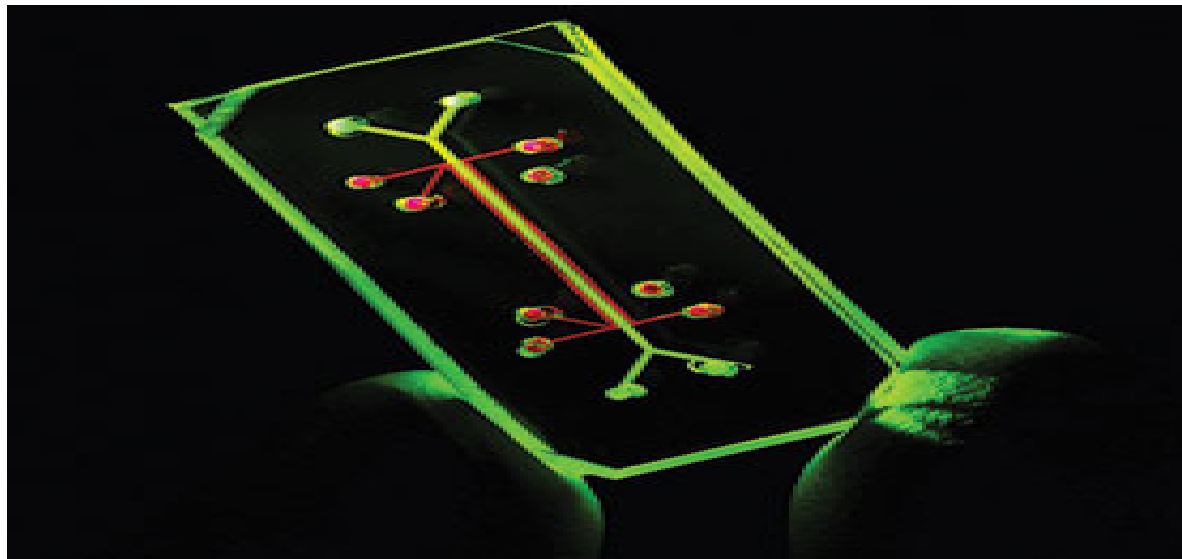


Advancing Regulatory Science At FDA

Suzanne Fitzpatrick, PhD, DABT, ERT
US Food and Drug Administration
ICCVAM Public Meeting
May 23, 2017



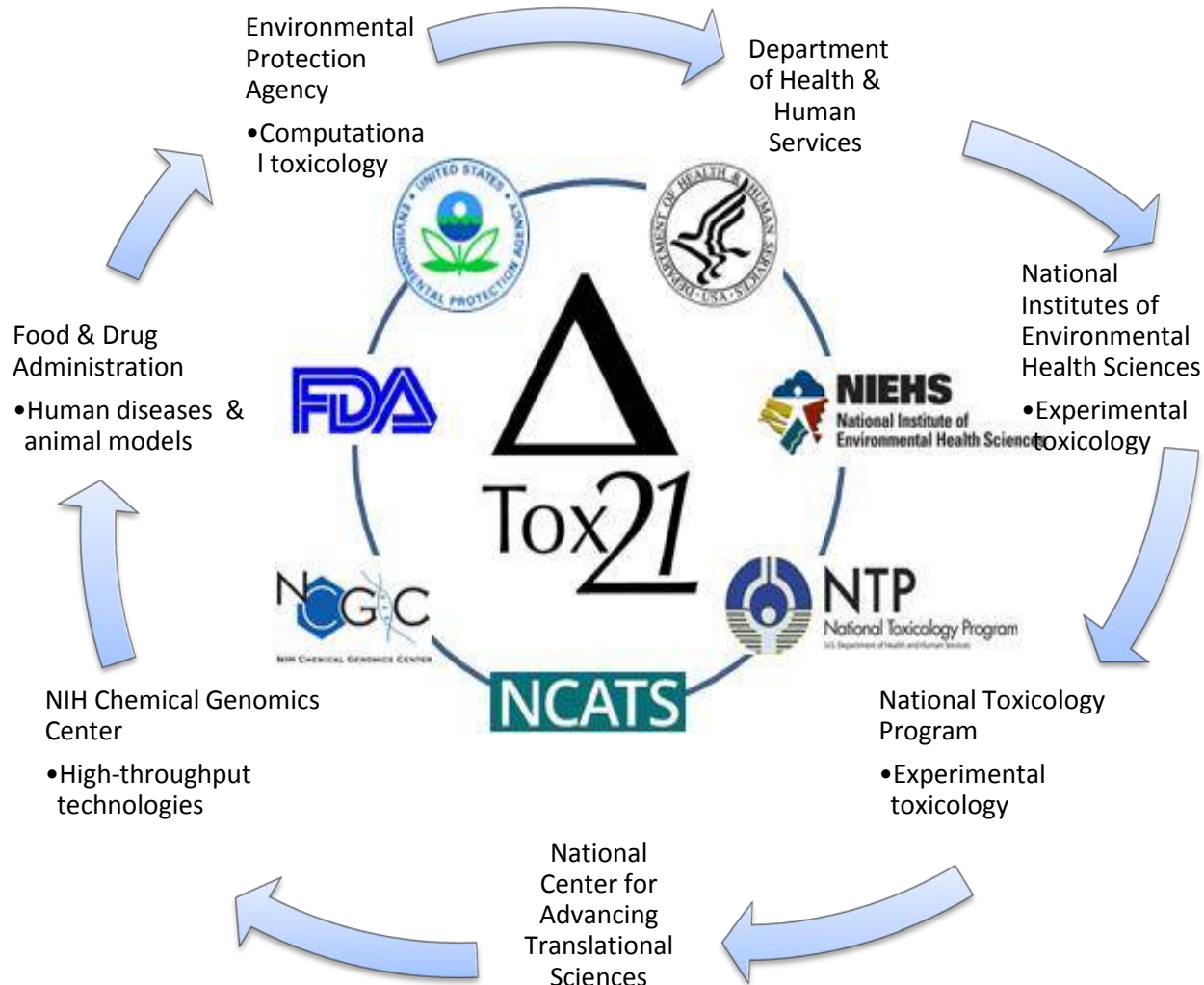
What is FDA Doing To Advance Regulatory Science?

