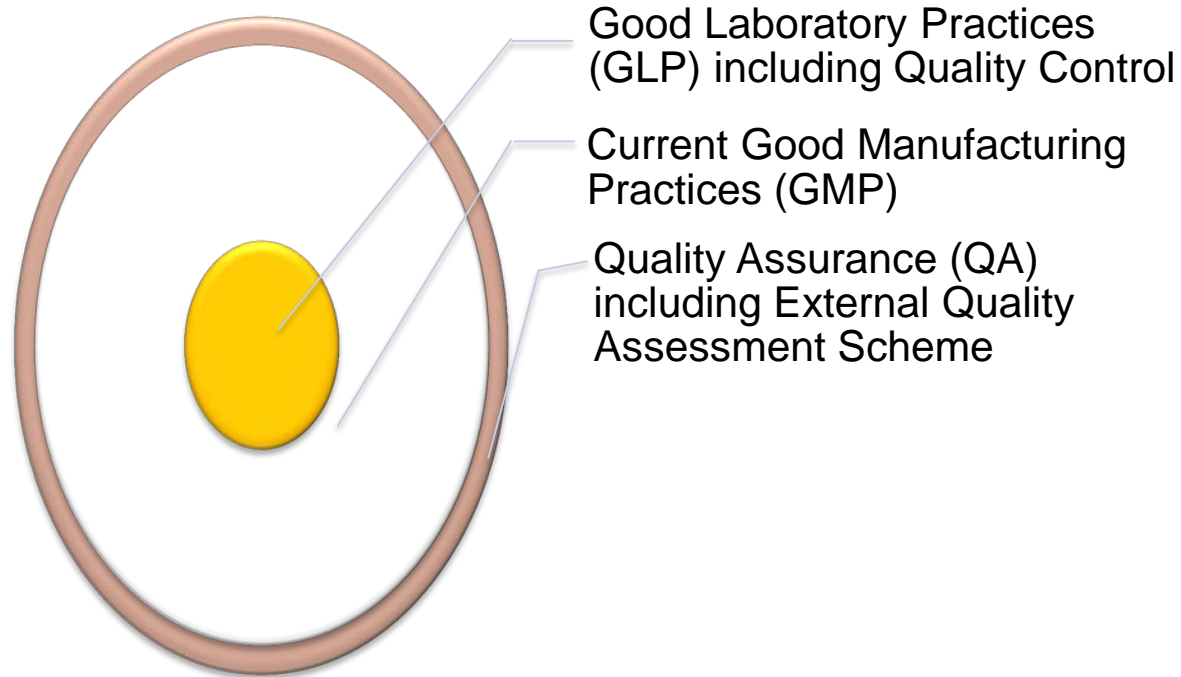
Potency

Efficacy

Quality is everyone's responsibility

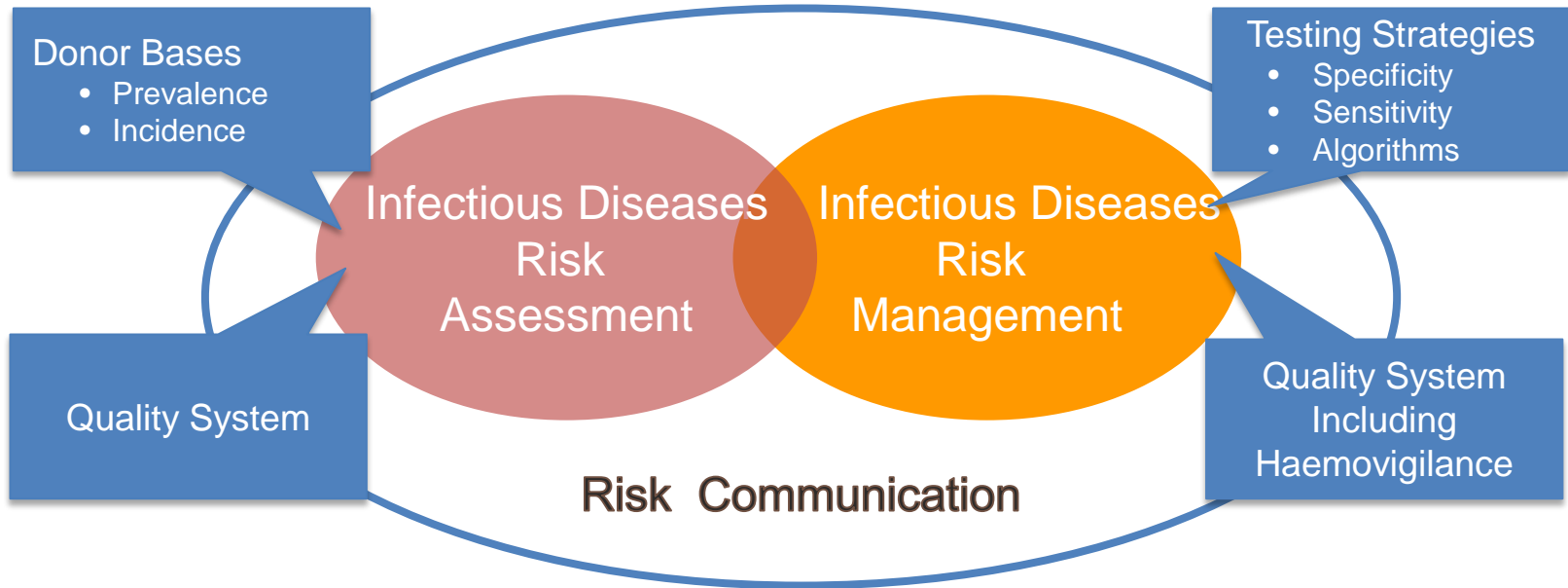
Quality System is Key in Every Organization

