



# Plasma: what it is and how is it collected



Dr. René Büchel, Head 3<sup>rd</sup> Party Plasma EU  
Baxalta GmbH/Takeda, Switzerland

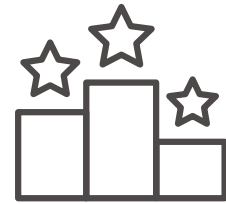
**Better Health, Brighter Future**

# Agenda

- **Introduction to Takeda**
- Plasma
- Recovered Plasma
- Source Plasma
- Where is plasma coming from
- Situation in Latin America



Our heritage, expertise and continued commitment put us in an unrivalled position to redefine the plasma landscape for the benefit of patients



**TOP 3**

in plasma

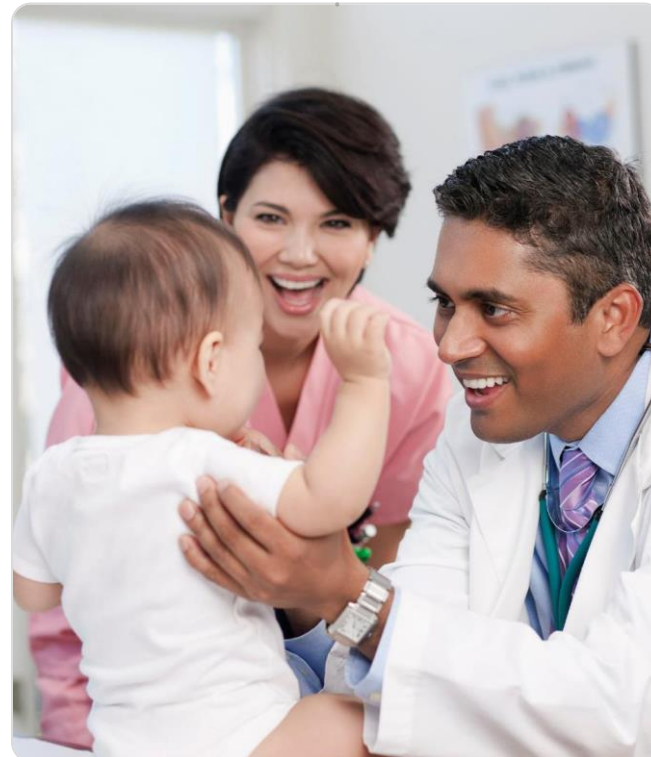
**65+ YEAR**

pioneer legacy in plasma  
product manufacturing

**> 20**

**PLASMA DERIVED  
THERAPIES** with no patent  
expiry

**BROADEST AND MOST  
DIFFERENTIATED  
PORTFOLIO**



**DEDICATED PLASMA-DERIVED  
THERAPIES BUSINESS UNIT**

investing to grow

**PLASMA-  
FOCUSED**  
R&D Team

**7**

MANUFACTURING  
SITES

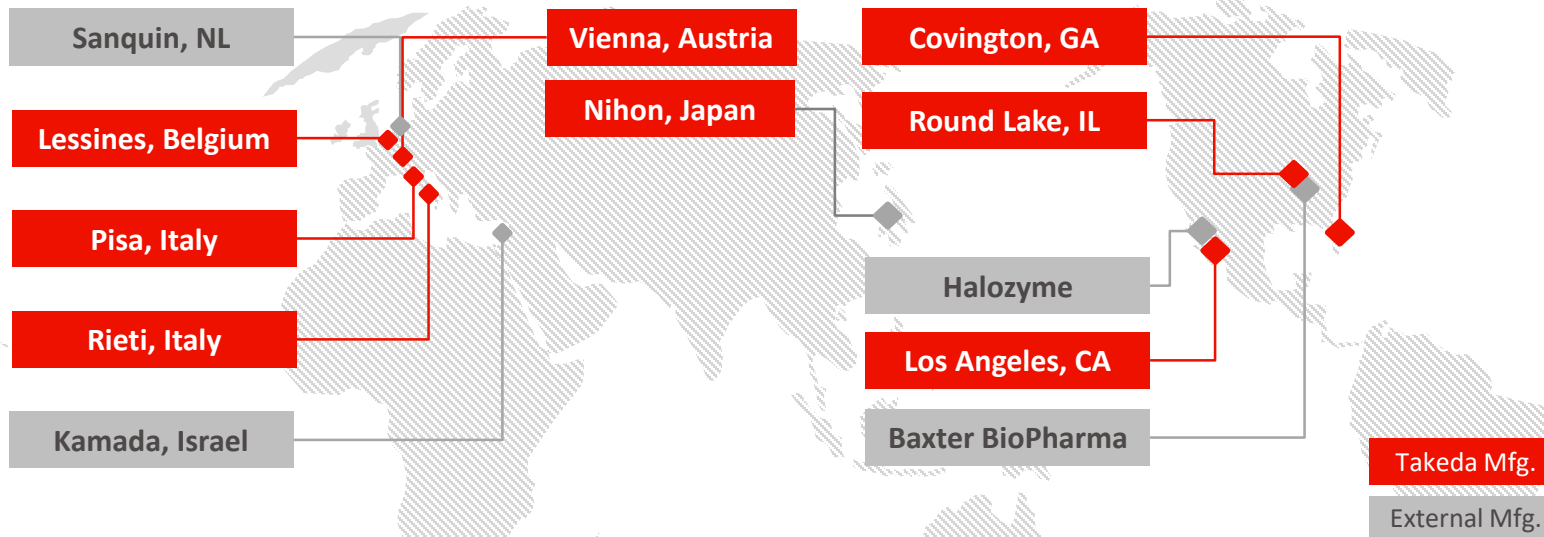
**140+ PLASMA  
COLLECTION CENTRES**

**13,000 EMPLOYEES**

worldwide, focused on plasma business



We are also a pioneer and world leader in plasma therapy manufacturing with the highest quality standards



