Moving research from the laboratory for field trials: Regulatory pathway for genetically engineered organisms and their derived products

November 19, 2019
Gaylord National Resort & Convention Center, Riverview Ballroom 2 & 3
National Harbor, MD, USA

Overview: Advancing in research to development of a product and eventually commercialization requires regulatory approval from designated national government agencies. This knowledge about how international and national frameworks works is not widely shared among oversight review committees, principal investigators, senior scientists, post-docs, and other investigators. This workshop aims to provide a basic understanding of regulatory considerations and issues recognized internationally for conducting field trials of investigational genetically engineered organisms and their derived products for applications in public health, agriculture and protection to the environment. The organizers aim to provide a fundamental understanding of regulatory sciences and decision-making processes that will help bridge the gap between conducting basic research and translation research moving towards product development.
Target audience: Scientists (principal investigators, post-doctoral fellows), institutional oversight committees (IBCs, IACUCs, ERBs), policy makers and other interest groups from public health, animal, conservation, or agricultural research applications conducting or planning to conduct basic science and early translational projects that could lead to product development efforts in the future. This workshop is designed for those who have no, or not very substantial, experience with regulatory processes within and external to the United States.

Agenda

8:00-9:00 am	***Registration and Breakfast***	
Session 1: Opening Remarks and Orientation		
9:00-9:30	Welcome Goals and expectations	Stephanie James, FNIH Willy Tonui, EHS Consultancy Ltd
Session 2: Regulatory approaches on genetic engineered organisms and derived products Learn about important differences between research and regulatory sciences; distinctions concerning process and product-based regulatory systems; and complexities and considerations of working internationally.		
9:30-10:00	Differences between research and regulatory sciences	Camilla Beech, Cambea Consulting Ltd
10:00-10:30	Non-compliance consequences	Brinda Dass, FNIH
10:30-11:00	*Break*	
11:00-11:30	Considerations for working across international borders	Hector Quemada, Western Michigan University

11:30-12:00	Regulatory approaches: Panel Q&A	Camilla Beech, Hector Quemada, Brinda Dass
Session 3: Risk assessment and mitigation tools Discover the what, when, why, and how of risk assessment and participate in an interactive mini-problem formulation exercise.		
12:00-12:30	General Risk Assessment, Risk Assessment for Organisms (plants, animals, insects, microbes)	Brinda Dass
12:30-2:30	Guided mini-problem formulation exercise Working Lunch	Andrew Roberts, ILSI Research Foundation
2:30-2:50	*Break*	
Session 4: Regulatory processes - real life experiences Consider real-life experiences and consequences of regulatory process in different settings.		
2:50-3:10	Target Malaria, Burkina Faso	Abdoulaye Diabate, Institut de Recherche en Science de la Santé/Centre Muraz, Burkina Faso
3:10-3:30	GBIRd	Royden Saah, Island Conservation
3:30-3:50	MosquitoMate, Inc.	Stephen Dobson, University of Kentucky and MosquitoMate, Inc.
3:50-4:10	GM crops	Nigel Taylor, Donald Danforth Plant Science Center
4:10-4:40	Regulatory processes: Panel Q&A	Abdoulaye Diabate, Royden Saah, Steve Dobson, Nigel Taylor
Session 5 4:40-5:00	***Lessons learned, additional resources, and final comments***	Stephanie James and Willy Tonui
5:00	**Adjourn**	