Advancing Regulatory Science At
FDA
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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)

Department of Health & Human Services
National Institutes of Environmental Health Sciences
- Experimental toxicology

National Toxicology Program
- Experimental toxicology

National Center for Advancing Translational Sciences
NIH Chemical Genomics Center
- High-throughput technologies

Food & Drug Administration
- Human diseases & animal models

Environmental Protection Agency
- Computational toxicology
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.
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 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
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