## **PIONEER: 65+ years**

of developing plasma products at commercial scale

## **8 STRATEGIC LOCATIONS**

allowing independent yet inter-related manufacturing operations

## **FUTURE CAPACITY**

to increase production of our portfolio to meet market growth

## **CONTINUALLY INVESTING**

in state-of-the-art facilities that meet the highest quality standards

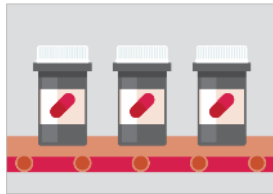


Production of plasma-derived therapies, like immunoglobulins, is complex and lengthy, requiring up to 12 months from donation to delivery

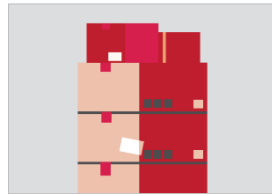
### 'Traditional' pharmaceuticals



Compound  
mixing



Capsule  
filling/tableting



Packaging  
& distribution

Final  
product is  
determined  
up to ~6 months  
before delivery

START

3 MONTHS

6 MONTHS

9 MONTHS

12 MONTHS

### Plasma-derived therapies



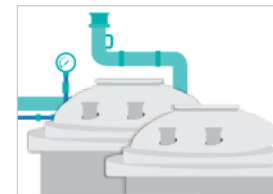
Plasma  
collection



60-day required holding  
period for testing



Fractionation



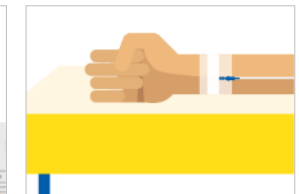
Purification



Filling



Packaging &  
distribution



Administration

Supply chain manages significant complexity across the network

# Agenda

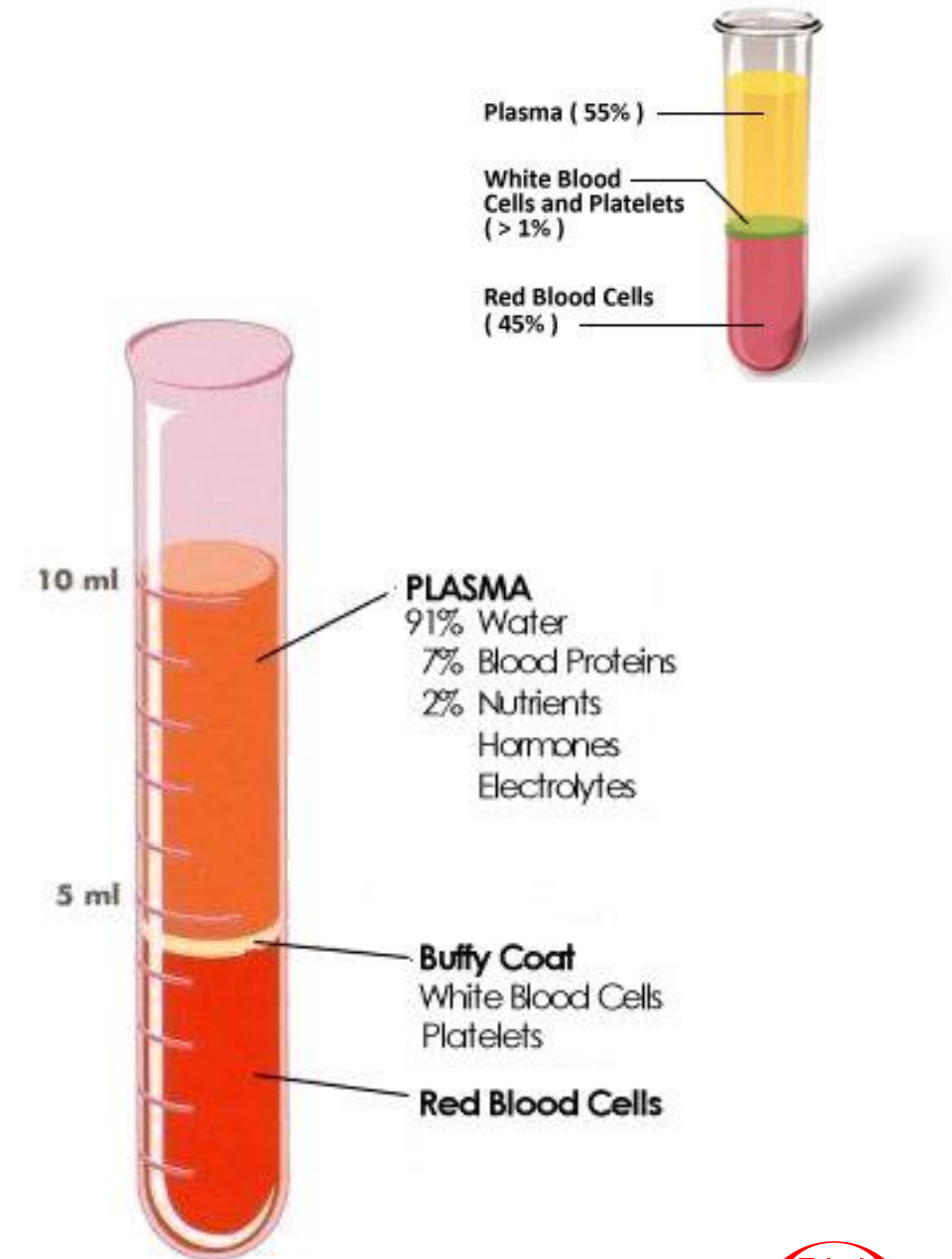
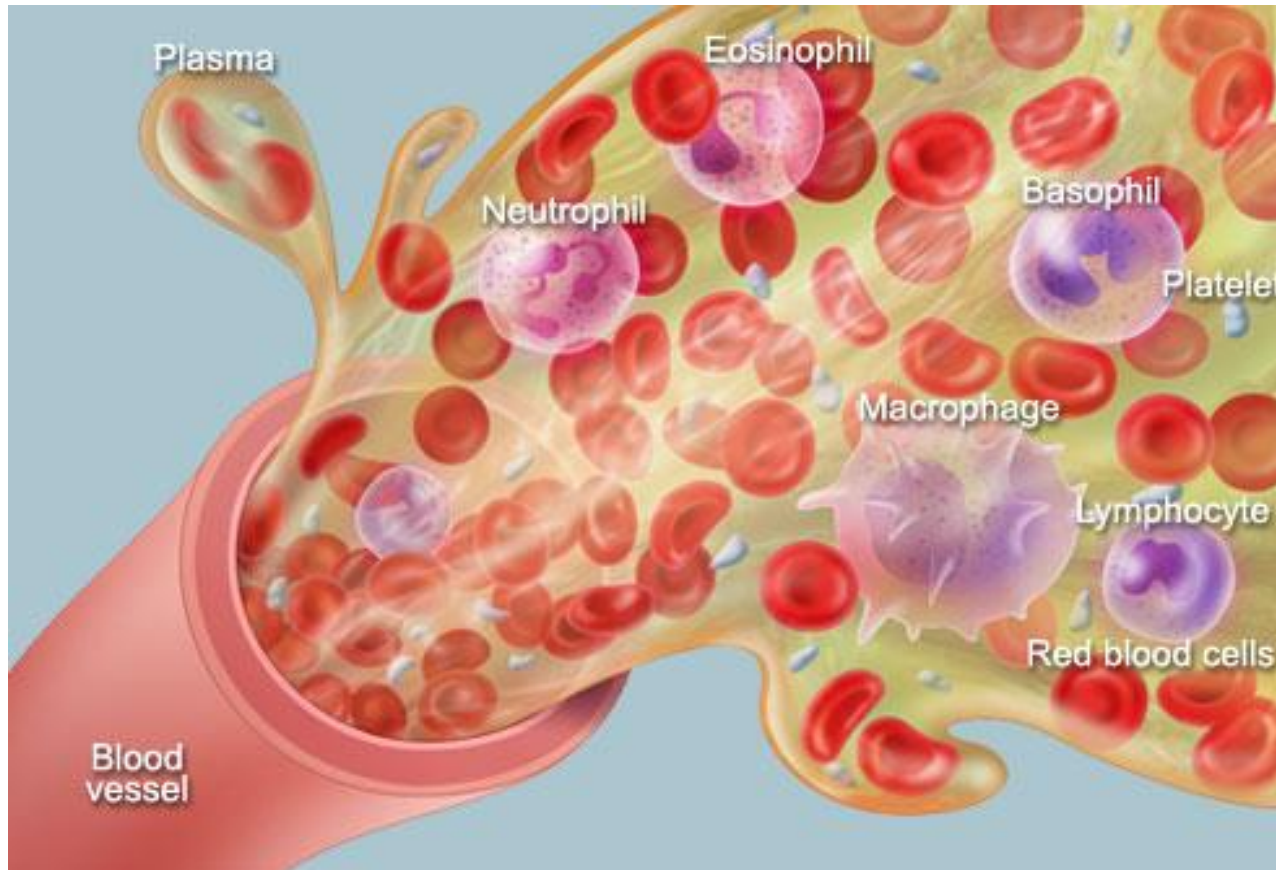
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# What is Plasma?

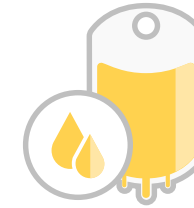
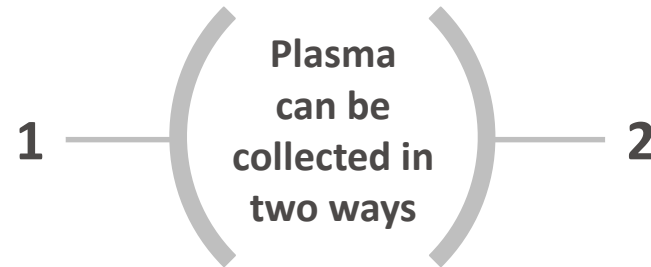
Plasma is the liquid part of blood



# While many people know about blood donation, few know about plasma donation



## Source plasma



## Recovered plasma

During 'plasmapheresis', blood is collected by a machine that separates plasma from red cells and platelets, which are returned to the donor

