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Global Drug Regulators And Manufacturers Grapple With How To Ensure Global Quality Standards (Part 1 Of 2)

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KUALA LUMPUR, Malaysia - With global resources shrinking and the need for quality control in the drug supply chain greater than ever, regional solutions offer a look at how Asia fits into the regulatory scheme for assessing good manufacturing practices.

"We have a better understanding for the guidelines than before because we are actively involved in the discussion," China's State FDA - Division of Pharmaceuticals Director Ding Jianhua told attendees of the International Federation of Pharmaceutical Manufacturers & Associations' Fifth Asian Regulatory Conference March 11 in Kuala Lumpur. He explained that prior to 2004, International Conference on Harmonization discussions were relatively closed to non-ICH countries, but a number of regional initiatives have shifted the focus to collaboration among regions and sharing inspectional resources.

Northern and Southeast Asia have formed two separate groups to better share resources: the Regional Harmonization Initiative, or RHI, makes up China, Korea and Japan; and the Association of Southeast Asian Nations, or ASEAN, comprises the Southeast Asia countries of Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam ([PharmAsia News, March 13, 2008](#)).

Global Cooperation Group Expands Beyond Asia

The ICH Global Cooperation Group has expanded membership to include the RHI, as well as Australia, Brazil, Russia and Taiwan. The aim of the GCG is to form links with ICH groups and begin working toward a two-way collaboration to address technical and regulatory requirements for pharmaceuticals.

"Because we have a good understanding [of the ICH requirements], we have a very good interpretation for the countries where English is not their first language because in the translation we lose certain meaning," Ding stressed. He said that through the GCG, China's SFDA has the opportunity to discuss interpretations and to participate in drafting guidelines, as well as having access to qualified experts.

"The region is harmonizing ideas and discussing between regulatory authorities the philosophy behind the regulations to reduce duplication," Ding said. He noted that discussions with other regulatory authorities in the region offer an opportunity to share information and experiences

"to learn from each other."

"We made a collective agreement on how to implement ICH guidelines in a regional manner," he said, noting that the group is planning training sessions in Tokyo next month on good manufacturing practices quality documents as well as good clinical practices training.

The GCG's first training workshop was held in Korea in September 2007 with 200 participants from 17 countries. It provided a "good model for future training workshops," Daiichi Sankyo Asia Clinical Development General Manager Kohei Wada told meeting attendees.

"ICH does not yet involve regulatory requirements," Kohei said, "because it is up to each regulatory agency to decide what to do. ICH says how to do something; it will not impose its views on any region or country."

"There are drastic changes in global drug development, and ICH reflects this change," Kohei said, adding that "the success of collective efforts and spirit of cooperation" was the most important element.

Establishing Quality Standards Globally

ICH has established roughly 10 guidance documents that cover quality topics for implementing GMPs. ASEAN and GCG are finalizing discussions on implementing Q8, Q9 and Q10, which cover how to prioritize pharmaceutical development, risk assessment and quality systems, respectively.

The Asia-Pacific region is catching up quickly to good regulatory practice guidelines established in the U.S. and European Union, according to a 2007 survey of regulatory agencies in emerging markets conducted by the CMR International Institute for Regulatory Science, based in the U.K.

The survey provides a generic model for comparing how agencies in the region process applications and review drugs for quality, safety and efficacy. When asked the importance of GRP, agencies all said: consistency, predictability and transparency, CMR director Stuart Walker told the conference.

Whether companies are using traditional approaches or newer approaches is not the important factor, said Pfizer Global R&D Regulatory CMC Policy Executive Director Robert Baum.

"We focused on impact for assurance of product quality," he said, "because we already defined quality in Q8." He said "quality by design" can be described as a systematic approach to development based on sound science, but it "doesn't say anything about traditional approaches being bad and quality by design being better. It is just an approach," Baum said. He said to assure quality, a global systems approach for implementation is needed, which includes understanding the key concepts and terminology described in ICH documents.

Act Globally, Think Locally

"If we don't understand the new terminology, we can't go anywhere," Baum stressed. "How do various languages interpret these terms?"

World Health Organization exec Lembit Rago suggested that prequalification is another tool to ensure that quality is built into products. However, he also stressed that if local regulators want to have an impact, they must involve local manufacturers in the dialogue because at the end of the day, they must learn how to build quality into their products.

"Quality has to be built into the product," Rago said, adding that "it is very different to test and assess, which is the manufacturer's responsibility. But this is the only thing that works and this

is why we have a lot of problems with manufacturers that don't have this concept of building quality into the products. They make the product, but they don't know how to build in quality."

- Tamra Sami (t.sami@elsevier.com)

[Editor's note: This is part one of a two-part feature on ensuring drug quality, as discussed at the Fifth IFPMA Asian Regulatory Conference in Kuala Lumpur. Look for part two, which covers regional solutions for GMP inspections, in a subsequent issue of PharmAsia News.]

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