wiley

MEDIA MENTION

Sonali Gunawardhana Previews Upcoming AdvaMed Panel on the Department of Justice's Focus on Safety and FDA cGMP Enforcement

Med Device Online
September 24, 2014

Sonali P. Gunawardhana, an attorney in Wiley Rein's Food & Drug Law Practice, talked with *Med Device Online* about a panel she will chair next month regarding enforcement repercussions for manufacturers who fail to comply with the U.S. Food and Drug Administration's (FDA) Current Good Manufacturing Practices (cGMP). The October 7 legal track panel discussion, part of the AdvaMed 2014 conference in Chicago, will focus on steps medical device makers can take to avoid the types of compliance failures that have led to civil and criminal fines for some pharmaceutical companies.

Ms. Gunawardhana's panel also will feature Ralph J. Caccia, a partner in Wiley Rein's White Collar Defense & Government Investigations Practice.

"The message of this panel is, 'Hey, medical device community, don't be asleep at the wheel,'" Ms. Gunawardhana—who previously served as regulatory counsel at the FDA—said in yesterday's article. "You should be learning from the mistakes of your pharmaceutical brethren. Similar issues can occur in the medical device world, and you should be prepared to address these issues so as to avoid such costly penalties for cGMP noncompliance."

Click here to read the full article.

Related Professionals

Ralph J. Caccia
Partner
202.719.7242
rcaccia@wiley.law

Practice Areas

Food & Drug

White Collar Defense & Government Investigations