



Donor Health: A Priority

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PPTA member companies could not make lifesaving therapies available to patients without the committed donors who collectively give nearly 80,000 liters of plasma each day. Much of the source plasma used to make plasma protein therapies to treat patients worldwide originates from donations by individuals in the U.S. In 2001, there were little more than 400 International Quality Plasma Program (IQPP)-certified centers collecting plasma throughout the world. Currently, more than 600 IQPP-certified centers operate worldwide to collect the necessary plasma, with about 550 in the U.S. and more than 50 in Europe. The health of the individuals who donate plasma is a priority for the companies that make up our industry. As we will show, IQPP standards and national regulations include many measures, which collectors take to maintain donor health.

HEALTH REQUIREMENTS FOR DONOR ELIGIBILITY

In the U.S., donor eligibility requirements set by the U.S. Food and Drug Administration (FDA) are key to ensuring donor health. Donors must meet strict criteria before donating for the first time as evidenced by a documented physical examination and health history questionnaire.

Donors may not donate if they are not in good health on the day of donation or if the center identifies any factors that may cause the donation to adversely affect the health of the donor. For example, a donor may be ineligible to donate for having symptoms of a current or recent illness or for receiving certain medical treatments or medications or due to recent pregnancy. Plasma centers must determine—on each day of donation and before collection—that the donor is in good health based on a number of factors in addition to the health history questionnaire. These factors include temperature, blood pressure, pulse rate, hematocrit, weight, and a visual arm inspection to ensure that the phlebotomy site is free of infection/inflammation/lesions. Plasma centers must also determine that the donor has a normal total plasma protein level before each plasmapheresis procedure.

Donor health is also monitored over time and across donations. FDA regulation requires that the physical examination be repeated at intervals of no longer than one year as long as the donor continues to donate plasma. In addition, a sample of blood must be drawn from donors prior to their first plasmapheresis procedure and

at four-month intervals thereafter. A serologic test for syphilis, a total plasma or serum protein determination, and a plasma or serum electrophoresis to determine immunoglobulin composition of the plasma or serum sample must be performed. The accumulated laboratory data—including any tracings of the plasma or serum protein electrophoresis pattern, the calculated values of the protein composition of each component, and the collection records—must be reviewed within 14 days after the sample is drawn to determine whether the donor is eligible to continue donating plasma.

DONOR INFORMATION REQUIREMENTS

The donor receives information from the plasma center that is important to maintaining the donor's health. Per FDA regulation, prior to each donation, the plasma center must provide certain information to the donor and obtain the donor's acknowledgement that the donor has reviewed the information, including details regarding risks and hazards and the specific donation procedure. The donor also has the opportunity to ask questions and withdraw from the donation procedure. In addition, informed consent of the plasma donor must be obtained prior to the first day of donation and at subsequent intervals of no longer than one year.

EUROPEAN REQUIREMENTS

European regulatory authorities place controls on plasma used for manufacturing therapies in that region, even when the plasma was collected in the United States. Collection centers in the U.S., which export to Europe for manufacture, must be approved by European authorities to be included in a fractionator's plasma master file and are regularly inspected by European national authorities, in addition to undergoing FDA inspections. European national authority auditors must also inspect according to European-wide requirements. The bottom line is that any plasma or plasma product imported into Europe must meet the requirements of the country of origin, in addition to European Union requirements.

VOLUNTARY STANDARDS

PPTA administers a global standards program with requirements that often go beyond regulation. Centers in the U.S. and Europe are certified as compliant with the PPTA IQPP standards. The program comprises 11 standards with provisions to ensure the safety of collected plasma and maintain donor health. Plasma centers follow these standards voluntarily. Six of the standards are designed to help protect the health and safety of donors. Plasma centers are assessed by an independent auditor for compliance with the requirements in these standards.

These donor health standards are:

- **Cross Donation Management Standard:** Plasma donors may misunderstand the reasons for limiting the number of times that they can donate per week. Infrequently, a donor may attempt to donate more often than is allowed. While these are rare occurrences, it is necessary to take measures to protect the health of the donor and minimize the risk of cross donation. The Cross Donation Management Standard requires that all potential donors be checked against a national database to see if they are at risk of exceeding allowable donation frequency. Individuals who are at risk are not allowed to donate.
- **Donor Adverse Events Recording Standard:** All IQPP-certified centers have processes in place to monitor, manage, and document donor adverse events (DAEs). This standard requires that plasma centers classify and record DAEs in accordance with defined parameters.
- **Donor Education Standard:** It is important that donations are collected from a low-risk population. This standard requires new donors to engage in an educational program regarding HIV/AIDS and activities that place them at risk for HIV/AIDS. These donors are also required to complete a follow-up assessment. The educational program also encourages donors to lead a healthy lifestyle.
- **Donor Fluid Administration:** This standard contains requirements to enhance donor safety by assisting donors in sustaining hydration on the day of donation. Plasma centers are required to administer fluids as part of the donation process.

The **National Donor Deferral Registry Standard** and the **Qualified Donor Standard** are also part of the IQPP program and help ensure that plasma is used only when it comes from healthy donors. Visit www.pptaglobal.org/safety-quality/standards/iqpp for more details about the IQPP standards.

DONOR HEALTH IS KEY TO ALL STAKEHOLDERS

Plasma donors are the foundation of our industry. Healthy and committed donors are paramount for preparing safe and effective therapies. Our therapies would not exist without the generosity of our donors. Donors receive compensation for the time, travel, and energy they dedicate to helping us provide safe and effective therapies. We strive to ensure that state-of-the-art measures are implemented in each and every collection center, regardless of its geographic location, to help maintain the health and safety of these valued individuals. **We depend on plasma donors—our patients rely on them.** •