Donation ~ 1 hour

~ 800 ml donated

- USA: donation permitted x2 p/week (104 donations/year)
- Non-USA: donation frequencies generally lower (50–60 donations/year)

Few countries allow donor compensation, e.g. USA, Germany, Austria, Hungary, Czech Republic

Commercial plasma centers owned and operated by fractionators, or by third party collectors who resell the plasma to fractionators

Whole blood is collected, then separated into transfusable components (red cells, plasma and platelets)

Donation ~ 15 minutes

~ 280 ml recovered

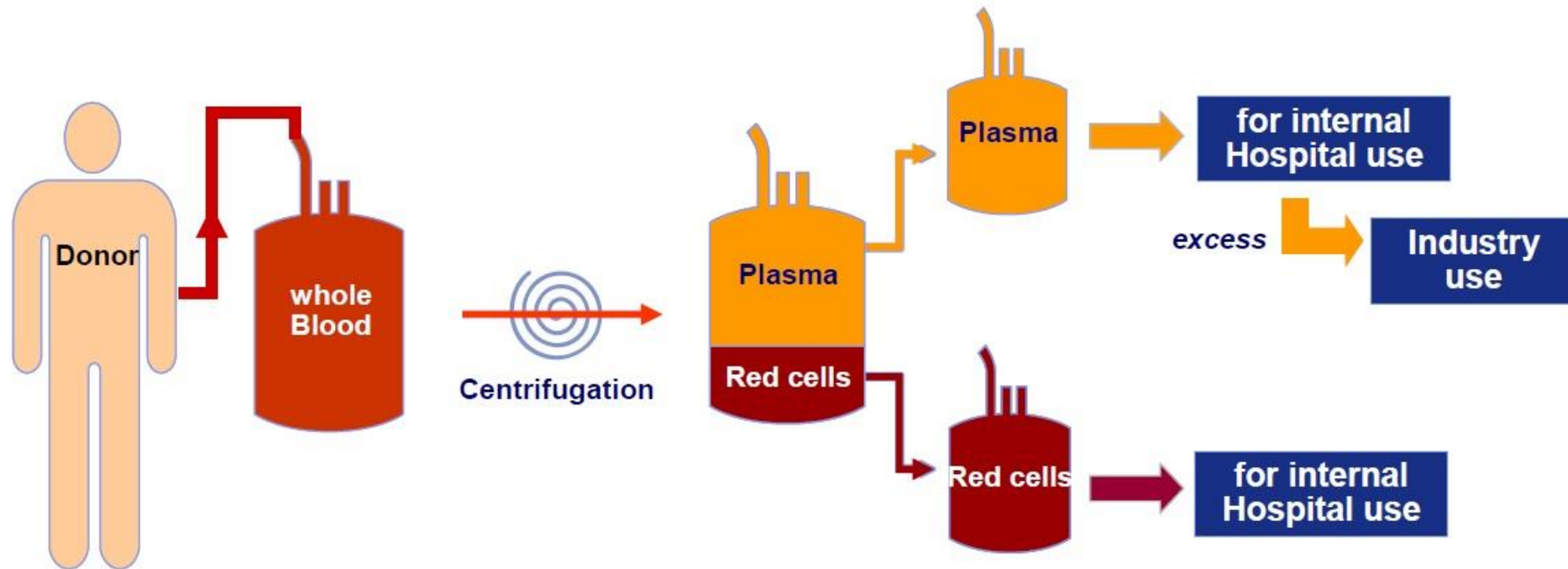
Donor can donate blood every 56 days (6 donations/year)

Non-compensated



# Recovered Plasma

Blood donation (average 40 min. process)



- Blood donor must wait minimum two months to repeat donation
- Standard plasma bag containing an average of 250 ml of plasma

