



China in the Spotlight

BY JULIA FABENS, MANAGER, INTERNATIONAL AFFAIRS

During the summer and fall of 2017, PPTA was extremely active on the China front, culminating in a weeklong visit to Beijing to co-host and host several important meetings and events.

CFDA GMP INSPECTOR TRAINING – SEPTEMBER 5

The China Food & Drug Administration (CFDA) conducted a daylong training session in Beijing for more than 120 new CFDA GMP inspectors from multiple provinces (31) and municipalities in China. PPTA Vice President, Global Regulatory Policy, Mary Gustafson, presented two modules covering regulations on plasma products in foreign countries and safety controls of plasma products. PPTA President & CEO Jan M. Bult presented a module on the global need for plasma.

The presentations were followed by a question-and-answer period. Senior officials in attendance asked questions, not the new inspectors. Topics of interest included lot/batch release, use of recovered plasma for fractionation, clinical trial requirements, use of nucleic acid testing, and justification of China's policy on quarantining (re-test the collection vs. hold in inventory).

The meeting was extraordinary in the sense that this was the first time that CFDA reached out to PPTA to share insights.

At the end of the meeting, the request was made to hold additional meetings with more in-depth discussions.

PLASMA PROTEIN INDUSTRY SUMMIT – SEPTEMBER 7-8

The Plasma Protein Industry Summit at the Parenteral Drug Industry Congress in Beijing gathered approximately 150 attendees. The Summit featured Chinese fractionators; PPTA members and staff; independent experts; and Chinese regulators. There was strong participation from domestic Chinese fractionation companies, with representatives from 15 local fractionators registered for the event. Representatives from two Chinese fractionation companies—Shanghai RAAS and Shangdong Taibang Biological—also gave presentations.

The first panel covered different aspects of manufacturing and collecting, offering valuable insights into best practices. The panel featured the following PPTA members: Roger Brinser, BioLife Plasma Services LP/Shire and Chair of the PPTA Source Board of Directors, discussed modern plasma collection; Charles Auger, Grifols Plasma Operations, reinforced the importance of quality systems; and Thomas R. Kreil, Shire, explored industry efforts in pathogen reduction and bovine spongiform encephalopathy/Variant Creutzfeldt-Jakob Disease. Additionally, Mr. Du

Xiangjun, a respected independent researcher, shared his suggestions for Chinese plasma collection centers, the majority of which focused on enhancing donor safety.

The second panel of the afternoon focused on standards. Joshua Penrod, PPTA Vice President Source & International Affairs, covered PPTA's voluntary standards program. Ms. Guo Zhongping from the Chinese Pharmacopoeia Commission discussed standards and the development plan for plasma protein products in the Chinese Pharmacopoeia. Her remarks were particularly timely in light of the ongoing revision of the China Pharmacopoeia, which will be released in 2020. She was pointedly critical of domestic industry in some areas and stressed that forthcoming GMPs will have a much stronger focus on safety. Dr. Hu Weibing of Shanghai RAAS discussed production management for blood products and shared his company's thinking on the future of high-tech and automated manufacturing.

The final panel of the afternoon addressed regulatory issues. PPTA's Mary Gustafson updated the audience on trends and new considerations in global regulatory policy. She was joined by Dr. Guo Xiuxia of the CFDA, who gave a regulatory update and discussed trends in plasma products in China, and Mr. Gao Xiuqiang, Director of the Division of Medical Safety and Blood of the National Health and Family Planning Commission, who spoke about regulatory policies for Chinese plasma collection centers. Additionally, Mr. Ma Shan of Shandong Taibang Biological gave an introduction of, and suggestions for, clinical trials of plasma products in China. The Chinese regulators were remarkably open in their remarks and noted there is room for improvement in some areas of the domestic industry, including donor health and safety.

The second day began with a panel on the profile of the plasma protein therapeutics industry. PPTA President & CEO Jan M. Bult covered the global footprint of the industry, and Matthew Hotchko of the Marketing Research Bureau presented on global clinical usage, highlighting the clinical need for greater access to therapies in China. Professor Liu Zhong of the Institutes of Blood Transfusion of the Chinese Academy of Medical Sciences rounded out the panel with his thoughts on the current status of, and future prospects for, plasma protein therapies in China. Professor Liu made a point of mentioning that there is limited competition in the Chinese market and there are great gains to be made in better domestic plasma usage.

The last panel of the conference addressed clinical aspects of the industry. Dr. Fabrizio Fabbrizzi, a consultant for Kedrion, shared some exciting recent clinical data regarding albumin, which is the only plasma protein therapy currently allowed to be imported into China and is heavily utilized in the Chinese health care system. His remarks were followed by a discussion of the epidemiology, diagnosis, and treatment of primary immunodeficiency diseases by Professor Martin van Hagen of the Erasmus Medical Center in Rotterdam. For the final presentation, Sachi Satapathy of the World Federation of Hemophilia, gave a global snapshot of bleeding disorders.

The overall impression of the week was positive, both in terms of messages about the importance of donor and product safety, as well as the openness with which participants shared those messages. PPTA was pleased to give its members a platform to share their deep knowledge of domestic Chinese manufacturers, and we look forward to building on that cooperation going forward. ●

Speakers participating in the Clinical Aspects panel. (Left to right): Matthew Hotchko (Marketing Research Bureau); Jan M. Bult (PPTA); Professor Martin van Hagen (Erasmus Medical Center in Rotterdam); Dr. Fabrizio Fabbrizzi (consultant for Kedrion); Sachi Satapathy (World Federation of Hemophilia)

