

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



Application of *In Vitro*  
to *In Vivo* Extrapolation  
in Safety Assessment

December 1, 2016



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

## Welcome

### Mary Ditto, PhD

Director, Senior Science and Policy Staff

Office of Food Additive Safety

CFSAN, US FDA, College Park, MD





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## Colloquium Series

- Partnership SOT and US FDA Center for Food Safety and Applied Nutrition (CFSAN)
- High-quality, cutting-edge, future-oriented toxicological science
- Information for FDA employees and the public
- Not a public forum for discussion of toxicology regulatory issues



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## FDA Course: Computational Modeling and Simulation of Developmental Toxicity

**December 2, 2016 2:00 PM-4:00 PM**

Instructor: Thomas B. Knudsen, PhD

Developmental Systems Biologist, National Center for Computational Toxicology, US EPA/ORD

How tissues and organs are shaped during development is crucial for understanding human birth defects. High-throughput screening (HTS) assays on human stem cells may predict developmental toxicity with reasonable accuracy. Other models are necessary for mechanism-specific analysis because embryogenesis requires precise timing and control. Agent-based modeling and simulation (ABMS) virtually reconstructs these dynamics, cell-by-cell and interaction-by-interaction. Using ABMS, HTS lesions from ToxCast can be integrated with patterning systems in an *in silico* platform to model developmental toxicity from fundamental cell and molecular bioactivity data.



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## **FDA Course: Computational Modeling and Simulation of Developmental Toxicity**

**December 2, 2016 2:00 PM-4:00 PM**

**To Participate Connect at:**

**<https://fda.webex.com/fda/j.php?MTID=m182b8925c5d8a7ea7afda214b78a1a73>**

**Webinar Meeting Number: 740 792 331**

**Meeting Password: 112233**

**Toll Free Phone: 1-855-828-1770**



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

## **Welcome from SOT**

**Peter L. Goering, PhD, DABT, ATS**

Past President, Society of Toxicology

**SOT** | Society of  
Toxicology



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## Society of Toxicology Mission

To Create a Healthier and Safer World by  
Advancing the Science and Increasing the Impact  
of Toxicology

### Strategic Priorities

- Strengthen the Relevance and Impact of Toxicology
- Develop and Support Toxicologists to Capitalize on Future Opportunities
- Expand Outreach and Impact Globally





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## Nine Previous Colloquia: Topics

- State of the Science in Developmental Neurotoxicology
- Safety Assessment Approaches in Young Children
- Cramer Classification and Threshold of Toxicological Concern
- Mode of Action in Dose-Response Assessment for Carcinogens
- Computational and *In Vitro* Methods for Assessments
- Contemporary Issues in Risk Assessment
- Immunotoxicology in Safety Assessment:
- ADME/PK Studies to Improve Safety Assessments
- Clinical and Observational Data for Safety Assessment: Partially Hydrogenated Oils





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

## Survey Feedback—All 9 Colloquia

	Excellent + Good
Overall session quality	95%
Amount of time devoted to the topic	97%
Relevancy of content for my work	84%
Appropriate depth of content	91%
Match of colloquium to my expectations	89%
Overall session quality	95%

N=529

# SOT FDA Organizing Committee

**Ivan Rusyn, MD, PhD**, Committee Chair, Texas A&M University, College Station, TX

**Jason L. Aungst, PhD**, US FDA, CFSAN, College Park, MD

**Bryan Delaney, PhD, DABT, ATS**, DuPont Pioneer, Johnston, IA

**Suzanne Compton Fitzpatrick, PhD, DABT**, US FDA, CFSAN, College Park, MD

**Norbert Kaminski, PhD**, Michigan State University, East Lansing, MI

**Jieun Lee, PhD, DABT**, Kellogg, Battle Creek, MI

**Allen Rudman, PhD**, FDA Lead, US FDA, CFSAN, College Park, MD

**Jeffrey J. Yourick, PhD, DABT, ATS**, US FDA, CFSAN, Laurel, MD

**Peter Goering, PhD, DABT, ATS**, SOT Council Contact, US FDA, CDRH, Silver Spring, MD

**Richard Becker, PhD, DABT**, Colloquium Chair, American Chemical Council, Washington, DC





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

## **Colloquium Leads**

**Chair: Richard Becker, PhD, DABT**

American Chemistry Council,  
Washington, DC

**Co-chair: Lisa M. Sweeney, PhD, DABT**

Naval Medical Research Unit Dayton,  
Dayton, OH

# Agenda

8:50 AM–9:30 AM

- **Overview and Principles Underpinning *In Vitro* to *In Vivo* Extrapolation,**  
Lisa M. Sweeney, Naval Medical Research Unit Dayton, Dayton, OH

9:30 AM–10:10 AM

- **Data Requirements for Developing IVIVE Models,** Nynke Kramer, Utrecht University, Netherlands

10:30 AM-11:10 AM

- **Examples Illustrating Potential Applications of IVIVE in Chemical Assessment,** Miyoung Yoon, ScitoVation, Research Triangle Park, NC

11:10 AM-11:50 AM

- **Opportunities and Challenges for Using IVIVE to Improve Decision Making,**  
Weihsueh Chiu, Texas A&M University, College Station, TX

11:50 AM-12:50 PM

- **Roundtable Discussion,** Richard Becker, Moderator  
All Speakers





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## **Overview and Principles Underpinning *In Vitro* to *In Vivo* Extrapolation**

**Lisa M. Sweeney, PhD, DABT**

Naval Medical Research Unit Dayton, Dayton, OH