Public Workshop on Reproductive and Developmental Toxicology: From In Vivo to In Vitro

April 16, 2012
8:00am-5:30pm EST

Workshop Goals and Objectives:

The Food and Drug Administration (FDA), Office of the Commissioner, National Institutes of Health, National Institute for Environmental Health Sciences, the Center for Alternatives to Animal Testing, Johns Hopkins School of Public Health (CAAT), and the Middle Atlantic Reproduction and Teratology Association (MARTA) are co-sponsoring the training workshop entitled "Reproductive and Developmental Toxicology: From In Vivo to In Vitro" on April 16, 2012.

The FDA initiative on "Advancing Regulatory Science" focuses on developing new tools, standards, and approaches to assess the safety, efficacy, quality and performance of all FDA-regulated products. One of the key initiatives of the Regulatory Science implementation plan is modernizing toxicological methodology used in the safety assessment of FDA-regulated products. Safety assessment is particularly challenging in the reproductive/developmental toxicology field due to the complexity and unusually long timeframe of the reproductive cycle. The current animal testing requirements are for two animal studies-a two generation study in rats and in rabbits. The two generation study is among the most costly toxicology tests and uses up to 3,200 animals per substance. In addition, pronounced inter-species variances have been described showing not more than 60% correlation between different laboratory mammalian species in the area of developmental toxicity.

The overall objectives of this training program are to bring scientific information about new in vitro technologies for reproductive and developmental toxicology testing to the FDA as well as provide a forum for FDA scientists, academic scientists, and industry scientists to discuss how these new technologies could eventually be integrated into the FDA regulatory paradigm.

The anticipated outcome of such training sessions is to expedite the regulatory review of these new technologies while assuring that they are adequately validated and well-controlled.

This workshop supports FDA's innovation initiative on to improve the development and evaluation of new safe and effective medical products for diagnosing, treating, and preventing conditions and diseases by

Educating and raising awareness of the complex issues for FDA scientists in these technologies,

Encouraging dialogue between FDA and its partners in the scientific issues and related science, and
Bringing together scientific views that can be available as references for FDA initiatives

Workshop location:
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Great Room, Building 31
Silver Spring, MD 20993

Registration:
There is no registration fee for the public workshop. Early registration is recommended because seating is limited. To register, please send your name, affiliation, and email to OCSFDAWORKSHOP@fda.hhs.gov

Email your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by April 2, 2012.

Contact Person: Suzanne Fitzpatrick, PhD, DABT

Webcasting will be available at https://collaboration.fda.gov/reprotox/

If you have never attended a Connect Pro meeting before:

Test your connection:
https://collaboration.fda.gov/common/help/en/support/meeting_test.htm

Get a quick overview: http://www.adobe.com/go/connectpro_overview