IPFA 2nd Asia Workshop

The Key Elements for self-sufficiency of plasma-derived products

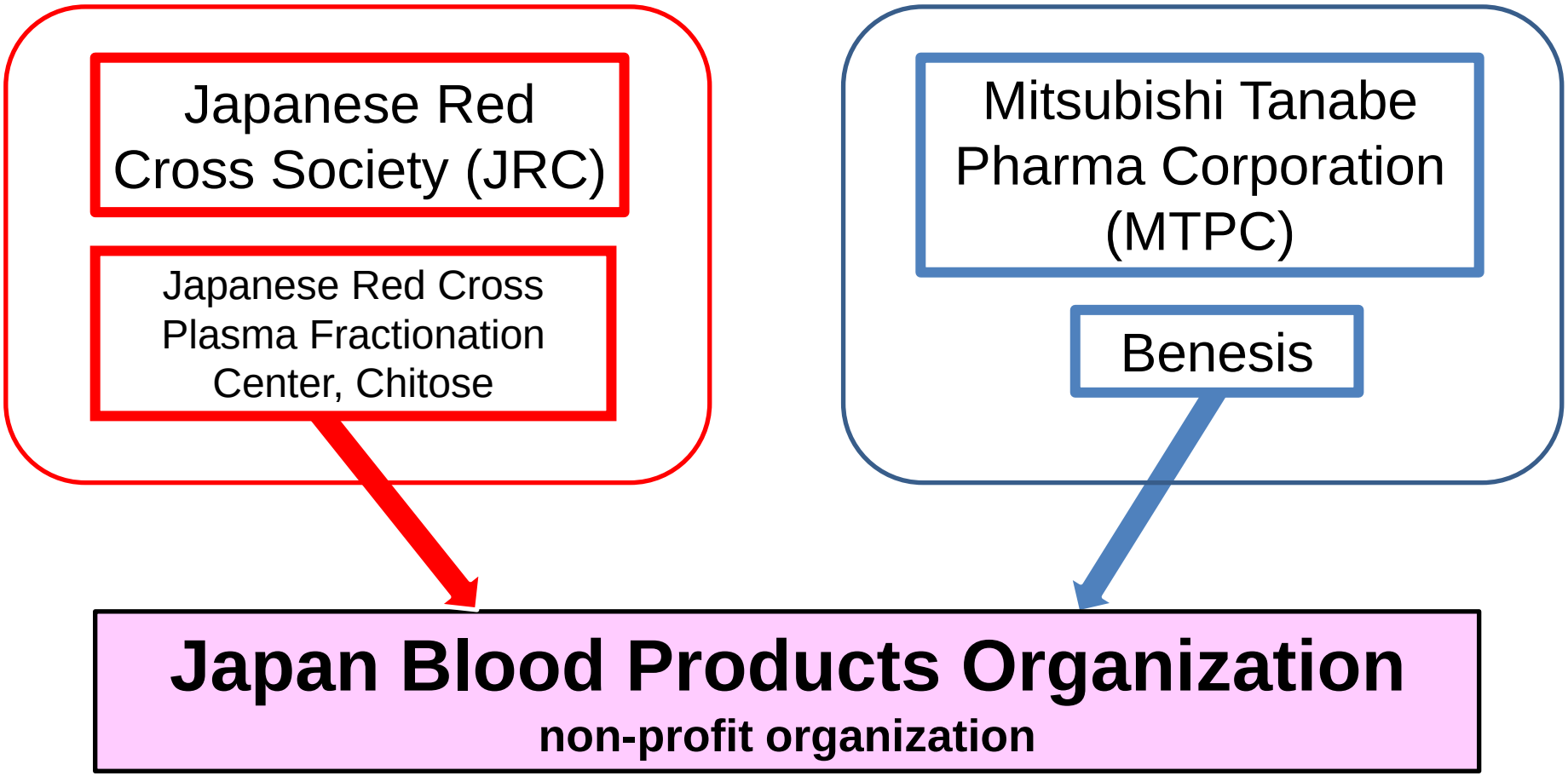
MAR 3, 2017

M. Tsuda

Japan Blood Products Organization

Introduction of JB

Establishment of JB



JB has started its operation from OCT 1, 2012

Philosophy

➢ Philosophy:

Bridging Good Faith and Healthcare

Through blood products derived from voluntary non-remunerated blood donations, we contribute to people's health with the highest sense of ethics and responsibility.

