

2011-2012 AFDO FINAL COMMITTEE REPORT

Drugs, Devices and Cosmetics Committee

***Chair:** Thomas Brinck, Texas Department of State Health Services, Austin, TX

Co-Chair: Dennis Baker, USFDA, Southwest Region, Dallas, TX

Charge 1: Plan, identify important topics, and secure presenters for the DDC program at the annual conference.

Discussion:

The Drugs, Devices and Cosmetics (DDC) Committee began a series of annual educational conference (AEC) planning calls in September 2011 in order to solicit topics and themes for the upcoming AEC. Based upon the initial conference calls, the DDC Committee established its intent to develop the 2012 AEC program using a format similar to the one used previously at the 2011 AEC. This 2011 format consisted of a two-day drug and medical device forum running concurrently with the AFDO food-related programs. It was recommended that the forum be developed under a co-sponsorship agreement with the FDA Northeast Regional Office. In addition, it was suggested and agreed upon by the Committee to add the Regulatory Affairs Professionals Society (RAPS) as a co-sponsor of the forum. Advertising the forum would be accomplished through the use of several methods that have previously been found to be effective, including direct mail notifications, email distribution lists and a notice in the Federal Register (FR). The Committee identified a group of members interested in serving on its AEC Program Development Team and accelerated its plans for finalizing the program agenda through additional conference calls during the fall of 2011. The Committee reached out to its associate and international members and to the FDA Northeast Region Small Business Representative for assistance with program development, including tasks associated with approval of the co-sponsorship agreement, posting of the FR notice and identification of potential speakers and attendees for the forum. The Committee has considered FDA involvement with this co-sponsored event to be a major factor in the success of its programs during past years. As a result of these planning sessions, the Committee focused on "Global Quality Systems and an Integrated Approach to Medical Product Safety" as its 2012 program theme and ultimately this theme was incorporated into AFDO's general AEC theme for 2012: "Leading the Way to Building Global Integrated Food, Drug and Medical Device Safety Systems". During subsequent conference calls, appropriate topics were identified and presenters were confirmed. The Committee attempted to secure presenters representing both FDA and regulated industries. Email and direct mail notifications were sent out with the assistance of the AFDO Office and the FDA Northeast Regional Office.

Recommendation:

Charge completed. Create a new charge to direct the DDC Committee to identify and develop similar objectives for next year's annual conference.

Executive Committee Action:

Approval



Disapproval



Date

5/23/12

Charge 2: Beginning in March, solicit mentors for First-Time Attendees for the Drug & Device Forum of the Conference and provide volunteers to Membership Committee Chairs and the AFDO Office.

**Responsible for submission of reports*

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Discussion:

In the spring of 2012, the Committee solicited assistance from its members to act as mentors for first-time attendees of the Drug & Device Forum at the 2012 AEC and to provide the Committee with any suggestions for development of a DDC mentor program. A number of members volunteered to assist at the First-Time Attendees Reception and/or volunteer their assistance to Membership Committee Chairs and the AFDO Office. The names of these mentors and volunteers were provided to the AFDO Office. The Committee received feedback concerning ideas for development of a DDC mentor program and will continue to evaluate the need for such a program.

Recommendation:

Charge completed. Create a new charge to direct the DDC Committee to identify and develop similar objectives for next year's annual conference.

Executive Committee Action:

Approval



Disapproval



Date

5/23/12

**Responsible for submission of reports*