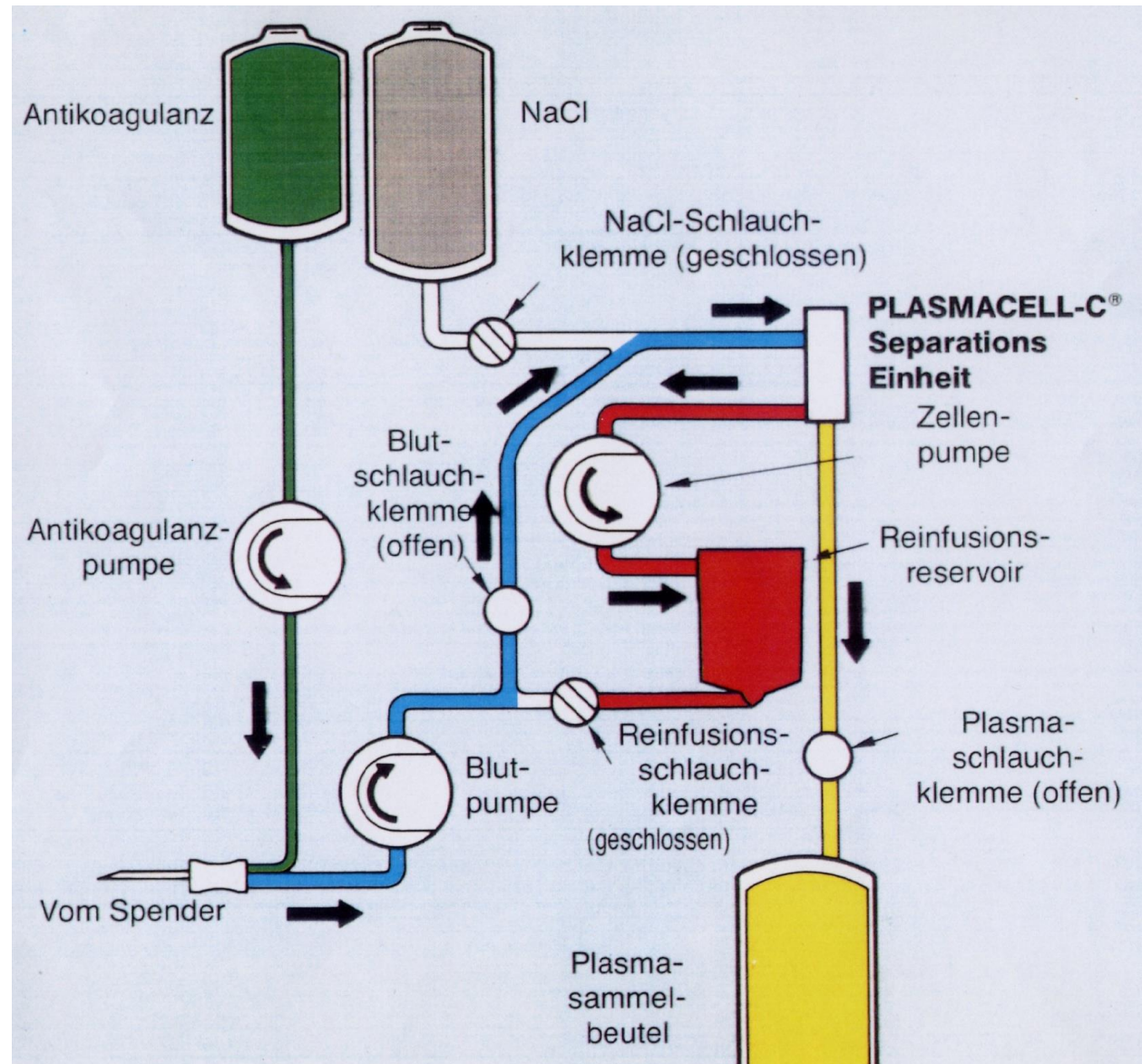
# Source Plasma

- Plasma donor must wait minimum two days to repeat donation
  - ✓ Different regulatory framework in all countries (from 15l to 100 l/y)
  - ✓ Different antibody profile and Ig content
- Standard plasma bag containing an average of 60-850 ml of plasma
  - The majority of Takeda's plasma is source plasma from qualified donors

# Source Plasma



# Blood Draw-Return of erythrocytes





# Final Product

Plasma bag with  
serology and NAT sample  
tubes attached



# Plasma after the donation

- After the donation
  - Serology and NAT samples are drawn from the plasma bag
  - The plasma bag is frozen to a core temperature of  $<-25^{\circ}\text{C}$
  - Storage of frozen plasma at  $<-20^{\circ}\text{C}$
  - Based on the results of the serological testing the lead physician releases the donations for shipping or destruction in case of abnormalities
  - Transport of plasma to the central plasma warehouse in Vienna with a freezer truck

