The FDA Office of Scientific and Professional Development (OSPD)

And

Health Research Alliance (HRA)

Present

“Gene Editing: FDA-Regulated Technologies and Applications”

November 1, 2016
8:00am - 5:00pm
White Oak Building 31
The Great Room

Description: Gene editing is the technique by which DNA is inserted, deleted or replaced in the genome of an organism using an exogenous editing nuclease, often delivered in a gene therapy vector. The most popular technology is built around the CRISPR/Cas9 enzyme system, but there are several other alternative systems such as Zinc finger and TALEN nucleases. The technology is being developed commercially to edit human genes both to correct specific pathogenic mutations, and to create resistance to pathogens like HIV. In this regard it represents a highly personalized medicine. The technology is also being used to design animal models of genetic diseases and to manipulate plants to make them more resistant to pathogens or improve crop yield. Gene editing applications have been approved for use in the agricultural industry and several companies are advancing rapidly towards proposed clinical trials.

The rapid development of gene editing technology creates new opportunities to develop innovative approaches in biomedical, veterinary and agriculture research, but also poses serious challenges for scientific community, regulators, industry, consumers, ethicists, and policy makers.

The goal of this workshop is to educate FDA scientists and staff on the latest discoveries related to gene editing technologies and their potential applications in biomedical, veterinary, and food industries. This workshop is co-sponsored and co-organized by the U.S. Food and Drug Administration (FDA) and Health Research Alliance (HRA), under a co-sponsorship agreement to conduct the FDA New Frontiers in Science Lectureship Program. The goal of this program is to foster expert scientific exchange between the scientific community and FDA, and expand the range of scientific professional development opportunities for FDA scientists and ensure they have the skills required to modernize or develop new regulatory pathways for its products.

Confirmed Speakers: Jennifer Doudna (UC Berkeley), Keith Joung (Massachusetts General Hospital), Matthew Porteus (Stanford), Joseph Tector (Indiana University), Paul Nakata (USDA/ARS at Baylor College of Medicine), Patrick Hsu (Salk Institute).
Planning Committee
FDA: Leslie Wheelock, Latonya Powell, Devin N. Thomas, Francis Kalush, Khaled Bouri, Jason Dietz, Larisa Rudenko, Malini Wileman, Jakob Reiser, Eric Schulze, Andrew Byrnes, Changting Haudenschild, Ying Huang, Denise Gavin, Mike Havert, Ruth Timme, Patrick Cournoyer, Kathleen Jones

Health Resource Alliance: Maryrose Franko, Rusty Kelley, Brian Mansfield.

Reasonable Accommodations
The FDA provides reasonable accommodations for all individuals with disabilities that apply for training or developmental opportunities. If you need a reasonable accommodation for any part of the training application process please notify the training contact for this particular event. Reasonable accommodation requests are granted on a case-by-case basis. Should you need sign language interpretation to attend this event, please send the request to Interpreting.Services@oc.fda.gov.

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