

FDAnews Announces: Combination Products Regulation, Policy & Best Practices, June 8, 2017

This full-day working session features 17 speakers including top regulatory lawyers, industry execs and knowledgeable consultants, and covering all the bases.

FALLS CHURCH, VA, UNITED STATES, May 19, 2017 /EINPresswire.com/ --Combination Products Regulation, Policy & Best Practices: It's a Whole New Ballgame — Are You All In? **Presented by FDAnews** June 8, 2017, Washington, DC www.fdanews.com/comboregs



Combination products are streaming to market just as Washington makes the game tougher to play. Manufacturers need to be on top of:

- The role of the Combination Products Policy Council, pre-RFDs, the pilot for improving inter-center review, and the expanded role of the Office of Combination Products
- Successful strategies for obtaining jurisdictional determination, assuring certainty with submission requirements, and overcoming barriers to combination product approval

It's a lot to know and a lot to comply with. Before leapin forward with combination products, manufacturers need to get up to speed.

Plan now to attend FDAnews's first-ever all-day conference on combination products featuring 17 experts from every background — drugs, devices, biologics, generics, regulatory, legal, consulting and more. Attendees will be able to:

• Understand postmarket safety reporting and current good manufacturing practices requirements for combination product and constituent part sponsors

• Comply with the unique considerations for advertising and marketing combination products. Know the important findings for a human factors study of a generic combination product with device delivery constituent part

• Implement best practices for submitting combination products directly to CDRH and implications of the Cures Act on these submissions

Attendees will come away with a regulatory survival strategies including safety reporting and cGMP, advertising and marketing in the combination-products era, how to submit combination products

directly to the CDRH and much more.

Attend this all-day Washington event in person if possible — the networking opportunities alone justify the time and expense. If not the entire conference is being livestreamed at registration savings of \$50.

The combination-products train is leaving the station. Get on board with this full-day working session featuring 17 speakers including top regulatory lawyers, industry execs and knowledgeable consultants, and covering all the bases. Time is short though.

Who Will Benefit:

- Combination products developers
- Compliance specialists
- Regulatory affairs professionals
- Quality specialists
- Attorneys
- Consultants

Conference Details: Combination Products Regulation, Policy & Best Practices: It's a Whole New Ballgame — Are You All In? **Presented by FDAnews** June 8, 2017, Washington, DC www.fdanews.com/comboregsDay1

Tuition: In-Person Briefing: \$397 Livestreaming: \$347

Easy Ways to Register: Online: <u>www.fdanews.com/comboregsRegister</u> By phone: 888-838-5578 or 703-538-7600

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Michelle Butler FDAnews 703-538-7600 email us here

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