➢ Vision:

- ✓ **We contribute to achieve secure supply and self-sufficiency of blood products, giving the highest priority to their safety and security.**
- ✓ **We strive to be the best partner for patients and healthcare professionals.**
- ✓ **We strive to be a leader of plasma fractionation operations in Japan and around the world.**
- ✓ **Bear in mind the limitation of blood resources, we strive to explore new possibilities of blood products through everlasting challenge to innovate.**
- ✓ **We foster the corporate culture which respects pride and satisfaction of every employee.**

JB Profile

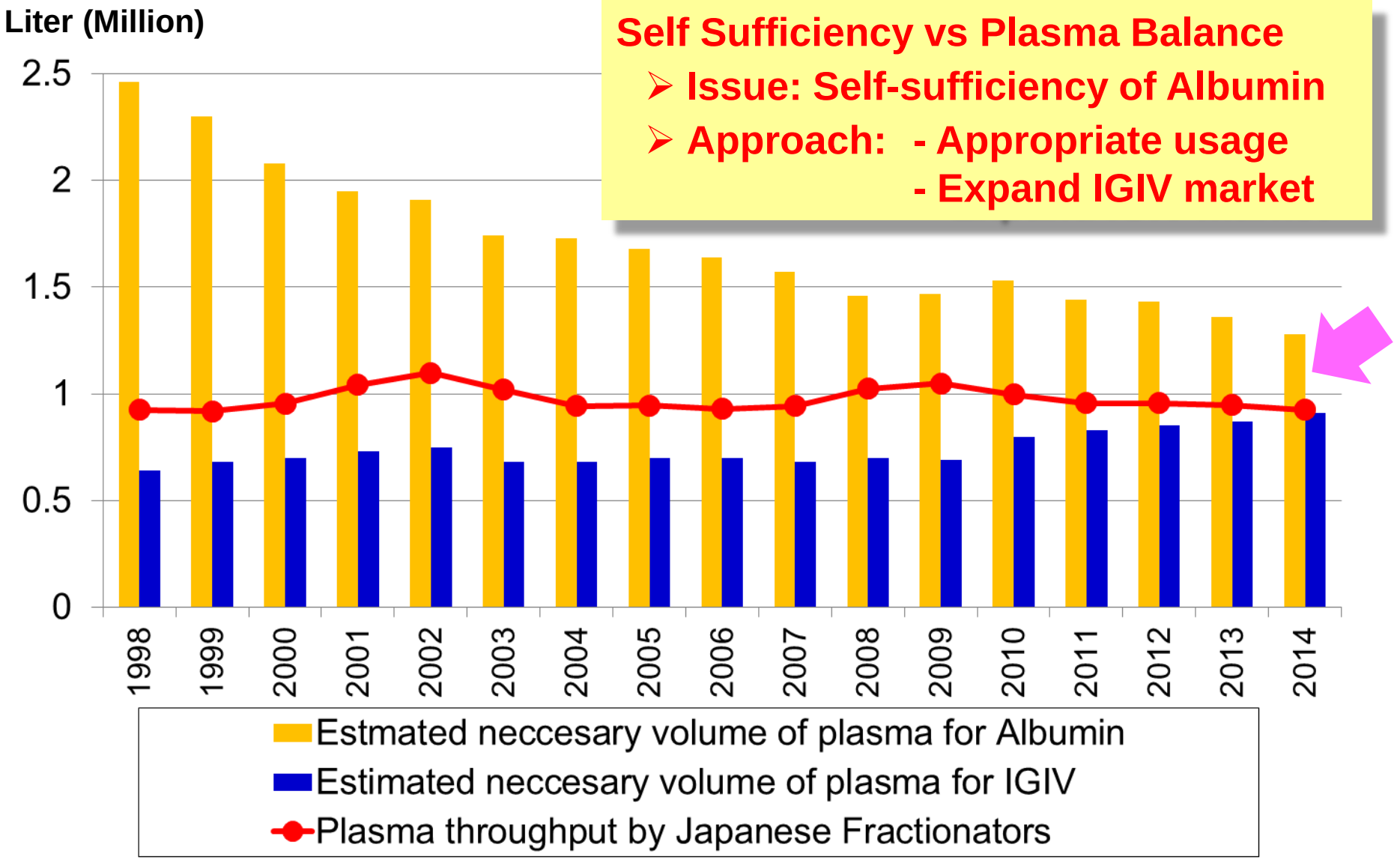
Name：	**Japan Blood Products Organization**
Head Office：	**Hamamatsu-cho, Minato-Ku, Tokyo**
Start-up：	**October 1, 2012**
Representative：	**Yuji Akiyama / Chairman of the Board** **Takahide Ishikawa / President**
Number of staff：	**approx. 1,100**
Business sites	
Headquarter:	**Tokyo**
Lab.：	**Port Island, Kobe**
Plants：	**Chitose Plant (former JRC)** **Kyoto Plant (former BC)**
Sales network：	**11 branches**

