



IQPP

**A LONG-TERM PROGRAM
CONSISTENTLY PROVIDING MEMBERSHIP VALUE**

BY JOSHUA PENROD

THE INTERNATIONAL QUALITY PLASMA PROGRAM (IQPP)

has been in place since the early 1990s, formed of the plasma collection industry's desire to demonstrate an active commitment to safety and quality of source plasma. During the first decade of its existence, the industry added several important components to the program, generating, in large part, the bulk of the standards known and understood around the world by the industry, patients, and regulators to be a symbol of the industry's commitment to improvement and enhancement.

In recent years, the IQPP has been reviewed, studied, and optimized with the changes in technology and needs of the industry and its stakeholders. The industry added the Cross Donation Management Standard in 2010, which helps to prevent over-donation, enhancing the levels of confidence in both the plasma collection facility and in the donor.

Currently, the IQPP consists of nine individual standards, all devoted toward the safety of the product, the safety of the donor, and the ultimate quality of the plasma collection facility. Audits are performed by unbiased, third-party auditors who contract with PPTA to perform the audits; all auditors have many years of experience and are

certified to perform quality audits. Audits are also performed on a regular basis and plasma centers are scored according to their performance on the audit. Similarly, IQPP audits are performed on corporate headquarters of PPTA member companies subscribing to the program as well; this helps generate a complete picture for review.

The Standards which make up the body of the IQPP have been covered elsewhere in recent articles and other publications, so we won't recount them in detail here. Instead, we'd invite the reader to examine the IQPP first hand, at www.pptaglobal.org/standards. For convenience, however, the nine Standards currently part of IQPP are:



**International Quality
Plasma Program**
The Worldwide Standard for Plasma

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| 1 Community Based Donor Standard | 6 Use of the NDDR Standard |
| 2 Qualified Donor Standard | 7 Personnel Education and Training Standard |
| 3 Viral Marker Standard | 8 Professional Plasma Facility Standard |
| 4 Donor Education Standard | 9 Quality Assurance Standard |
| 5 Cross-Donation Management Standard | |

Value to Patients

IQPP's value to the patients takes many forms and has changed over the years of its existence. What remains the same to the patient communities is the assurance and confidence that IQPP is there as a central part of the industry's commitment to assuring patient well-being. This assurance and confidence is well-founded and longstanding.

In dialogue with PPTA, many patient group representatives have emphasized the importance they place on IQPP. With regular updates to stakeholders, PPTA and members of the industry educate the community about the IQPP program and its benefits. On several occasions in the recent past, PPTA, its members, and the stakeholder groups have used the IQPP as a common ground of conversation to discuss pressing issues involving all parties. These included discussions related to viral marker rates and epidemiology, donor recruitment practices, and the quality and safety of donors.

The IQPP, in its totality, represents a separate commitment by the industry to the patient community for ongoing efforts at improvement in the quality and safety of collected plasma. IQPP fits with the regulatory networks and the methods and practices of the companies to help contribute to this enhanced margin and safety and the confidence expressed by the users of these life-saving therapies.


Value to Regulators and Policymakers

PPTA has presented the IQPP to regulatory authorities on several occasions, in Asia, Europe, and the United States Food and Drug Administration. The IQPP frequently serves as a model for thinking through issues of safety and the correct, most effective approach to resolve questions involving the practice of plasma collection and regulatory concerns. The plasma industry efforts in standards have also received recognition by regulatory authorities, such as demonstrated in Europe in 2002, in a CPMP position statement that discussed the safety and quality of plasma collected from both remunerated and non-remunerated sources. The statement noted: "For plasmapheresis donors . . . there are additional voluntary standards to ensure that plasma originates from a low risk donor population. These include qualified donor programs and inventory hold of donations." (See EMEA/CPMP/BWP/1818/02/Final)

The long-term impact of IQPP as it fosters a greater appreciation among policymakers and regulatory authorities is clear. Many of the advocacy efforts advanced by the Association to legislators and legislative staffs depend on the showing of the quality and safety for the products, their uniqueness and their high-impact value. IQPP bolsters the high individualized and specialized nature of the industry, the products, and the patients who use them.

Value to Industry

IQPP continues to pay dividends of goodwill and confidence on the part of the industry with each passing day. Examining the ways in which the program has manifested value time and again during its history underscores the discussions involving the assurances given to the regulatory authorities, the patient groups, and the public. But another important component showing value to the industry, regulators, and patient groups is the benefit shown to the donors with the IQPP. The Donor Education Standard works in conjunction with regulatory requirements to inform donors about risky behavior, offering them a chance not only to choose not to donate, but also to have a better understanding about what relates to risk. In addition, the recent Cross-Donation Management Standard helps facilities ensure that that donors donate within the safe limits of regulatory requirements. Companies use this in conjunction with their own educational efforts to communicate with donors regarding donation practices and ensuring that the donation experience remains a fulfilling one.

All of these components of IQPP, along with sound regulatory structures and industry practice and commitment to quality, help provide assurance to patients, donors, regulators, policymakers, the industry, and the public at large that the plasma collected and therapies created are as safe and high quality as possible. 

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