Activity Outline
FDA Grand Rounds: FDA's Predictive Toxicology Roadmap: Implications and Opportunities for Stakeholders
May 10, 2018
WO Bldg 2, Room 2031

Activity Coordinator
Devin Thomas
Devin.Thomas@fda.hhs.gov

Series Description
The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description
Toxicology is critical to FDA's mission because it is applied across the breadth of FDA-regulated product areas. Toxicological testing is done during the development and evaluation of FDA-regulated products, from human and animal drugs and medical devices to food and food ingredients, human biologics, and tobacco products. Today's advances in systems biology, stem cells, engineered tissues, and mathematical modeling are offering exciting opportunities to improve toxicology's predictive ability, potentially enhancing FDA's ability to quickly and more accurately predict potential toxicities--and reduce associated risks to the public. These breakthroughs also hold the potential for replacing, reducing, and/or refining animal testing.

This presentation will discuss FDA's Predictive Toxicology Roadmap, its six-part framework for integrating novel predictive toxicology methods into safety and risk assessments of its products. In this context, the presenter will detail FDA's collaborative efforts to advance toxicology toward a more predictive science with NIH, EPA and other federal agencies through programs such as Toxicology Testing in the 21st Century (Tox21) and the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). FDA's unprecedented role in the development and evaluation of the organs-on-a-chip technology with sister federal agencies and industry will be described and offered as an example of how FDA is enabling innovation in this exciting field.

Finally, Dr. Fitzpatrick will discuss the ways in which FDA is encouraging diverse stakeholders to work with the agency to share ideas, discuss new technologies, and highlight collaborations that are developing and testing new methods.

References

- Ankley G.T., et al, (2010). Adverse outcome pathways: A conceptual framework to support ecotoxicology research and risk assessment. Environ.Toxicol. Chem. 29, 730-741.
- Bus J.S., Becker, RA (2009). Toxicity testing in the 21st Century: A view from the chemical industry. Toxicol. Sci. 112, 297-302
- Andersen M.E., Krewski, D. (2010) The Vision of toxicity testing in the 21st Century: Moving from discussion to action. Toxicol.Sci. 117, 17-24

Series Objectives

- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

Learning Objectives After completion of this activity, the participant will be able to:

- Explain the unprecedented nature of FDA's collaborative efforts with sister federal agencies and the scientific community to develop organs on a chip.
- Describe the role of regulators in driving innovation, and how FDA's engagement has changed the way new predictive toxicology methodologies and technologies are advanced.
- Describe three ways FDA is working within the agency and with external partners on concepts for bringing predictive toxicology forward.
- Discuss the challenges FDA and its partners in the scientific community face in developing tools to transform predictive toxicology testing and to reduce the need for animal testing.
- Describe how stakeholders can work with FDA through training, partnerships, and dialogue

Target Audience
This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 May 10, 2018

Time	Topic	Speaker
12:00 - 1:00 PM	FDA's Predictive Toxicology Roadmap: Implications and Opportunities for Stakeholders	Suzanne Fitzpatrick, PhD DABT ERT

Continuing Education Accreditation

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)* ™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This activity has been assigned 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacy participants: partial credit cannot be awarded, therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Fitzpatrick, Suzanne, PhD DABT ERT, Senior Science Advisor for Toxicology, Food and Drug Administration - nothing to disclose

Planning Committee

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- KEMPF, LUCAS, MD - nothing to disclose
- Lee, Christine - nothing to disclose
- Parish, Eileen, MD, Medical Officer, FDA/OC/OCS/OSPD - nothing to disclose
- Wheelock, Leslie, MS, RN, Director, OSPD, FDA, OC, OCS, OSPD - nothing to disclose

CE Consultation and the Accreditation Team

- Bryant, Traci, M.A.T., CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.