# Plasma Logistics & Dispositioning

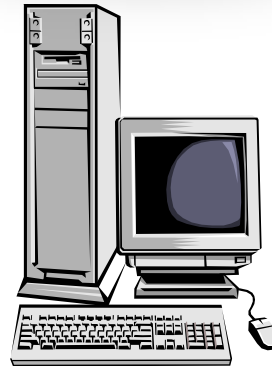
**Transport**



**Sample Logistic**



**Supply**



**APDS  
Plasma  
Admin.**

**Cold Storage**



**Sorting**



# Agenda

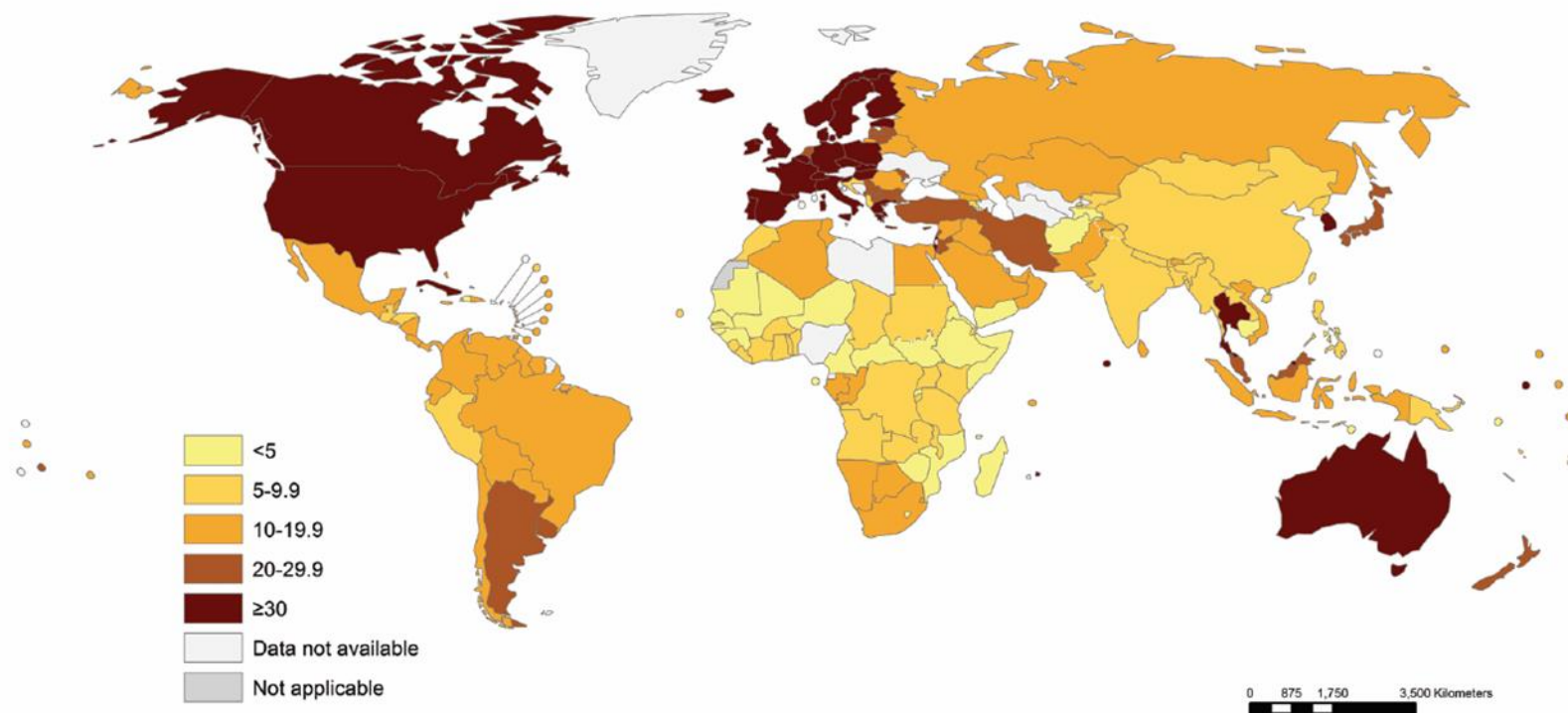
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# BLOOD COLLECTIONS IN LATIN AMERICA

**Figure 3. Whole blood donations per 1000 population, 2013**



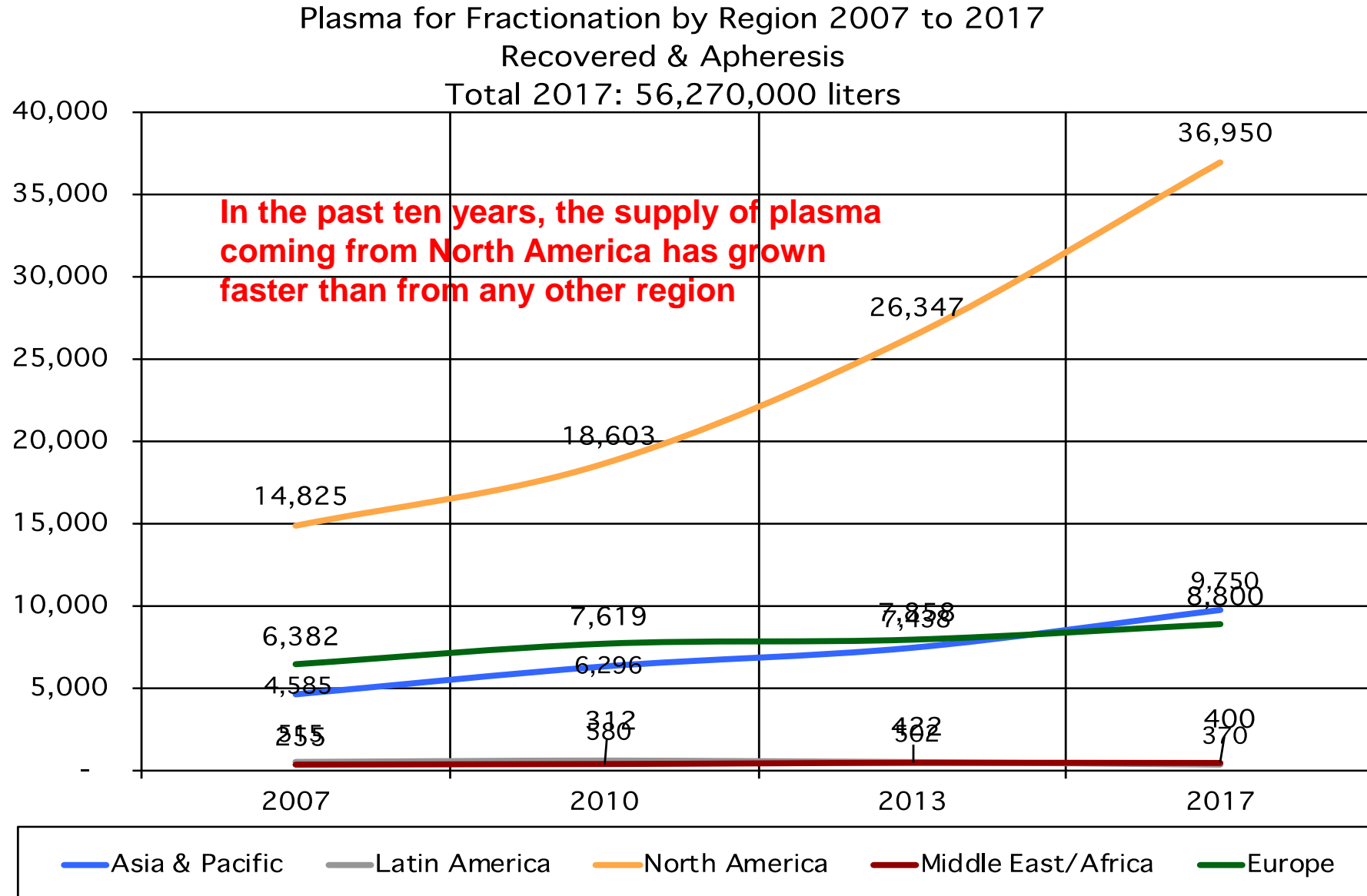
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: World Health Organization  
Map Production: Blood Transfusion Safety (BTS)  
World Health Organization