Self-Sufficiency in Japan

Self-Sufficiency in Japan

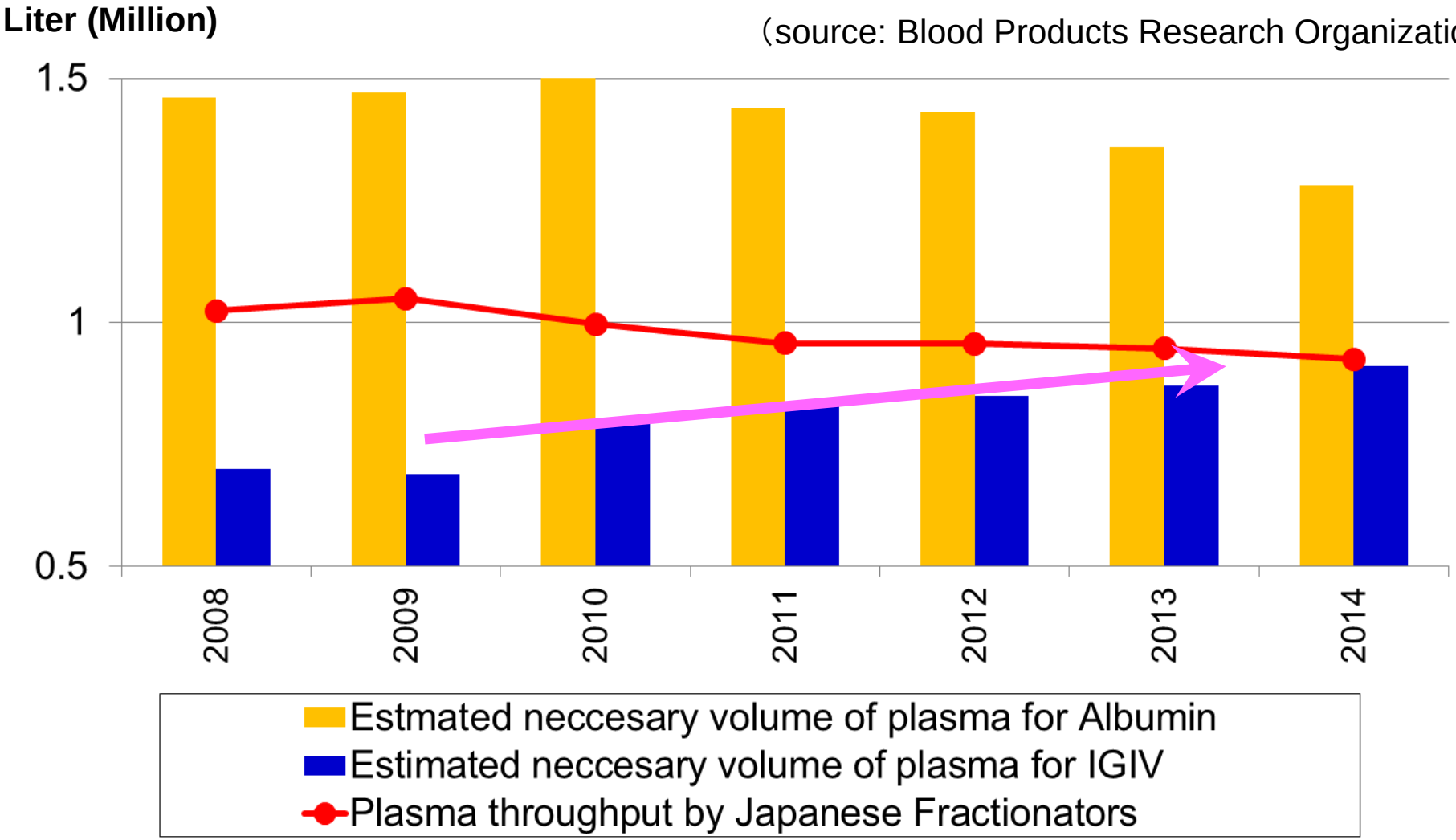
Self Sufficiency vs Plasma Balance

- **Issue: Self-sufficiency of Albumin**
- **Approach: - Appropriate usage**
  - Expand IGIV market



