



Press Release

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Senior Panel Outlines Strategies for Streamlining Regulation of Combination Products

Baltimore, MD—When a company has an idea for a new drug, biologic or groundbreaking medical device, it must first put its product through a long and arduous regulatory path before it can reach the public. When two different types of medical products are combined into a single “combination product”—such as a drug-eluting heart stent—the journey increases exponentially. Combination products are a growing—and relatively recent—phenomenon, which is why the Regulatory Affairs Professionals Society (RAPS) hosted a summit this week where regulatory affairs (RA) professionals drafted recommendations to address the challenges of this often vexing area of medical product regulation.

Among the concepts emerging from the summit—that featured nearly 150 RA professionals and a distinguished panel of senior RA executives—was a desire for the US Food and Drug Administration (FDA) to apply a more consistent approach toward reviewing combination products. Drugs, medical devices and biologics are each regulated by separate centers within FDA. The summit participants noted that dissimilar processes and “cultures” among these FDA centers tend to result in differing approaches toward reviewing the combination products that are submitted for FDA approval. According to the summit’s participants, this environment can produce dramatically different regulatory processes for very similar combination products.

To address this concern, the summit’s panel and participants recommended that FDA modify its intercenter agreements to more clearly delineate each center’s roles and responsibilities for handling approvals of combination products, modifications to existing combination products and labeling review.

In addition to calling for greater predictability from the process of combination product regulation, the panel expressed a need to develop a common set of terms and definitions related to combination products that RA professionals and FDA staff can agree upon and utilize. Examples might include definitions and descriptions of the various types of combination products, and clear definitions of what is—and what is not—a combination product.

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According to several summit participants, differing understandings of such industry terms and concepts underscored not only the need for clearer definitions, but for the combination products summit itself.

“It is very gratifying to produce a tangible document through this meeting that incorporates so many different voices,” remarked one summit panel member.

Sherry Keramidas, PhD, CAE, Executive Director of RAPS, called the summit “historic,” noting that 25 percent of RA professionals are now engaged in combination product regulation, according to RAPS’ 2003/2004 North American Compensation Survey of the RA profession. “This summit is about the voice of the RA profession. RAPS represents the profession and those individuals engaged in shaping regulatory policy,” explained Keramidas.

The summit’s panel and participants also called for enhanced training in the complexities of combination products for both FDA staff and those involved in the medical product industry. Many felt that increased training specific to combination products would ultimately lessen the burden involved with regulating the products.

While the summit participants were vocal in expressing their concerns over the process of combination product regulation, they generally felt that FDA’s Office of Combination Products (OCP) was on the right track. An informal poll of the summit participants revealed nearly unanimous sentiment that the OCP was not in need of an overhaul.

Although the OCP is not an FDA center, and therefore does not review product submissions, it does identify the regulatory pathway that each combination product that is submitted to FDA will follow.

According to Mark Kramer, director of the OCP and a speaker at the summit, the panel’s recommendations will be useful. “While we can’t solve all of the issues addressed here overnight, your input will be very helpful to us,” explained Kramer.

The panel relied on the input of the summit participants in developing its draft recommendations document. Moving forward, the panel will allow the summit participants to review and comment upon the draft, after which a final paper will be prepared. The final document will be available on the RAPS Web site at www.raps.org.

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