Like an egg it has several parts



GMP Requires Risk Assessment

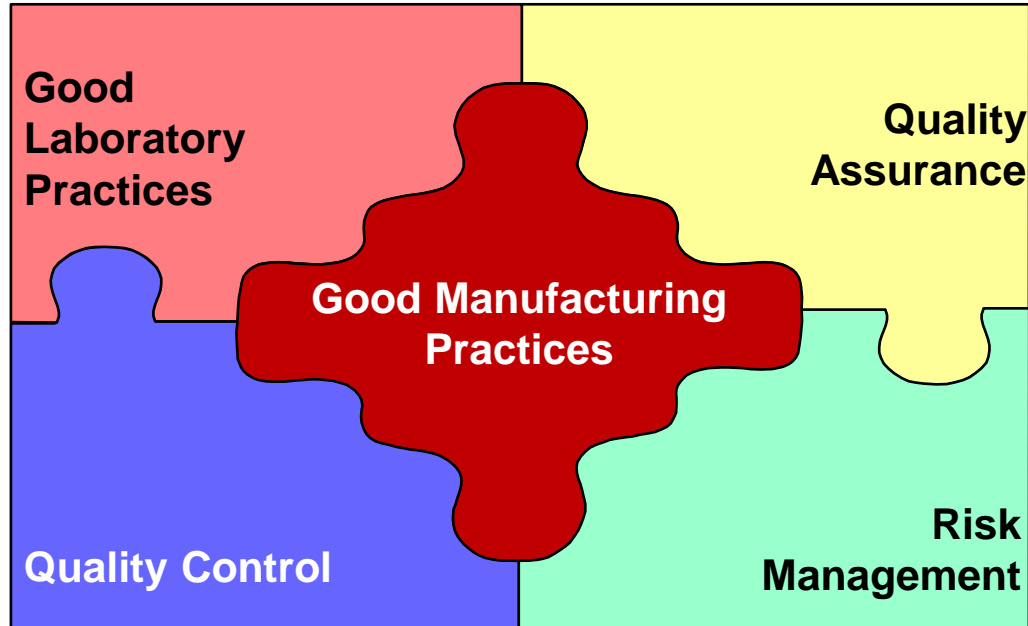
Managing the blood/plasma supply and safety



Sources: Holmberg et al. in Hemovigilance, 2013 Wiley-Blackwell page 328.