(source: Blood Products Research Organization)

Growth of IGIV Market in Japan



IGIV market is growing with new indications

Approved Indications of IGIV in Japan

Approved year	Indication
1980	Primary Immunodeficiency / Secondary Immunodeficiency
	Severe Infectious Disease such as sepsis
	Idiopathic Thrombocytopenic Purpura (ITP)
1990	Kawasaki Disease (KD)
1996	Chronic inflammatory Demyelinating Polyneuropathy (CIDP) / Multifocal Motor Neuropathy (MMN)
2000	Guilllain-Barre syndrome (GBS)
2008	Pemphigus
2010	Churg-Strauss Syndrome / Allergic Granulomatosis angiitis
	Polymyositis / Dermatomyositis
2011	Myasthenia Gravis
2014	Toxic Epidermal Necrolysis (TEN) / Stevens–Johnson Syndrome (SJS)
2015	IgG2 Deficiency
	Bullous Pemphigoid

Approach to Self-sufficiency of Albumin

Japanese fractionators are performing clinical trials for new indications of IGIV.

(Even if we have the height numbers of indications of IGIV)

Development Phase	Investigational Indication
P III	Microscopic PolyAngiitis (MPA)
P III	Optic Neuritis
P III	Infertility
P III	Kidney Transplantation
P II	Optica Spectrum Disorder

Our Approach:

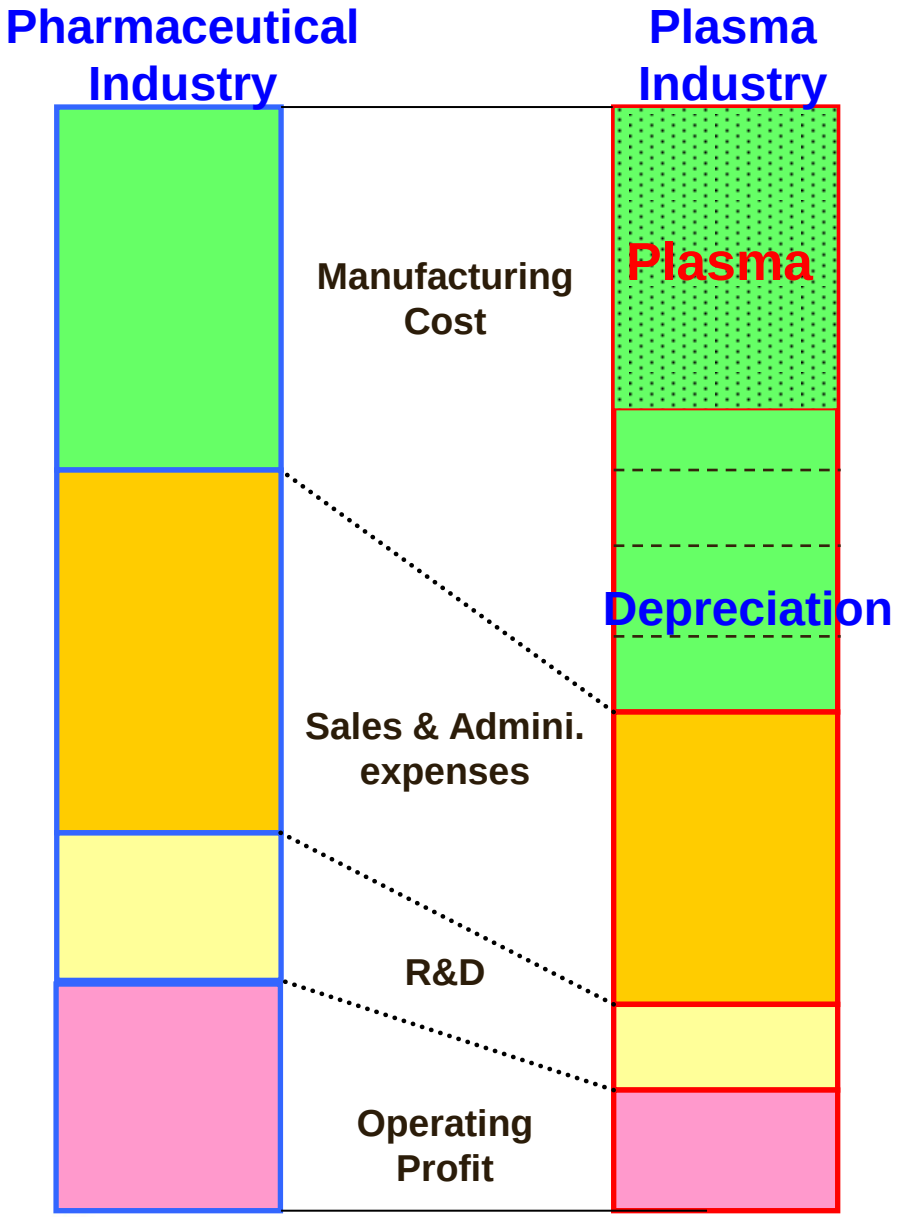
- Expand IGIV market with new indications.
- Increase plasma throughput for IGIV.
- Achieve self-sufficiency of Albumin by increasing plasma throughput.

