

NOVEL FACILITY DESIGN FOR PLASMA PROCESSING OPERATIONS

Eric Youssef, IPFA ASIA PACIFIC WORKSHOP, Taipei, March 2016

MERCK

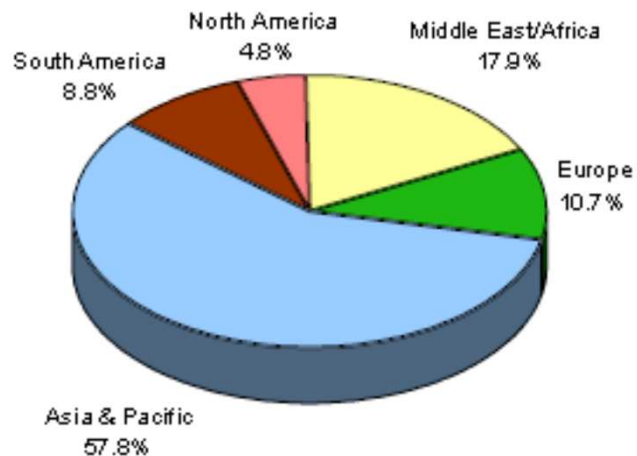
Agenda

1. Look at the current situation
2. Options available for setting up a facility
3. Modular Facility with Hybrid Technology
4. Conclusion

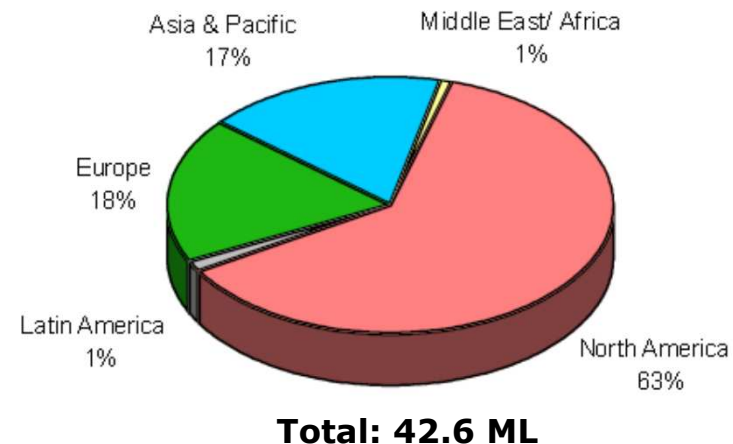
Emerging and access to care

Snapshot of the global Supply of Plasma for Fractionation

World Population by Region - 2013



Plasma for Fractionation by Region 2013
(Recovered & Source)



Source: Patrick Robert, Marketing Research Bureau, 4th Annual Bioplasma World Asia 2015

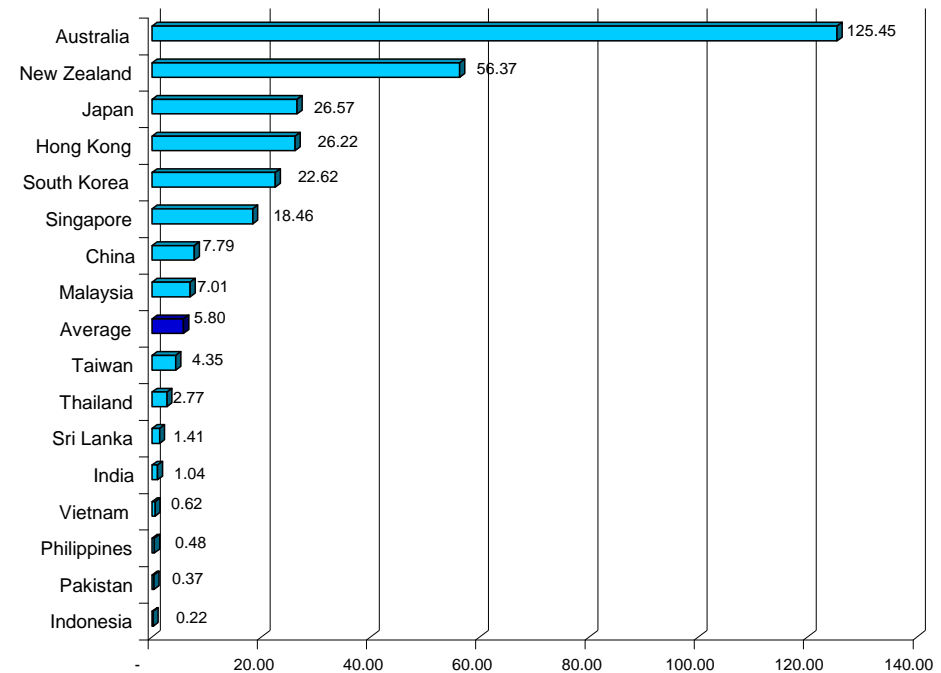
- Asia contributes to 17% of the world's plasma for fractionation and has 57% of the world population
- In Asia, two thirds of the plasma supply for fractionation is collected and processed in China
- The plasma available for fractionation in the other Asian countries is mainly processed in the region (Australia, Korea) on contract

