9. Health & safety for donors

The safety of people donating plasma is tracked by the Safety of Intensive Plasmapheresis studies (SIPLA I 2003; SIPLA II 2013), and further European donor safety studies of several million donor experiences (PPTA 2016; 2018).

They assess detailed clinical data on the effect that extensive participation in the plasma donation process using plasmapheresis has on frequent plasma donors.

The results of these studies conclude that participating in plasmapheresis, and further European donor safety studies of several million donor experiences (PPTA 2016; 2018) is safe, even for first-time and inexperienced donors.

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Donor Health & Safety

A range of European plasma donor studies have tracked the safety of intensive plasmapheresis, and analysed risk factors such as the intensity of donation, plasma volume per donation, frequency and the maximum plasma volume that one person can donate per year. The overall results show low risk and adverse events figures for the European donor population.

This body of evidence concludes [25]:

- No significant adverse effects were registered on donor health by long-term intensified plasmapheresis if Hemoglobin, Total Protein and Immunoglobulin levels are monitored regularly.
- Donors and non-donors have equivalent humoral immune responses.
- Risk of adverse events decreases with the number of donations.
- Cardiovascular risk for donors is unaffected by plasmapheresis, evidenced by biochemical cardiovascular risk markers.
- Plasma donors have less Dialysis-Associated Encephalopathy than Whole Blood donors and Blood Platelet donors.

SIPLA 2 study concludes that plasmapheresis is safe (based on max. 60 donations/year & volume depending on body weight).

Cross-industry assessment of donor adverse events

A further study by PPTA analysed adverse events over millions of plasma donations tracked across plasma protein therapy producers. It found that the majority of donor adverse events observed were mild and the need for medical intervention was rare [26].

In Germany, guidance on donation frequency is set by the science-based data provided by the German Chamber of physicians. [27, 28]

2016 Data Collection Study Highlights	
Data collection period	3 months in 2016
Total plasma donations	7.6 million (79% of industry)
Dialysis-Associated Encephalopathy (DAE) recorded	15,300
Overall DAE rate	2.09 per 1000 donations
Top 2 DAE Categories 75% of all Adverse Events (AE)	Hypotensive/vasovagal prefaint with no loss of consciousness (57% of all AEs). Local injury (hematoma/bruise) related to phlebotomy (18% of all AEs).
Most rare DAE categories	Severe hypotensive events (0.06 per 1000 donations) Hypotensive events with prolonged loss of consciousness (0.01 per 1000 donations) Hypotensive injury (0.007 per 1000 donations)
2018 Data Collection Study highlights (publication in preparation)	
Data collection period	4 months in 2018
Total plasma donations	12.5 million donations
Overall DAE rate	1.58 per 1000 donations
Top DAE Categories	Vasovagal
Rare occurrences	Medical intervention Donors needing transportation to the hospital within 24 hours, including donors who has AEs after leaving the donation centre (0.04 per 1000 donations).

Product safety in the plasma process

Plasma donation is a safe procedure. The donor screening and plasma protein therapy manufacturing processes ensure safety of final products. Over the past two decades no transmissions of blood-born infections have been reported in association with the use of plasma protein therapies.

Plasma donors' health is protected by European regulations that govern the operation of plasma donation centres – including quality standards, the frequency and volume of donations for each donor, infrastructure and personnel requirements.

Plasma purity and safety is ensured by three processes in the pathway from plasma donation to manufacturing of plasma protein therapies:

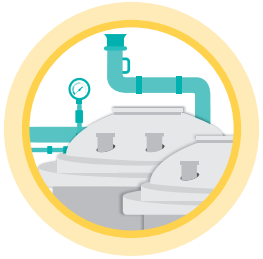
- Donor screening and exclusion of high-risk donors
- Testing for virus pathogens
- Elimination of contaminants potential pathogens from the manufacturing process.

Plasma safety & purification process in medicines production

1. Donation

Only people passing rigorous safety screening are accepted as donors in plasma centres.

2. Pooling



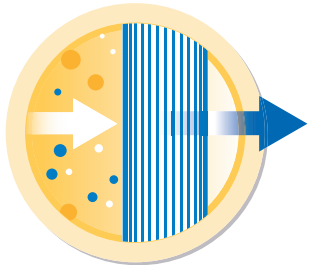
3. Purifying & Testing

Screening for a wide range of pathogens and viruses, including:

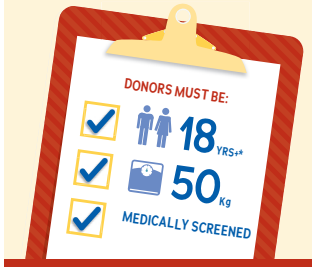
- Human immunodeficiency virus (HIV)
- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Hepatitis A virus (HAV)
- Parvovirus B19

Further testing of manufacturing pool using Nucleic Acid Testing ensures that only plasma safe for medicines production moves into fractionation, where proteins are separated from the plasma.

4. Fractionation



The fractionation process includes further steps of contaminant removal and inactivation.



The PPTA independent Qualified Donor programme requires all prospective donors giving for use by its partners to have two satisfactory health screenings and negative test results within six months, before being authorized to give plasma.
Without meeting this requirement their plasma will not be used to manufacture plasma-derived medicines. This policy is important, firstly to protect donors' health and wellbeing, and to help ensure the quality and safety of the therapies that patients need to treat life-threatening diseases.