ICCVAM: Validation Workgroup

Updating the ICCVAM Report

ICCVAM Sponsor Agencies:
CPSC, FDA/CFSAN

Participating Agencies:
EPA/OPP, EPA/ORD,
ATSDR, VA ORD, DOD,
NIST, OSHA, NIEHS, NIH,
FDA/CDER, CTP, OCS, CDRH

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Roadmaps all emphasize the 3 C’s- Collaboration, Communication, and Commitment
Why a New Guidance?

• Underlying principles from OECD 34 remain the same in this new Guidance.

• Introduce the “context of use” terminology

• New guidance will emphasize that validation process should be flexible and adaptable.

• Emphasize the need for communication because regulatory needs may vary across the federal agencies
Guiding Principles

Key Concepts: Flexible, Fit-for-Purpose NAMs Validation

- Context of Use
- Biological Relevance
- Data Integrity
- Technical Characterization
- Information Transparency
- Independent Review
Start with a Regulatory Question-
Context of use

• What question needs to be answered and for what purpose?

• How much “validation/qualification” is needed for a particular assay will depend on the particular context of use.

• Helps define acceptable applicability domain and limitations
• Context could be expanded over time
• Choice of Reference Standards Related to Context of Use
Topics Covered in this Guidance

Foster the use of efficient, flexible, and robust practices to establish confidence in new methods

- Clearly delineate testing requirements and context of use
- Promote the use of new approaches for establishing confidence
- Utilize public workshops and/or public-private partnerships to promote cross-sector communication and cooperation
Topics Covered in the New Guidance

- Relevance of New Approach Methods
  Biological Relevance
  Biological Plausibility
  Mechanistic Relevance
- Importance of Quality Reference Data
- Role of Legacy Animal Data
Topics Covered in New Guidance

- Examination of best practices for quality and quality systems development
- Assessment of key sources of variability in the NAM
- Discussion of “Good or Better Standard” for qualification/validation.
- Incorporation of selected data quality tools such as:
  – Building a statistical model
  – Setting specifications
Topics Covered in the New Guidance

- How new principles of validation can fit into a globally harmonized approach to allow for continued mutual acceptance of data

- Reference to existing and well-vetted documents (e.g., GIVIMP, OECD GD34, GD69 on QSAR Validation, FDA Guidance for Industry, etc.)
Role of ICCVAM

• Assure an independent validation process
• Advise federal agencies on validation strategies
• Facilitate cross-agency collaborations through work group/conferences
• Encourage global communication/harmonization on validation criteria through conferences, seminars and meetings
Next Steps Prior to Finalization

– Format and organization of the document still under consideration.

– Input from the ICCVAM Federal Agencies still being incorporated through the VWG

– Draft document will be sent to ICCVAM agencies for review and sign off.

– Stakeholders will have opportunity to comment on the document.