Emerging and access to care

Future and challenges to meet patients' need

- Worldwide plasma supplies are a finite resource and demand for Plasma derived therapies is increasing (more diagnosis, access and awareness)
- The growing demand will require that large quantities of plasma be collected and fractionated to meet self-sufficiency.
- For a given country, self-sufficiency is its ability to secure all the therapeutic plasma products needed by its population from its own plasma, regardless of where it is fractionated and how it is supplied
- There are 2 major identified supply strategies:
 - Toll fractionation
 - Investment in local fractionation facility

AVERAGE IVIG/SCIG CONSUMPTION IN SELECTED COUNTRIES - 2009
(Kilograms per Million People)



Source: Patrick Robert, Marketing Research Bureau, 2th Annual Bioplasma World Asia 2013

⇒ **Which strategy is the best for my country/population?**

Emerging and access to care Challenges to build its own facility

• Points to consider before investing:

- Economics
- Plasma supply and quality
- Technical and Regulatory knowledge
- Timing and resources
- ...

• Several options if investing:

	Brick and Mortar	Single-use	Modular/ Hybrid
Fractionation	✓		✓
Novel process		✓	

⇒ Which option is the best for my country/population?



Picture Source: Dr Pierre-François Falcou, 4th Annual Bioplasma World Asia 2015

Plasma Processing Operations Facility Options

Budget...

- How will the project be funded?
- How to assess financial impact and gains of different options?
- Cost impact in case of relocation/ repurpose ?

**Your choices
will impact
your success**



Location...

- Do you have an existing building?
- « Clonability in other locations?
- Possibility to relocate?

Time...

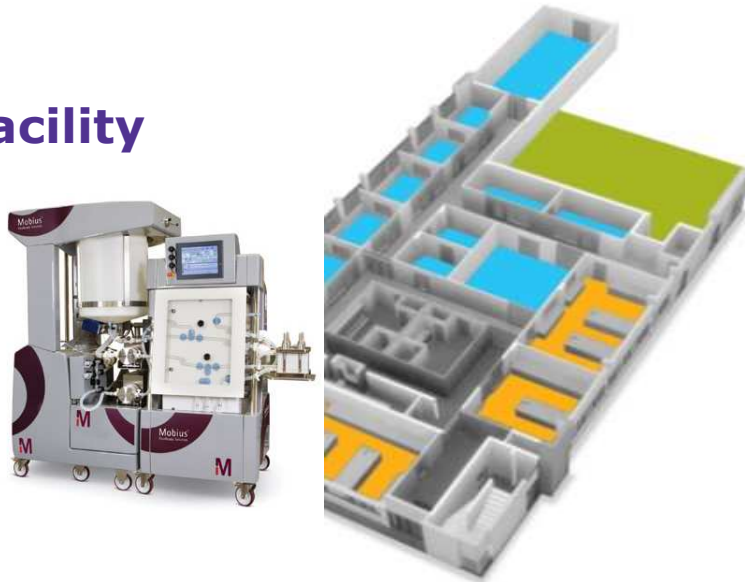
- Need of a rapid deployment?
- Fast timing constraints?

Drug production forecast...

- Single product or multi products plant?
- What is the expected annual capacity?
- Capacity scalability needs (up and down)
- Possibility to repurpose?

