

**From:** "Nan Matthews" <rmras@themattgrp.com>  
**Subject:** Jan 12th Webcast - CGMPs for Combination Products  
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*Please join the Rocky Mountain Regulatory Affairs Society at Regus Business Center in Westminster to take advantage of discounted fees for the following Webcast*

## **CGMPs for Combination Products: An Interactive Analysis with Industry and FDA**

January 12, 2010  
9:00 am – 11:30 am [3:00 pm]\*

On September 23, 2009, the FDA proposed rules to codify current Good Manufacturing Practices (CGMPs) for combination products. This highly anticipated proposed rule will have significant implications for entities that develop and commercialize combination products.

Offered in collaboration with RAPS and the Combination Products Coalition (CPC), this program offers a unique opportunity to examine the contents of the proposed rule and the agency's implementation plan. Hear directly from FDA's Office of Combination Products and industry representatives about what the proposed rule includes and how it may affect you. Independently or with colleagues review the case-study exercises to identify the rule's strengths, weaknesses, ambiguities, unintended consequences and more. Onsite groups will report their results live.

Speakers include:

- Leighton Hansel, Director, Regulatory Affairs, Abbott Quality and Regulatory, Abbott Laboratories
- Tom Hutchinson, Vice President, Quality Assurance, CR Bard, Inc.
- Nancy Kazantzis, MBA, Senior Principal Scientist, Global Chemistry, Manufacturing and Controls, Pfizer Inc
- Thinh Nguyen, Director, Office of Combination Products, US FDA
- John (Barr) Weiner, JD, Associate Director for Policy and Product Classification Officer, Office of Combination Products, US FDA

This program will allow you to:

- Engage in discussions to determine how the rule may affect you and your company
- Analyze the rule's strengths, weaknesses and ambiguities by applying it to case studies during intensive, small group exercises on site or with your colleagues at your office
- Get insight into FDA's implementation plan by speaking directly with representatives from the Office of Combination Products
- Give your feedback and contribute to a summary document that will be compiled by RAPS and submitted to FDA following the program.

**\*[There is the possibility that the Webcast will also include a case study which could extend the time an additional 3 hours.]**

The cost of this Webcast is \$60.00. To register, please go to [www.regonline.com/CGMPs](http://www.regonline.com/CGMPs)

We must have at least 10 people register in order to host this meeting. Your credit card will not be charged until we reach that number.

For questions, please contact Nan Matthews, [rmras@themattgrp.com](mailto:rmras@themattgrp.com) or 303-843-6414.