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

Mary E. Torrence, DVM, PhD, DACVPM
Director, OARSA
FDA CFSAN
8301 Muirkirk Rd, MOD-1
Laurel MD 20708
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 at least 8 countries
- Resource for 24/7 learning
  - [http://www.toxicology.org/events/shm/fda/fda.asp](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.
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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Integrate and apply modern toxicological approaches to support regulatory and public health decision-making on chemical hazards in foods, dietary supplements, and cosmetics.
Speaker Introductions

Margaret Kraeling
Colloquium Co-chair
US FDA, CFSAN
Laurel, MD
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
# Alternative Methods for Predictive Safety Testing: 3D Bioprinted Tissue Models

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>10:20 AM–11:00 AM</td>
<td>Uses of Bioprinted Liver Tissue in Drug Development</td>
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<td>Jean-Louis Klein, GlaxoSmithKline, Collegeville, PA</td>
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<td>11:00 AM–11:40 AM</td>
<td>Biofabrication of 3D Tissue Models for Disease Modeling and Chemical Screening</td>
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<td>Marc Ferrer, National Center for Advancing Translational Sciences, NIH, Rockville, MD</td>
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<td>11:45 AM–12:45 PM</td>
<td>Roundtable Discussion</td>
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<td>Moderator: Edward LeCluyse, LifeNet Health, Research Triangle Park, NC</td>
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<td>Margaret Kraeling, US FDA, Laurel, MD</td>
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<td>All speakers</td>
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Edward L. LeCluyse
Colloquium Chair
LifeNet Health
Research Triangle Park, NC