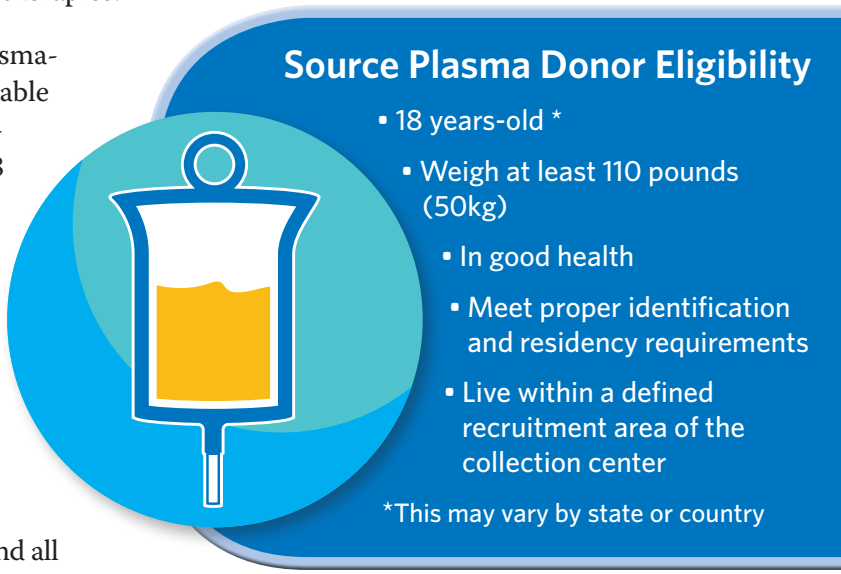
PPTA
Plasma Protein Therapeutics Association

THE FACTS ABOUT...

SOURCE PLASMA DONORS

The quality and safety of plasma-derived and recombinant analog therapies (collectively referred to as plasma protein therapies) is the highest priority for manufacturers worldwide that produce these life-saving medical treatments. While the U.S. and European government authorities license and regulate all plasma collection and manufacturing operations, the industry has gone beyond those requirements by proactively developing rigorous, voluntary standards for certification that help ensure that plasma protein therapies are of the highest quality. These robust programs are in their second decade, showcasing the industry's commitment to continuous improvement and to helping ensure the availability of effective and high-quality plasma protein therapies.

One vital component of ensuring that plasma-derived therapies are of the highest attainable quality is to place strict eligibility requirements on donors giving plasma in the 408 government licensed and International Quality Plasma Program (IQPP)-certified plasma collection centers located in the United States, Europe and Canada. Those layered requirements follow:



- Only people lawfully permitted to be in the country can give plasma in a government licensed plasma collection center, and all individuals are asked to provide a valid, government-issued photo identification.

- In addition to verifying their identity, donors must provide proof of a local residential address in a defined donor recruitment area near the plasma collection center. Plasma collection center staff verify the information against a list of known, transient addresses such as temporary housing and hotels prior to permitting the donation.

- All new donors in the U.S. are checked against the National Donor Deferral Registry (NDDR) database, a leading-edge program containing information about persons permanently deferred from donating plasma due to positive test results for HIV, hepatitis B (HBV) and hepatitis C (HCV). The NDDR prohibits deferred donors from giving plasma at any IQPP-certified plasma collection center. The NDDR is a first-of-its-kind program in the source plasma collection industry.

NDDR
National Donor Deferral Registry

International Quality Plasma Program
The Worldwide Standard for Plasma

- Potential donors must pass two separate medical screenings and testing for HIV, HBV and HCV on two different occasions. Only after those satisfactory screenings and negative test results does that person become a Qualified Donor. If a donor does not return within six months, that person loses his/her Qualified Donor status and must qualify again. Therefore, plasma from a one-time-only donor (even when all test results are nonreactive) cannot be used for further manufacture. The standard results in committed donors and eliminates the risk that so-called "test-seekers" are accepted.

- In addition to identification verification, medical screening and plasma testing, it is important that plasma is collected from a low-risk population. New donors are required to engage in an educational program and follow-up assessment regarding HIV/AIDS and activities that place them at risk for HIV/AIDS. The educational program also encourages donors to lead a healthy lifestyle. Those potential donors, who acknowledge being involved in defined high-risk behaviors, are deferred from donating.

The plasma protein therapeutics industry is proud of its leadership in establishing plasma collection standards, which further ensure that only plasma from healthy, committed individuals is used to manufacture the replacement therapies that enable patients worldwide to lead healthier, productive and fulfilling lives.

	SOURCE PLASMA DONATION		WHOLE BLOOD DONATION	
	U.S.	EUROPE	U.S.	EUROPE
REGULATED FREQUENCY	Up to twice a week with two days in between	Up to twice a week, but limited to 33 times per year	Once every 56 days	Up to 6 times a year for men and 4 times a year for women, minimum of 2 months in between
NUMBER OF FACILITIES*	380	27	2,000	No data available
USES	Produce life-saving therapies	Produce life-saving therapies	Primarily for transfusion medicine in local hospitals	Primarily for transfusion medicine in local hospitals
TIME TO DONATE	1.5 to 3 hours	1.5 to 3 hours	Less than 1 hour	Less than 1 hour
UNITS DONATED**	18.8 million	1.4 million	14 million	18.8 million

*Source plasma centers that are government licensed and IQPP-certified. Blood center number from FDA registered blood establishments (June 24, 2008 FR notice) and does not include mobile collection units.

**Figure refers to number of source plasma donations made in government licensed and IQPP-certified centers in 2008. U.S. blood donation figure cited from FDA and the American Red Cross websites. European blood donation figure cited from the Council of Europe (2003).

Information as of May 2009

SOURCE PLASMA DONORS

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