

NCRAF Annual Roundtable Dinner

Thursday, November 8, 2012, 5:30 - 9:00 pm

Location:

The Friday Center
100 Friday Center Dr.
Chapel Hill, NC 27517

Registration Fee:

To register, please select your preferred table topic in the registration form. Registration is \$25 for NCRAF members, \$40 for nonmembers. TO RECEIVE THE MEMBER DISCOUNT, your membership must be current and you must first log in with your username and password.

Event Description:

As in years past, our Roundtable Dinner will feature a networking reception with complimentary bar, followed by buffet dinner with seating at approximately a dozen tables, each featuring a speaker who will lead the dinner discussion on a different topic. Each table therefore will be a unique opportunity to learn about and discuss a topic of your choosing with a local expert in the topic, in a small-group setting (5-10 persons/table).

Speakers and Topics are:

1 Susan Zecchini - Advertising and promotion review. FDA hot buttons.

- Mission and scope of Office of Prescription Drug Promotion ("formerly DDMAC")
- Regulations and Guidances that govern a sponsor's distribution and use of advertising and promotional materials (including printed material, websites, and social media)
- Requirements for submission of materials to OPDP
- FDA hot buttons
- Substantiation evidence standard
- FDA enforcement Actions

2 Nancy Chew - PreIND/IND Wonder Submissions: Your Bread and Butter.

3 Michele Pruet - Working in the twilight zone: "GMP" and quality elements for non-regulated R&D Labs

Non-GLP biomedical research has traditionally been considered to be off-limits for formal quality systems or compliance management. Scientists in general regard their work as a highly intellectual activity where quality is knowledge and experience is an integral part of the scientific rigor that they apply. A longstanding tradition of quality control in science has been peer review of the results, but when we are asked to move forward with research we enter the Zone.

4 Dana Minnick - ICH M7: Qualification of impurities and everything else in that goop you call a drug.

The draft FDA Guidance for Industry "Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches", December 2008 along with ICH Q3 A(R) and ICH Q3B(R) guidances form a framework to address genotoxic impurities in pharmaceuticals. However, there has been considerable debate on acceptable limits, qualification of genotoxic impurities and the scope of these guidances. In addition, there exists conflicting information in these guidances. An expert working group has spent the last few years drafting the ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk with these considerations. This guidance will describe the evaluation, qualification and control of genotoxic impurities in medicines during development and after licensing. An update on the ICH M7 guidance will be reviewed and discussed in relation to the existing guidances.

5 Esther Villiard and Maria Oyaski - Case Report Form Design - How to make textbook cases, not basket cases

DUE TO EXTENUATING CIRCUMSTANCES THIS TABLE HAS BEEN CANCELED.

6 Erin O'Reilly - ClinicalTrials.gov Registrations. Big Brother wants your data

Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) requires Responsible Parties to register and submit summary results of clinical trials with ClinicalTrials.gov. The law applies to many clinical trials of drugs (including biological products) and medical devices. We will cover the following topics:

- What trials require registration and results reporting by law?
- Who is the Responsible Party?
- What results must be reported and when?
- What are the penalties for non-compliance?
- What other reasons are there for registering my trials (e.g. ICMJE policy)?
- What changes can I expect in the future?

7 Celine Clive - Risk Based Monitoring: Sanity returned or cheap trials?

8 Drusilla Scott - PDUFA V: Get with "The Program"!

The FDA Safety and Innovation Act signed into law in July 2012 included re-authorization of the Prescription Drug User Fee Act (PDUFA), bringing us to PDUFA V. A chief component of PDUFA V is a new review program ("the Program") for NME NDAs and original BLAs, which has a goal of increasing first-cycle approval rates for these applications. We will discuss the Program, which incorporates a new review clock and additional communications throughout the NDA/BLA review, and also focuses on reaching agreement at the pre-NDA/BLA meeting on what will constitute a complete and reviewable application.

9 Ida Cancel - Clinical Studies in Africa and S. America.

The topic of this round table is to present an overview of the clinical trial regulations in various countries in Africa. We will discuss the status of harmonization in the African region, the various research ethics and regulatory agency models and real life examples of some challenging situations and resolutions.

10 Don Alexander - Regulatory Affairs Careers. Get One.

The focus of the round table will be on the use of social media in job search and networking strategy. We will focus on the tools and the techniques one can use as an adjunct to or in lieu of online application processes and content that can create buzz and draw a strong network of trusted contacts. We will also discuss the best ways of getting response from "cold" contacts and will leave time to discuss other questions that may be pertinent to job search, networking and/or advancing one's career in regulatory affairs

11 Ken Edds - Hey! I'm talking here! Device Pre-Submission discussions and meetings with FDA.

A new draft Guidance has been published by the FDA on Pre-Submission discussions and meetings. These meetings have been called Pre-IDE meetings in the past and have been inconsistent regarding what is most useful in these discussions and the level of "help" the FDA has provided. The guidance seeks to set a level playing field for all and presumes to set the norm for what is required for a positive and helpful pre-submission discussion between the company and the FDA. The salient features of this draft guidance will be discussed.