Structure of Plasma Fractionation Business

Common Success Elements in Plasma Business

- **Raw Material:**
  - ✓ Source Plasma (volume & quality)
- **Revenue from Plasma:**
  - ✓ Market Size
  - ✓ Well-balanced consumption of each product
- **Investment:**
  - ✓ Plant Investment
  - ✓ Continual Technology Update
- **Others**
  - ✓ GMP regulations
  - ✓ Safety (e.g. Virus)
  - ✓ …..

Cost Structure Comparison (Image)



- High cost of Plasma
  → Revenue from Plasma
  - ✓ Market Size
    Certain Scale of Market (Revenue)
  - ✓ Well-balanced products (Plasma balance: Profitability)
- Large Plant Investment
- Small R&D Investment

Plant Investment & Technology

- **Large Plant Investment:**
  - ✓ **Long manufacturing processes for plasma-derived products require large space and a lot of equipment**

- **Updating a Technology (R&D Investment):**
  - ✓ **External environment, cost structure and progress of science require to update a technology.**
    - **Product / manufacturing process / Yield**
    - **Virus safety**

Plasma business requires large investment.

Current Situation in Southeast Asia

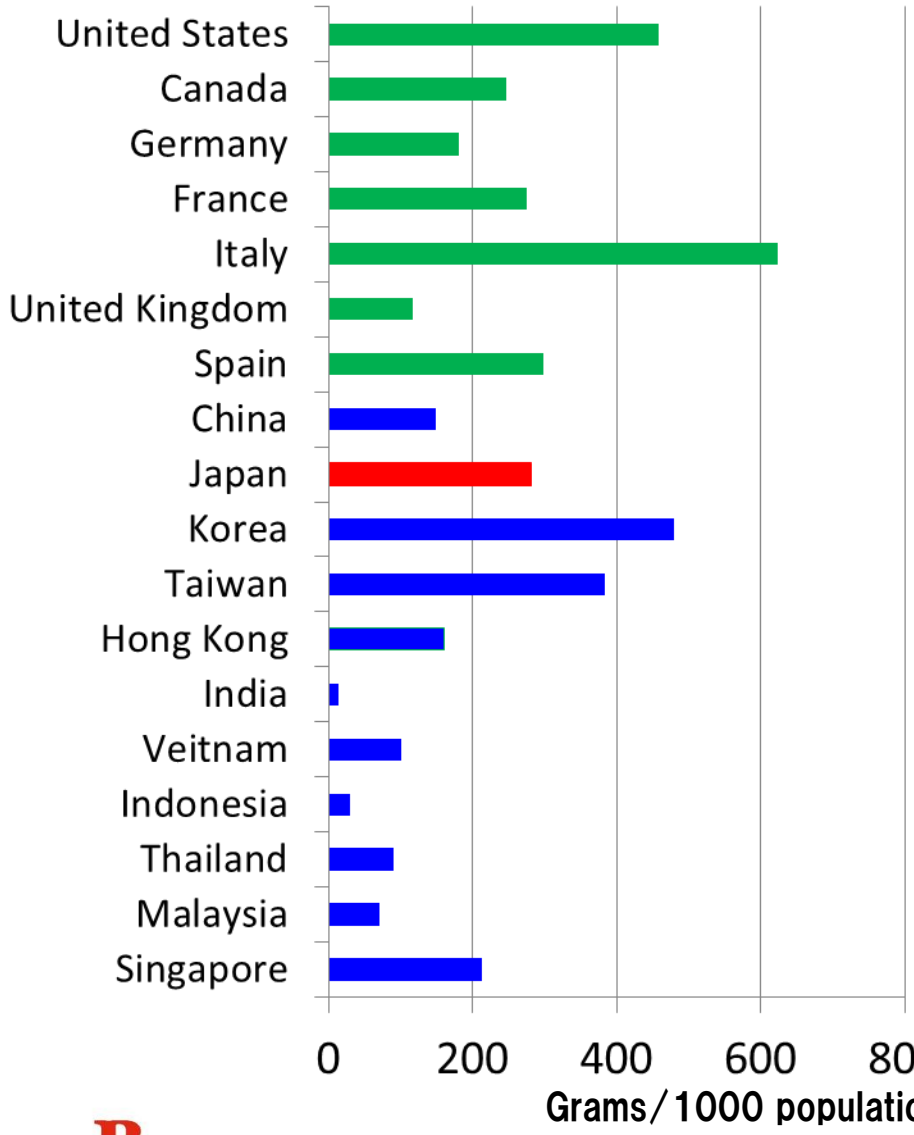
Market in Southeast Asia

- **Small Market:**
  - ✓ **Difficulty to use plasma-derived products due to economical background.**
- **Low Profitability:**
  - ✓ **Unbalanced consumption of Albumin and IGIV.**

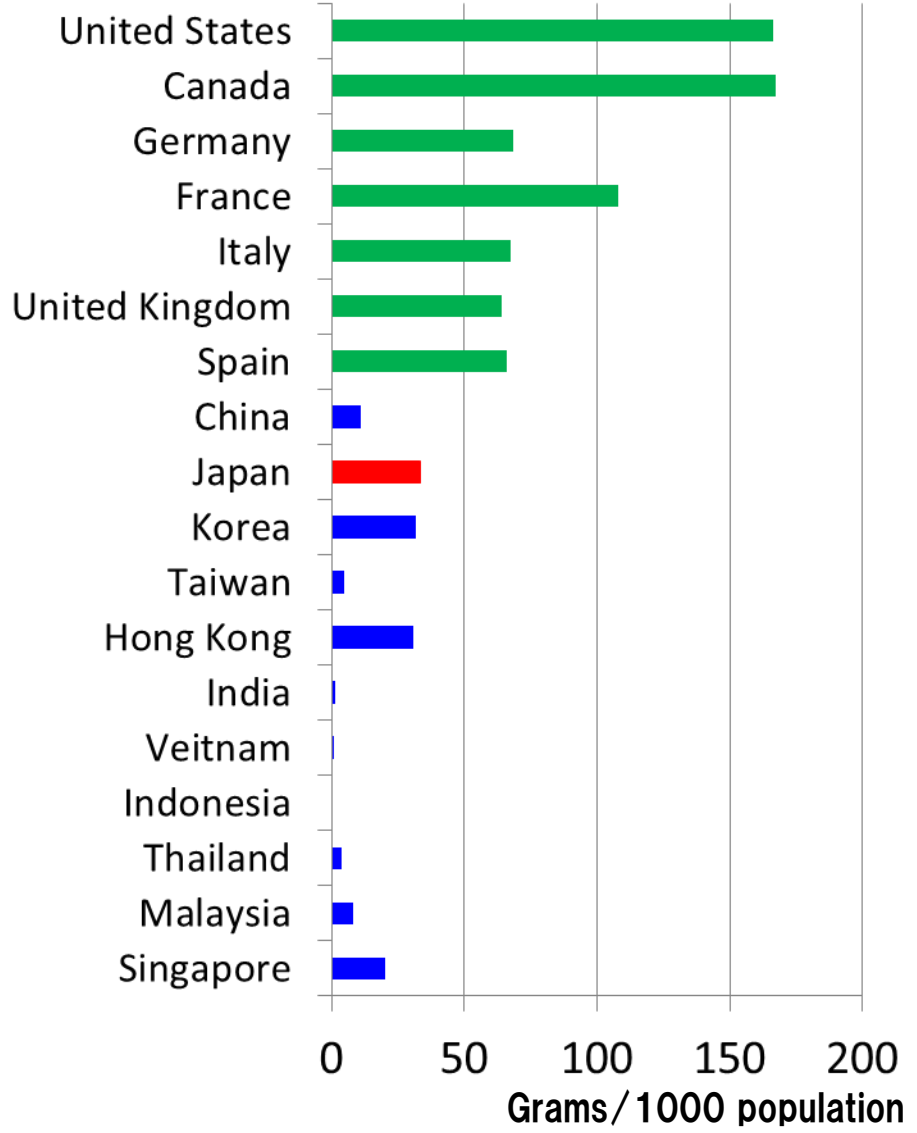
- **Difficulty to get enough revenue**
- **Difficulty to continue business operation**