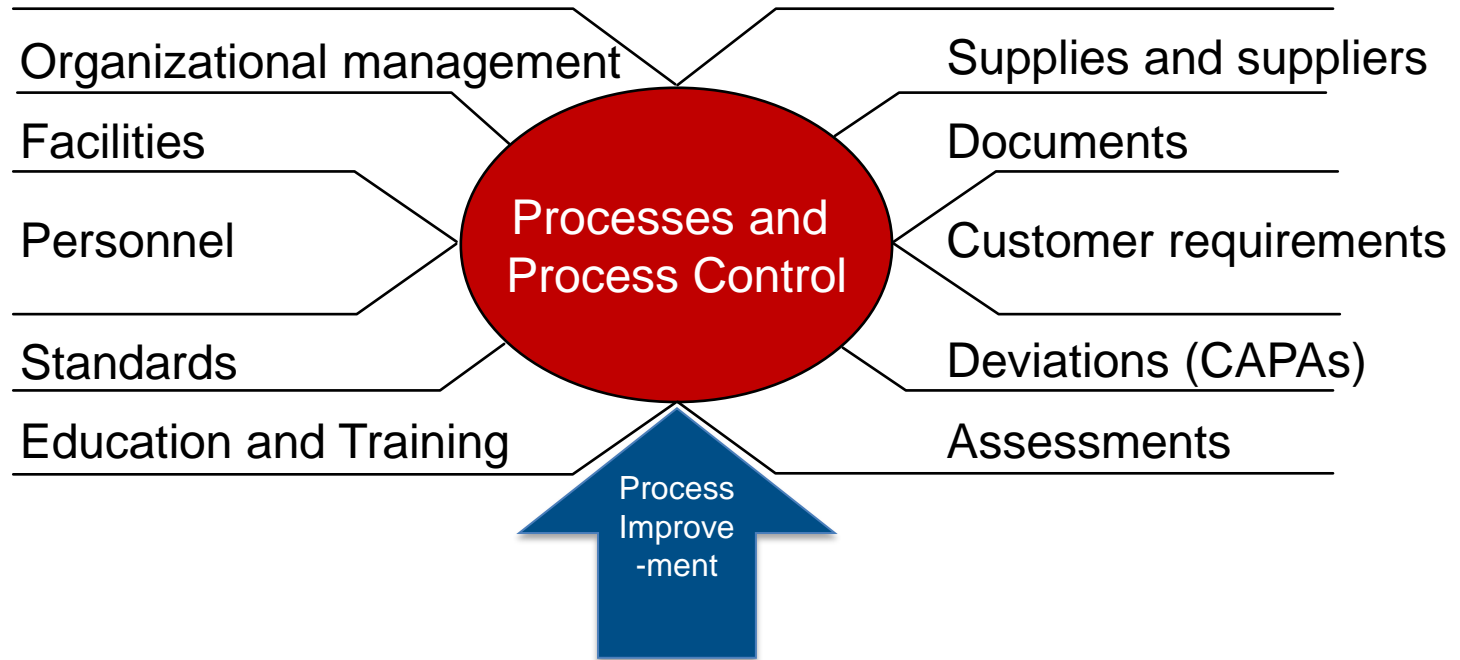
Quality Management System is Complete

Each part interacts and is part of the whole system



Quality Management System

Systems approach



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APEC Safe Blood Supply Initiative

1

THINK BIG

21 economies agree
On ONE roadmap



Step 1 – Engage

2

START SMALL

Select ONE economy
ready to invest in GMP
upgrade in 2016: **Vietnam**



Step 2 – Implement

3

SCALE FAST

Expand lesson learned to Indonesia then third
economy by 2020: Indonesia and Philippines



Step 3 – Expand

H
O
S
T



PNG 2018, Chile 2019



Healthy Asia

How Do We Support these Economies?

We encourage policy change for better QMS



Track 1 Policy Building

- **1st Policy Forum**, Roadmap, Manila, Philippines - October 2014
- **2nd Forum** on sustainability of policies focused on Quality, California - Oct 2015
- **3rd Forum** – GMP Compliancy, Hanoi, Vietnam - Dec 5 & 6, 2016
- **4th Forum**, Indonesia, Q4-2017



Track 2 GMP Training

- **1st Training (Pilot)** – Lima Peru - June 2016
- **2nd Training (Pilot)** – Hanoi, Vietnam - December 2016
- **Online Training platform** – Collaboration with Grifols Academy
- **Onsite 1-week long training by consultant expert in GMP** – Nov-Dec (5 ctrs)
- **IPFA / NRL Symposium** – Indonesia, March 2017
- **August 2017 APEC Health Ministers meeting** – Status and Progress

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APEC Policy Forum

Hanoi, Vietnam December 2016



Emphasizes the importance of GMP and setting GMP as a priority



DRAFT VERSION: 16 Feb 2017

DRAFT

APEC Hanoi Recommendations on Implementation of Good Manufacturing Practices for Blood and Blood Products

The APEC Blood Supply Chain 2020 Roadmap, welcomed by APEC Ministers and Leaders in 2015, calls on APEC Economies to implement GMP throughout the blood supply chain to improve the availability of safe and quality blood and blood products. Good Manufacturing Practices (GMP) can help ensure the use of efficient processes that lower safety risks while improving quality and availability. Currently, implementation and adherence to GMP standards for blood and blood products varies widely across the APEC region.

Summary

Quality

- APEC Emerging Economies are looking at safe blood:
 - To build a safe recovered & source plasma supply
 - To recognize plasma as a strategic resource
 - To prepare for imminent demand from an aging middle class
- Quality is key to the 2020 APEC roadmap with a need to include GMP
- APEC approach
 - Think big
 - Start small
 - Scale up

APEC priority are economies with interest for change

Thank you

“Strategic independence of plasma should be endorsed on a global level.”

Strengers and Klein, Transfusion, 2016, doi:10.1111/trf.13913