

"Global Regulatory Systems: A Strategic Primer for Biopharmaceutical Product Development and Registration

Henrietta Ukwu, 2011, 323 pages, CenterWatch, \$195

Review by Norman M. Goldfarb

"Global Regulatory Systems: A Strategic Primer for Biopharmaceutical Product Development and Registration" is a solid primer on drug development regulatory systems around the world. The book covers a lot of ground, so, the chapter on the European regulatory system, for example, is 36 pages long. The following extract from the chapter on Japan illustrates the level of detail and quality of the writing:

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6.2 Japan product development

The product development process follows the conventional global development process for pre-clinical, clinical and registration phases, with requirements to generate pharmacokinetic, pharmacodynamic and some pivotal or bridging clinical data from Japan. The Japan PAL and follow-on ordinances and notifications provide specific regulatory guidelines on Japan's requirements. All applications for correspondence and submission on product development are sent from the sponsor/Japanese partner to the MHLW. At the request of the MHLW, the PMDA conducts the application and compliance reviews for clinical trial notifications and NDAs, and provides review, advice and guidance through consultations on the clinical trial protocols.

The development process in Japan still expects phase I studies to be conducted in Japanese subjects to explore correlation through the pharmacokinetic and dose-ranging studies between Japanese and Caucasian data. This explains whether Japan can join the global studies from phase II (i.e., if no PK/PD differences) or whether separate pan-Asian studies have to be conducted for global registration (i.e., PK dose-response data differences from Caucasian data). If correlation exists, then Japan can join the global confirmatory or phase III trials. Most companies have introduced a development path that conducts phase I studies in parallel with similar phase I study in Japan. Clinical trials in Japan are subject to the ICH-GCP guidelines, with some modifications to accommodate some unique Japanese medical practices, including administering of the study contract between the sponsor and head of the Clinical Trial Institute (and not directly with the investigator). Due to the drug lag, the choice of an active comparator for global studies including Japan maybe problematic, as the active comparator may not yet be approved in Japan.

The development process in Japan follows the ICH guidelines for the most part: non-clinical studies follow the ICH M3; clinical trials are under ICH-GCP and require CTN application sub-mission and review; NDA submission is in ICH-CTD format; NDA review timetable takes 12 to 24 months. (PMDA is making efforts to reduce); GMP, pre-approval inspections are in place. PMDA has established a consultation process to enhance interaction with sponsors, improve the quality of clinical trials and ensure compliance with Japanese registration requirements for product development. The

development plans need to incorporate the drug pricing strategy as well as the post-marketing surveillance system.

The revisions to the JPAL are improving the regulatory environment for the pharmaceutical industry, and the MHLW is promoting innovation and enabling achievement of the simultaneous global development of innovative products.

Simultaneous global development of products including Japan will enable global simultaneous filing and eventually product launch, thereby definitively eliminating the innovative drug lag in Japan.

The book includes 10 chapters:

- Global regulatory agencies
- Global regulatory affairs — role in the biopharmaceutical industry
- Global biopharmaceutical product development
- United States regulatory system
- The European regulatory system
- Japan regulatory system
- Australia regulatory system
- Canada regulatory system
- Regulatory systems — Opportunity market countries: Latin America, East and Central Europe
- Regulatory systems in [other] opportunity markets [Middle East, Africa, East Asia, Southeast Asia]

The book is available at <http://www.centerwatch.com> and in bookstores.

Reviewer

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