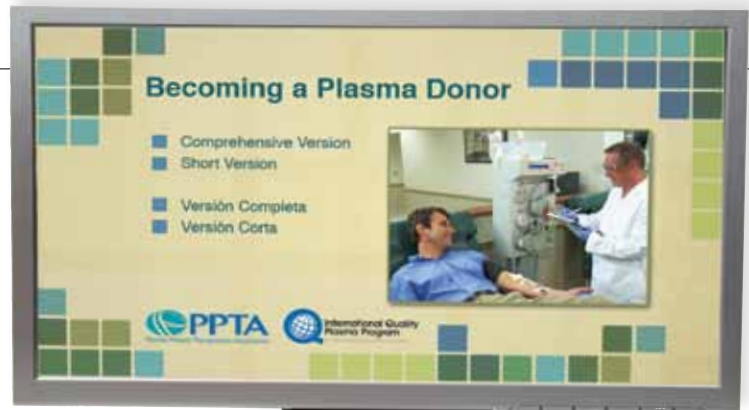


INSIDE PPTA

PPTA NEWS FROM
AROUND THE GLOBE

PPTA RELEASES NEW VIDEO “BECOMING A PLASMA DONOR” ▶

Earlier this year, PPTA released a new DVD “Becoming a Plasma Donor,” which features information on plasma donation and what a donor can expect if they want to become a plasma donor at one of 400+ U.S. Food and Drug Administration-licensed and International Quality Plasma Program-certified plasma collection centers in the U.S. The ten minute video also discusses how critically important plasma donors are to the production of safe, effective, lifesaving therapies that help individuals with rare, chronic, life-threatening diseases. PPTA’s DVD highlights how plasma is donated and what happens when someone arrives at a plasma collection center. Featured in the video is a plasma donor who takes viewers through the steps that someone would experience when they donate plasma. The DVD is available in English and with Spanish subtitles, and a German language version of the DVD filmed in Austria and Germany is also



expected to be available from PPTA later this year. To view the DVD online, please go to www.donatingplasma.org, select Newsroom and then Videos. To obtain a copy of the new DVD, please contact Diana Krueger at dkrueger@pptaglobal.org or (443) 433-1107.

▼ PPTA RECOGNIZES STAFF PERFORMANCE

The following staff were promoted in 2011 in recognition of their contributions to organizational excellence:

Congratulations!



Sybille Beck
Assistant Director
Source Europe
and Germany



Albert Farrugia
Vice President
Global Access



Mike McCormick
Director
IT & Facilities



Charon Smith
Manager
Accounts
Receivables/
Payables



Jay Greissing
Senior Director
Federal Affairs



John McKnight
Director
Federal Affairs



Bill Speir
Director
State Affairs



Kym Kilbourne
Director
Public Affairs
North America



Laura Savini
National Affairs
Manager



Alexa Wetzel
Assistant

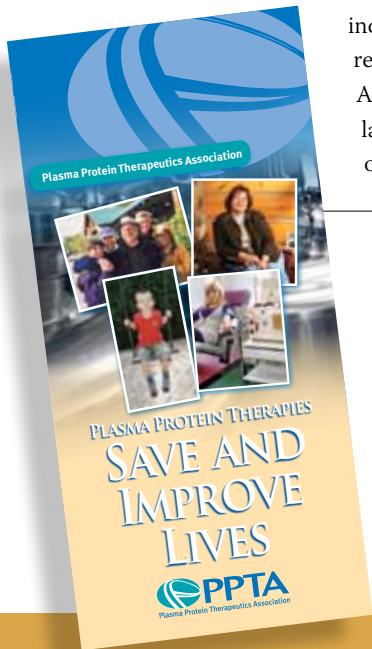


INSIDE PPTA



▲ FDA PUBLISHES GUIDANCE

Recently, the U.S. Food and Drug Administration (FDA) published a Final Guidance titled “*Process Validation: General Principles and Practices*.” PPTA formally commented on the Draft Guidance, and it was discussed during last year’s FDA Liaison Meeting. FDA implemented some of PPTA’s suggested changes, including the addition of a glossary, references regarding Process Analytical Technology, and language regarding manufacturers of legacy products.



◀ UPDATED BROCHURE “SAVING AND IMPROVING LIVES” FOR EUROPEAN AUDIENCES

The Association recently updated the brochure “Saving and Improving Lives” for use with audiences in Europe. The 10-page brochure describes plasma protein therapies, their highly complex manufacturing process and voluntary industry standards. In addition, the life threatening chronic, genetic medical conditions treated with plasma protein therapies are highlighted with photos of real-life donors and patients. To obtain a copy of the brochure, please contact PPTA’s European office in Brussels, Belgium at +32.2.705.5811.



▼ GERMANY TO CONSULT PPTA IN DEVELOPMENT OF ALBUMIN GUIDELINES

PPTA’s approach to the German Physician Association (BAK), following the finding of scientific fraud by anti-albumin advocate Joachim Boldt, has been followed by the BAK’s withdrawal of the German albumin guidelines authored by Boldt. The BAK has written to PPTA, assuring that the Association will be consulted during the development of the next edition of the guidelines, which have become increasingly relevant and used by German reimbursement organizations.



GLOSSARY OF TERMS

CDC	Centers for Disease Control and Prevention
EMA	European Medicines Agency
EU	European Union
EVM	European Vaccines Manufacturers
FDA	U.S. Food and Drug Administration
HBIg	Hepatitis B Immune Globulin
HES	Hydroxyethyl Starches
HPSC	Health Policy Steering Committee
IPFA	International Plasma Fractionation Association

IPPC	International Plasma Protein Congress
MHLW	Ministry of Health, Labour and Welfare
IQPP	International Quality Plasma Program
PLUS	Plasma Users Group
PMF	Plasma Master File
TGA	Australian Therapeutic Goods Administration
VAMF	Vaccines Antigen Master File
WHO	World Health Organization