

## **US Strategic Roadmap Goal: Foster the Use of Efficient, Flexible, and Robust Practices to Establish Confidence in New Methods**

**Presenter:** Dr. Emily Reinke, DoD

- **Update to ICCVAM's "Validation and Regulatory Acceptance of Toxicological Test Methods"**

**Presenter:** Dr. John Gordon, CPSC

- **OECD Perspective on Test Methods Validation**

**Presenter:** Dr. Anne Gourmelon, OECD

Failure to consider the ultimate context of use is one of the most frequently cited reasons for lack of agency and industry adoption of new approach methodology (NAMs). It is therefore important that agencies clearly communicate their needs along with all possible contexts for which data from both the existing animal study and NAM would be used. Agencies and stakeholders should use past experience as a guide for developing more flexible and efficient processes to evaluate fitness for purpose of a particular NAM. One example could be providing agency and stakeholder case studies illustrating how alternative approaches have successfully been evaluated or implemented.

Clearly, the successful development of NAMs will depend on the ability of federal agencies and stakeholders to work closely together via public-private partnerships that facilitate the sharing of both knowledge and data. Such collaborations will allow knowledge and experience gained throughout the product development and registration cycle to be incorporated into new test method development and application. Such collaborations will also allow the resources and collective expertise of ICCVAM agencies and their stakeholders to be leveraged to address parallel testing needs and requirements across product sectors, providing opportunities to impact alternative test method research and development, acceptance, and implementation.

Ultimately, federal agencies and their stakeholders must work together to establish confidence in NAMs using flexible, integrated approaches to testing that span from early development to the ultimate intended use. This will require:

- Clearly delineating testing requirements and context of use.
- Promoting the use of new approaches for establishing confidence.
- Utilizing public-private partnerships to promote cross-sector communication and cooperation.
- Creating centralized data access points that are publicly available and easily accessible.
- Actively soliciting the submission and collation of parallel data from animal studies and alternative methods.