Consumption of Albumin & IGIV

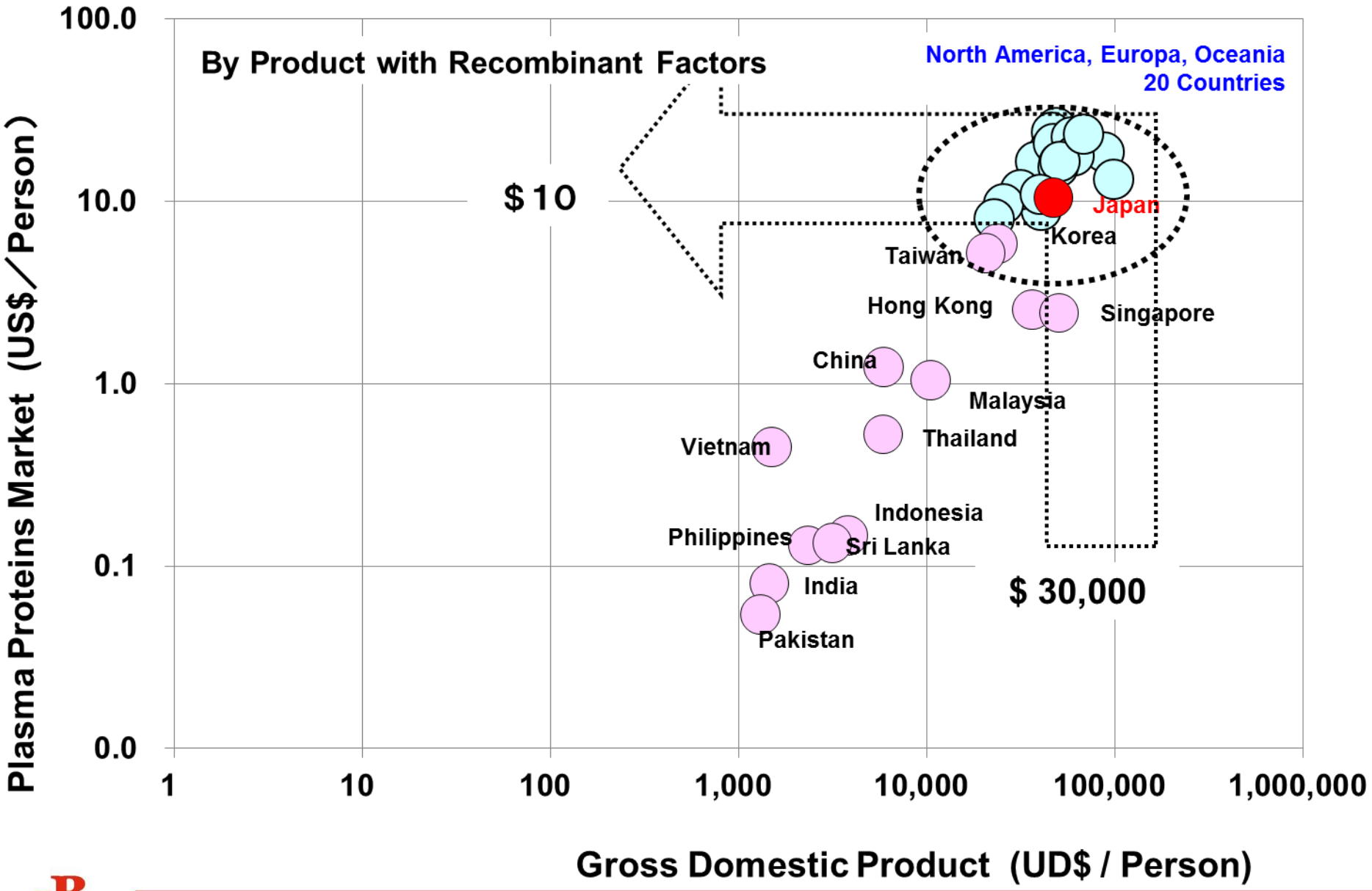
Albumin



IGIV (source: the Marketing Research Bureau)



