

SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety



Alternative Methods for Predictive Safety Testing: 3D Bioprinted Tissue Models

April 9, 2019



SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety

Welcome to the 3rd SOT FDA Colloquium in this 2018-2019 Annual Series

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SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety

Colloquium Series

- **Partnership of U.S. FDA's Center for Food Safety and Applied Nutrition (CFSAN) and the Society of Toxicology (SOT)**
- **Stimulate a dialogue among leading toxicology experts on future-oriented toxicological science relevant to food and food ingredient safety assessment**
- **Information for FDA employees and the public**
- **Not a forum for soliciting regulatory advice or discussing food or food ingredient regulatory issues**
- **They are a forum to discuss the latest toxicological science in the context of food chemical safety.**



Colloquium Impact

- Fifth year of quarterly colloquia
- Wide-ranging topics related to toxicology and food safety
- Global audience from all employment sectors
 - Onsite
 - webcast registrants from a least 8 countries
- Resource for 24/7 learning
 - <http://www.toxicology.org/events/shm/fda/fda.asp> for recordings and slides



Office of Applied Research and Safety Assessment (OARSA)

- **Mission statement--OARSA is a unique, collaborative research environment that contributes to the FDA's mission to protect Public Health by providing science-based data to support the Agency's regulatory food protection and cosmetic safety programs.**



Office of Applied Research and Safety Assessment (OARSA)

- **OARSA provides Center and Agency leadership in toxicology, with an emphasis on alternative methods for predictive safety testing.**
- **We work with the program offices and the field labs (ORA) to meet their needs and help achieve their goals as established through the research prioritization process.**
- **We serve as one of the Center's research liaisons with other FDA Centers and organizations outside the agency, including other Federal agencies, industry, and academia.**

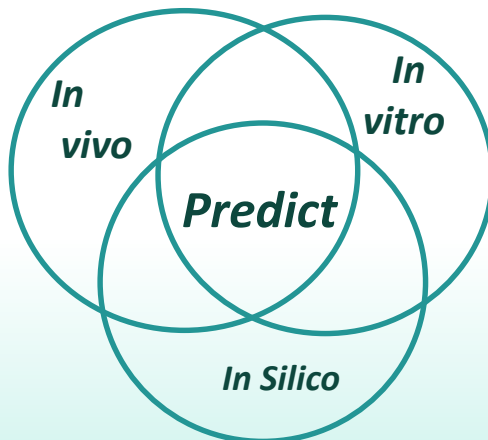


SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety

Office of Applied Research and Safety Assessment (Division of Toxicology)

Mission:

Integrate and apply modern toxicological approaches to support regulatory and public health decision-making on chemical hazards in foods, dietary supplements and cosmetics.



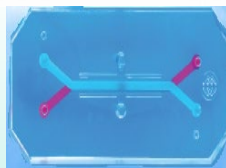
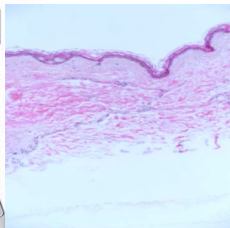


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*Future
Direction*



Speaker Introductions

Margaret Kraeling
Colloquium Co-chair
US FDA, CFSAN
Laurel, MD



Today

Alternative Methods for Predictive Safety Testing: 3D Bioprinted Tissue Models

8:30 AM–8:40 AM

Welcome and Overview

Mary Torrence, Director of the Office of Applied Research and Safety Assessment, US FDA, Laurel, MD

Speaker Introductions

Margaret Kraeling, US FDA, Laurel, MD

8:40 AM–9:20 AM

Overview and Challenges of Bioprinting

Sharon Presnell, Amnion Foundation, Winston-Salem, NC

9:20 AM–10:00 AM

Putting 3D Bioprinting to the Use of Tissue Model Fabrication

Y. Shrike Zhang, Brigham and Women's Hospital, Harvard Medical School, and Harvard-MIT Division of Health Sciences and Technology, Boston, MA

10:00 AM–10:20 AM

Break



Today

Alternative Methods for Predictive Safety Testing: 3D Bioprinted Tissue Models

10:20 AM–11:00 AM

Uses of Bioprinted Liver Tissue in Drug Development

Jean-Louis Klein, GlaxoSmithKline, Collegeville, PA

11:00 AM–11:40 AM

Biofabrication of 3D Tissue Models for Disease Modeling and Chemical Screening

Marc Ferrer, National Center for Advancing Translational Sciences, NIH, Rockville, MD

11:45 AM–12:45 PM

Roundtable Discussion

Moderator: Edward LeCluyse, LifeNet Health, Research Triangle Park, NC

Margaret Kraeling, US FDA, Laurel, MD

All speakers



Alternate Methods for Predictive Safety Testing: 3D Bioprinted Tissue Models

Edward L. LeCluyse

Colloquium Chair

LifeNet Health

Research Triangle Park, NC