- FDA has formed a FDA Senior Toxicologist Working Group to share information on new toxicology methods and to familiarize FDA Regulatory and Research Scientists on emerging toxicology tests and their usefulness in risk assessment.
- This work group charged with developing a Predictive Toxicology Framework for the agency. This framework emphasizes a “context of use” approach for determining confidence in emerging technologies.

Partnerships are Important for Accepting New Technologies

- Foster collaborations between government regulators, industry , stakeholders and academia to ensure the most promising technologies are identified, developed validated and integrated into regulatory risk assessment.
- Memorandum of Understanding between FDA, EPA, NIEHS and NCATS to form the “Tox 21 Community.
- MOU updated in 2015- CFSAN is the lead for FDA.

Toxicity Testing in the 21st Century (Tox21)



ICCVAM DART Working Group

- FDA/CFSAN chairs an ICCVAM working group to draft an ICCVAM strategy and roadmap for evaluating new methods for reproductive and developmental toxicity testing.
- Work Group will provide expertise in developing and evaluating alternative approaches to classify chemicals for reproductive and developmental toxicity hazards using in vitro and/or in silico methods.
- In addition to representatives from ICCVAM member agencies, ICATM partners (EURL ECVAM, JaCVAM, KoCVAM, and Health Canada) will be offered the opportunity to participate in the workgroup.

Conference



Predictive Toxicology and Preventive Medicine for Healthy
Children

November 14–16, 2018 | Washington,



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

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



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

SOT- FDA MOU Signed will Extend Colloquium Series

December 5, 2016 – Signing Ceremony with representatives from SOT and USFDA to renew the SOT-FDA Memorandum of Understanding that facilitates collaborative efforts in training, education, professional development, and innovative toxicology methods and regulatory science.



FDA-DARPA-NIH Microphysiological Systems Program

- Started in 2011 to support the development of human microsystems, or organ “chips,” to screen for safe and effective drugs swiftly and efficiently (before human testing)
- Collaboration through coordination of independent programs



Engineering platforms and biological proof-of-concept (DARPA-BAA-11-73: Microphysiological Systems)



Underlying biology/pathology and mechanistic understanding (RFA-RM-12-001 and RFA RM-11-022)



Advise on regulatory requirements, validation and qualification

This was a unique partnership because it involved regulatory scientists at the very beginning- was able to address identified gaps in knowledge need to regulate FDA products

***NATURE* | NEWS**

Miniature liver on a chip could boost US food safety

- CFSAN
Researchers will be evaluating the effectiveness of this technology to better understand the effects of medicines, disease-causing bacteria in foods, chemicals, and other potentially harmful materials on the human body



Recommendations to facilitate regulatory decision-making and acceptance

- Networking and communication- talk to FDA about new approaches
- Involvement from regulatory agencies during all stages of test method development
- Cross-sector collaboration
- International collaboration and harmonization of approaches
- Joint stakeholder development of specific criteria promoting acceptance
- Continuing education for regulators