Pharmacopeial Modernization and Harmonization Efforts Spurred by Global Supply Chain Regulatory Needs; China’s Pharmacopeia Among Asian Participants

The risks to product quality in an increasingly globalized supply chain – a prime driver of the CMC and GMP agendas of regulatory agencies – are also pushing pharmacopeias around the world to speed up their efforts to harmonize and modernize the compendial standards that support these regulatory processes.

At issue are the relatively slow-moving pharmacopeial harmonization efforts that are not keeping pace with the regulatory agency needs for updated specifications to detect and counter the supply chain threats. There is an increasing recognition of the pressing need for global, scientifically current monographs for a global supply chain.

At the IPEC ExcipientFest conference in late April in Raleigh, North Carolina, USP Excipients Senior Director Catherine Sheehan explored the impact the global supply chain is having on pharmacopeial harmonization and modernization and how the progress on these two efforts are interconnected.

“The risks associated with the global supply chain have led to the need for quality compendial specifications that are both harmonized and modernized,” she emphasized. Global specifications “will provide a much needed regulatory tool to qualify an excipient for its intended purpose.”

In USP’s case, some existing excipient monographs “migrated in from 1880 from the original National Formulary, and they have yet to be modernized,” she said. “We are sometimes dealing with 17th and 18th century analytics…. A smell test does not cut it in today’s global supply chain.”

In her presentation at the IPEC meeting, which was focused heavily on excipients, Sheehan discussed: ● USP quality standards and the law ● the role of the Pharmacopeial Discussion Group (PDG) ● the benefits and challenges of harmonization ● USP’s modernization initiative and strategies, and ● modernization efforts by other pharmacopeias.

China Participating in Harmonization Efforts

The USP and PDG modernization and harmonization efforts are helping drive parallel efforts in countries that want to ship products to the ICH countries.

USP, in particular, is “looking at other pathways that [it can] pursue with other pharmacopeias” in terms of harmonization and modernization, Sheehan explained.

USP has been working with China since a memorandum of understanding (MOU) was signed in 1995 with a goal to cooperate and develop quality standards for excipients in the global supply chain.
The USP established a new expert committee to support the development of new excipient monographs for potential adoption by both the Chinese Pharmacopoeial Commission and the USP National Formulary (NF). Key to advancing the initiative is the lab support provided by ChP that is used to develop and test analytical methods.

A report on the progress of the bilateral initiative was given at the USP annual Science & Standards Symposium (S3) in 2012. At that meeting, the work plan was also exchanged and discussed.

“They started with a list of about 900 excipients,” Sheehan said. “We whittled that down to a mutual list of 34.” Currently, there are 15 excipients that are being developed and will eventually be considered for inclusion in the NF and Chinese pharmacopoeia.

[Editor’s Note: The IPQ coverage provided in its July “Monthly Update” includes an in-depth review of the current USP/PDG and Asian pharmacopeia modernization/harmonization efforts along with Sheehan’s full remarks at the IPEC/ExcipientFest conference. An update on the ICH Q3D implementation effort, in which IPEC is involved, is provided.]

By special arrangement with IPEC, excipient suppliers who are members can receive a company-wide license for the normal price of the subscription for an individual user. The license allows everyone in a company to access all of IPQ’s coverage of the key drug/biotech CMC and GMP issues globally and the full searchable archives. Contact Wayne Rhodes (rhodes@IPQPubs.com, (202) 841-9720) for more information. IPQ will be providing in-depth coverage of a key excipient regulatory issue in each of its Monthly Updates, with an excerpt included in IPEC’s Insider.

Visit IPQPubs.com every day for IPQ’s real-time tracking of the latest CMC and GMP developments from “Inside the Global Regulatory Dialogue”

IPQPubs.com

IPQ Publications LLC, 7920 Norfolk Avenue Suite 900, Bethesda, MD 20814
Phone: 202-841-5027, Fax: 301-913-0119

Copyright 2014 IPQ Publications LLC. All rights reserved.