Plasma Processing Operations Modular Facility with Hybrid Technology

Facility

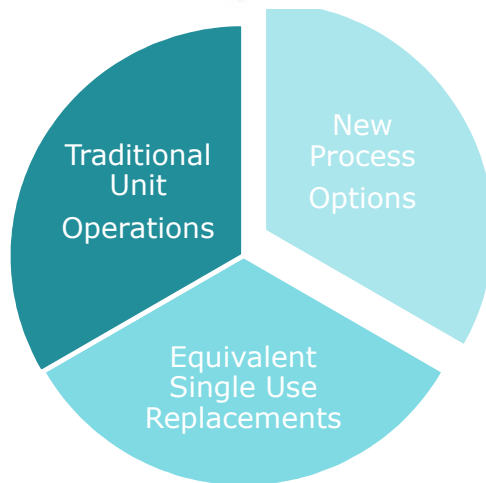


Our approach:

- Understanding process details
 - in partnership with the process originator
- Basic Design for multiple capacities
 - Facility layout
 - Facility sizing
 - Equipment list
 - Flow and personnel

⇒ **2 days workshop**
⇒ **First gate for Go/ No Go**

Technology & Validation

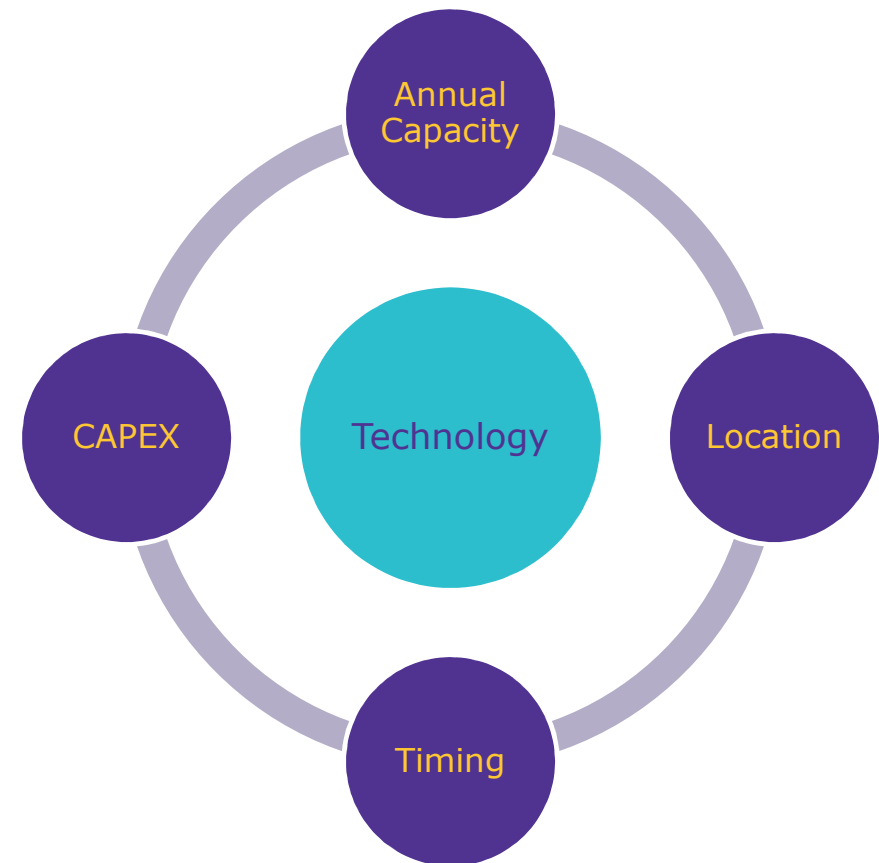


Plasma Processing Operations

Applicability – Modular Facility with Hybrid Technology

- Annual Capacity up to 150KL
- Variable Location Selection
- Project Duration of 12 to 24 months
- Technology 75% SU and 25% SS (conservatively) AND all are traditional unit operations
- CAPEX 50 to 80% lower than traditional facility
- Competitive COGs/OPEX

...where traditional offerings below 300KL annual capacity might not be economically viable



Future Challenges to Meet Patient Needs

One Possible Alternative – Modular Facility with Hybrid Technology

For a given country,
self-sufficiency to secure therapeutic plasma products
needed by its population from its own plasma.



Designing and constructing a facility to meet
capacity, budget and timing requirements



Finding the right balance between
traditional, single use and new technologies

THANK YOU FOR YOUR ATTENTION

ERIC YOUSSEF
ASSOCIATE DIRECTOR, PLASMA INITIATIVE

eric.youssef@merckgroup.com