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# PLASMA COLLECTIONS



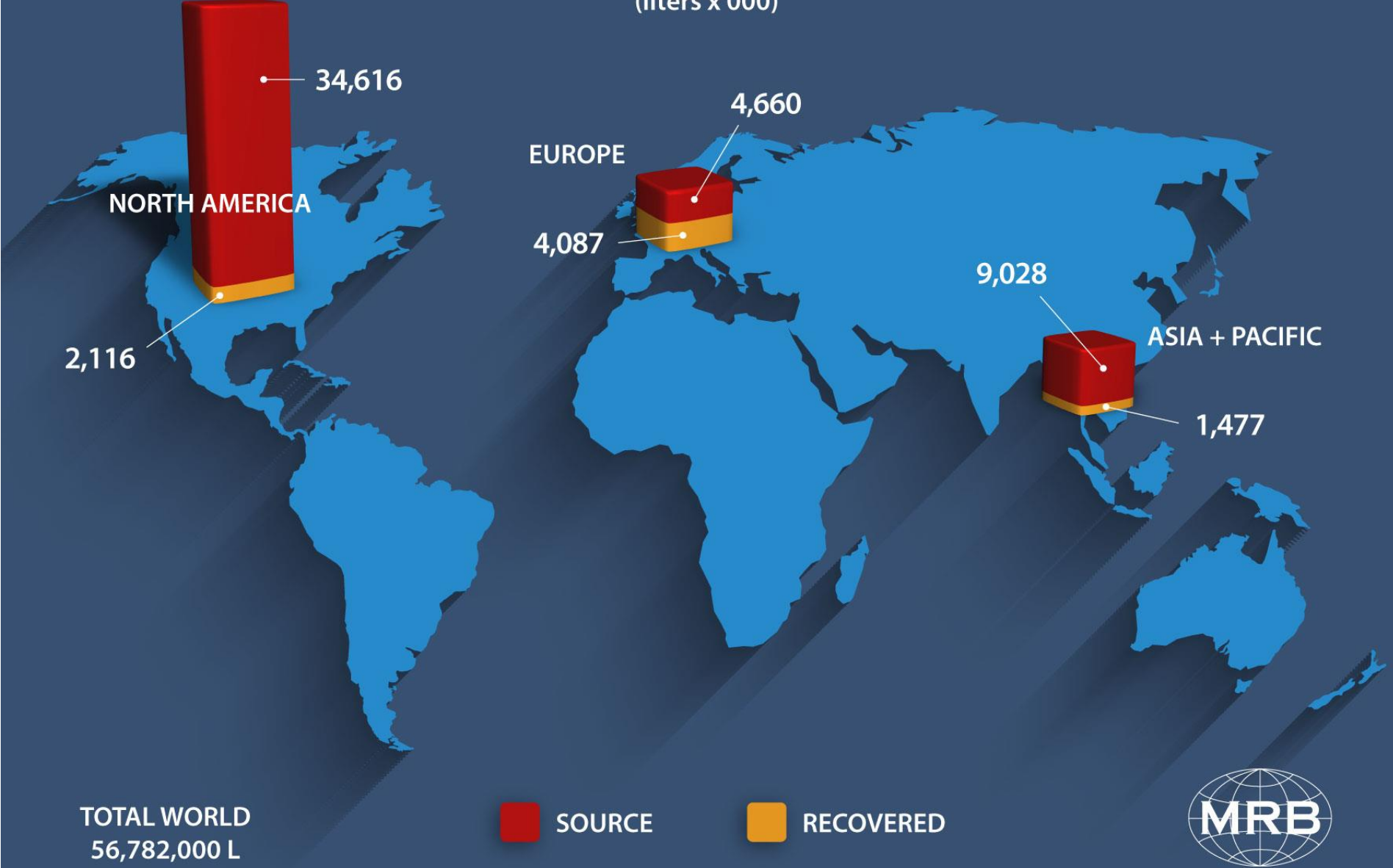
## US plasma – The worldwide producer of nearly 70% of PfF

Collection volume 2018 (2017\*) *per 1000* habitants achieved by a selection of countries:

- USA: 114 l (40 mio l / 350 mio hab) *still growing (new plasma centers)*
- AT: 69 l (600'000 l / 8.7 mio hab.) *limited potential to expand/rural communities*
- CZ: 61 l\* (640'000 l / 10.5 mio hab.) *limited potential to expand/strong public sector*
- DE: 35 l (3 mio l / 85 mio hab.) *difficult to expand/advertisement for cash forbidden*
- HU: 38 l (380'000 l / 9.9 mio hab.) *fast growing market (could reach 50 l in 2019)*
- CH: 8 l (68'000 l / 8.5 mio hab.) Red Cross only

# PLASMA FOR FRACTIONATION 2017

(liters x 000)



