



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

April 9, 2019

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

Wiley Auditorium, US FDA, CFSAN, College Park, MD

Chair: Edward L. LeCluyse, LifeNet Health, Research Triangle Park, NC

Co-Chair: Margaret Kraeling, US FDA, Laurel, MD

Food Safety Colloquia Series

The Society of Toxicology in conjunction with the US FDA Center for Food Safety and Applied Nutrition (CFSAN) have partnered to provide this colloquia series. The series presents scientific information that is high-quality, cutting-edge, future-oriented toxicological science to provide a well-grounded foundation to inform the work of US FDA employees. These sessions are open to the public to attend in person or via webcast. These events are not a public forum for discussion of toxicology regulatory issues.

Bioprinting of 3D human tissues is a newly developing field that is currently being pursued by private industry, academia, and government. Human 3D bioprinted tissues represent a valuable *in vitro* approach for chemical, personal care product, cosmetic, and preclinical toxicity/safety testing. Bioprinting applications are appealing alternative methods for cosmetics testing especially given the current regulatory situation in the European Union that bans animal testing on new cosmetic products. Bioprinting of skin, liver, and kidney is already appearing in toxicity testing applications for chemical exposures and disease modeling. The use of 3D bioprinted tissues and organs may provide future alternative approaches for testing that may more closely resemble and simulate intact human tissues to more accurately predict human responses to chemical and drug exposures.

Schedule (All times are Eastern US, GMT-4)

8:00 AM–8:30 AM	Badge Pick Up
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
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

US FDA, College Park, Maryland • Live Webcast

Organizing Committee

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Future Colloquia

May 2019 *In Silico* Methods for Food Ingredient, Dietary Supplement, and Cosmetic Safety

Watch for the announcement of the 2019–2020 Colloquia.

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- **Can Alternatives Inform the Risk Assessments of Mixtures in Food?**
- ***In Vitro* to *In Vivo* Concordance for Toxicity Prediction and Use in Safety Assessments**
- **Safety Assessment of Food Packaging and Other Food Contact Substances**
- **Considerations for the Determination of Adversity in Food Chemical Safety Evaluations**
- **Application of *In Vitro* to *In Vivo* Extrapolation in Safety Assessment**
- **State of the Science in Developmental Neurotoxicology**

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