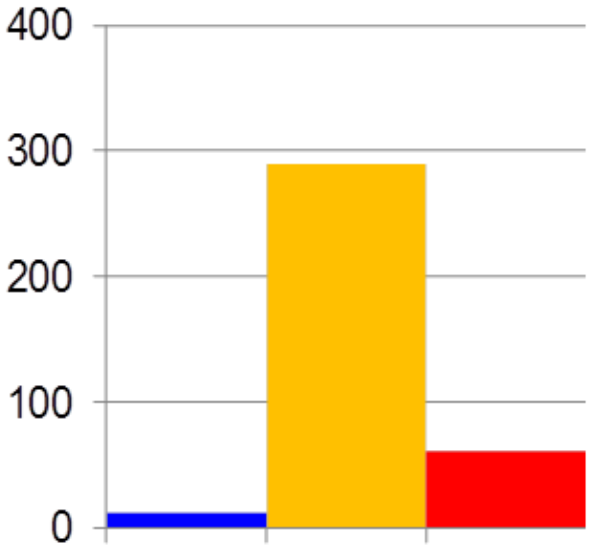
GDP vs Market Size



Plasma Balance in SE Asia

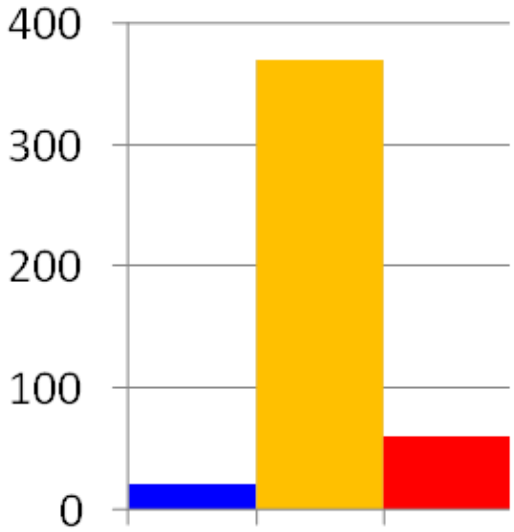
Thousand Liters

Indonesia



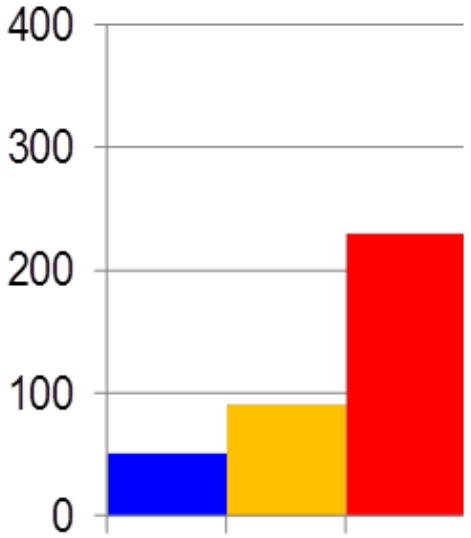
Thousand Liters

Vietnam



Thousand Liters

Malaysia



IGIV **Albumin** **FVIII**

(source: the Marketing Research Bureau)

Unbalanced consumption results unprofitability.

	US / EU	Southeast Asia
Revenue from Plasma	$ 400 – 700 / L Plasma	$ 127 / L Plasma

Plant Investment & Technology for SE Asia

- **Large Plant Investment:**
  - ✓ **Equipment is expensive as US / EU level.**
    - **Equipment for plasma fractionation are dedicated**
- **Update a Technology:**
  - ✓ **No goal even if technical transfer is finished from third party.**
  - ✓ **Need to introduce new technology by oneself.**
    - **Product / manufacturing process / yield**
    - **Virus safety**
  - ✓ **Cannot survive if don't have technology by oneself**

Profitability in Southeast Asia

- **Revenue from Plasma:**
  - ✓ **Small market of plasma-derived products (due to economical background)**
  - ✓ **Unbalanced consumption result unpofitability (Albumin vs IGIV)**
- **Investment:**
  - ✓ **Large plant investment (long processes and economical background)**
  - ✓ **Less technical capability and investment potential**

Summary

- **Plasma fractionation business is difficult.**
- **Business environment is not ready in Southeast Asia.**
- **Toll manufacturing is better until business environment is ready.**
- **Long term of technical guidance as well as initial technical transfer are important to construct plasma fractionation plant.**


Thank you