TOTAL WORLD  
56,782,000 L

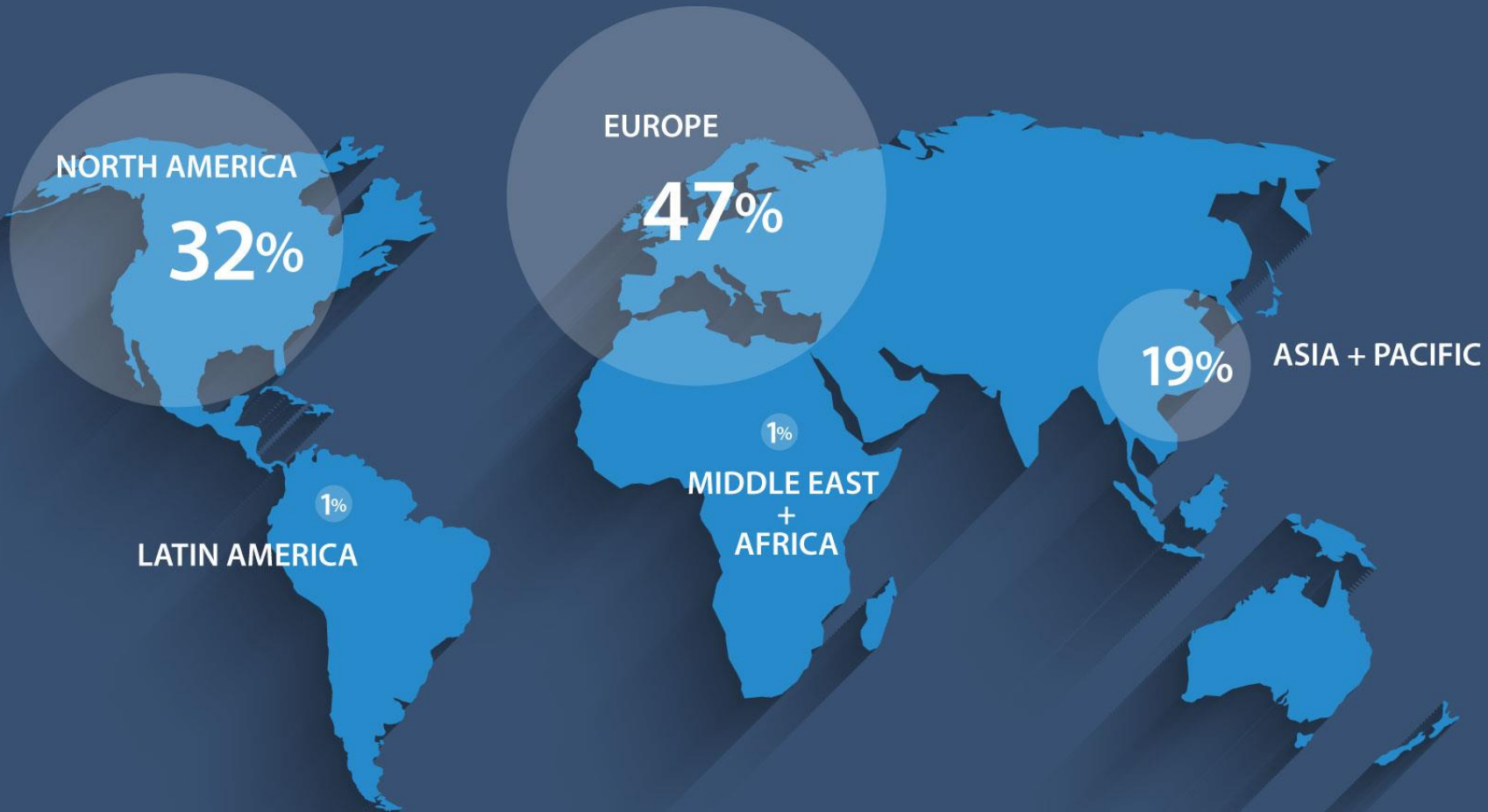
 SOURCE

 RECOVERED





## REGIONAL DISTRIBUTION OF FRACTIONATION THROUGHPUT 2017



GLOBAL FRACTIONATION THROUGHPUT 2017:  
54.5 MILLION LITERS



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## Current countries with fractionation capacity

- Argentina 200'000 l
- Cuba 130'000 l
- Venezuela 180'000

	<b><u>2015</u></b>			
	<u>NUMBER OF PLANTS</u>	<u>PERCENT</u>	<u>PLANT CAPACITY (000 LITERS/YEAR)</u>	<u>PERCENT</u>
EUROPE	26	33%	27,720	42%
NORTH AMERICA	8	10%	20,194	31%
ASIA & PACIFIC	37	47%	16,740	25%
SOUTH AMERICA	3	4%	520	1%
MIDDLE EAST/ AFRICA	4	5%	800	1%
TOTAL	78	100%	65,974	100%

Source: The Marketing Research Bureau, Inc.

## CONCLUSIONS

To produce PDMP we need PLASMA.

Due to low blood collections in Latin America and very low apheresis procedures, usage of FFP and WB in patients, the volume of available plasma is low and partly of insufficient quality because:

- No adequate freezing equipment
- Lack of transportation logistic (temperature controlled)
- Lack of centralization of collecting organisations
- Insufficient testing performed on blood
- Lack of GMP implemented and partly no Authority supervision
- Export of plasma to fractionators limited due to regulations





THANK YOU