

INDUSTRY IMPLEMENTS

CROSS DONATION MANAGEMENT STANDARD

BY JOSHUA PENROD

THE INDUSTRY HAS BEGUN IMPLEMENTATION of the new Cross Donation Management Standard (CDMS) under the International Quality Plasma Program (IQPP). The CDMS is the first new addition to IQPP in several years, and was authored by the IQPP Standards Committee and approved by the Source Board of Directors. Industry members and others contributed comments during the open comment period in autumn of 2009. We would like to thank all those who offered their input.

The CDMS focuses on exchanges of information between donor centers in a Donor Recruitment Area. These exchanges of information are related only to new donors who present for donation in a given center, which will then seek confirmation from a neighboring center as to whether the donor donated or not and, if so, in what time period. This helps to ensure that the donor is donating within the regulatory limits and is intended as an additional level of donor safety. The CDMS will work in concert with existing measures that centers may take to help ensure donor health and any new measures that centers may adopt in the future.

As the implementation period progresses, PPTA and members of the IQPP Standards Committee will be monitoring the CDMS and managing any issues that arise. It is expected that the CDMS



Implementation Period will end in August, 2010. PPTA and the IQPP Standards Committee will also be tracking the industry's compliance with the Standard throughout the period in order to anticipate any other challenges that may arise.

We are very pleased to have developed this new Standard and are looking forward to its implementation. It is a demonstration of the industry's willingness to go beyond the minimum requirements of the regulatory sphere and be proactive according to its two greatest areas of importance: product safety and quality, and health of the donor, with the latter being the focus of the new CDMS. ☞

JOSHUA PENROD is PPTA's Vice President, Source

PPTA TO HOST DONOR HISTORY QUESTIONNAIRE IMPLEMENTATION WORKSHOP ON JUNE 14, 2010

PLAN TO ATTEND PPTA's Donor History Questionnaire (DHQ) Implementation Workshop on Monday, June 14th in conjunction with the 2010 Plasma Protein Forum at the Hyatt Regency in Reston, VA.

After many years of work by PPTA staff and its Donor History Task Force, the U.S. Food and Drug Administration (FDA) provided preliminary approval for the PPTA DHQ in October 2009. The PPTA DHQ contains a full length and abbreviated standardized donor history questionnaires. These documents may be used by members to help streamline the donor screening process. Companies that wish to implement the PPTA DHQ before issuance of FDA final guidance may do so upon filing a Prior Approval Supplement (PAS).

In anticipation of final guidance, PPTA is holding a workshop that will cover an array of topics related to the PPTA DHQ and its corresponding documents. The agenda will include information on the format of the PPTA DHQ and how to implement its use, including presenting it on an automated DHQ platform, PPTA's role in maintaining the PPTA DHQ, and regulatory expectations. Look for a complete agenda soon!

To register for this workshop, please visit www.pptaglobal.org. Please contact Bridget Elis, belis@pptaglobal.org for more information. ☞

