OECD TEST GUIDELINES PROGRAMME UPDATE

Wanda Hall, National Coordinator for the Test Guidelines Programme

ICCVAM Public Forum
Thursday, 23 May 2019
NIH | Natcher Conference Center | Bethesda, Maryland

TEST GUIDELINES AND SUPPORTING DOCUMENTS APPROVED

- **1 New Guidance Document Approved:**
  - Guiding Principles on Good Licensing Practices for Protected Elements in OECD TGs
- **3 New Test Guidelines Approved:**
  - TG on the Xenopus Eleutheroembryo Thyroid Signaling Assay & Validation Report
  - TG on Vitrigel Eye Irritancy Test, Validation Report (VR) & Performance Standards (PS)
  - TG on Reactive Oxygen Species for Phototoxicity Testing
- **6 Updated Test Guidelines Approved:**
  - TG 203 on the Fish Acute Toxicity
  - TG 442C on *in vitro* skin sensitization addressing KE1 (MIE) covalent binding to protein [+VR/+Peer Review (PR)/+PS]
  - TG 492 on Reconstructed Human Corneal Epithelium for Eye Irritation Test (+VR/+PR)
  - TG 439 on Reconstructed Human Epidermis TM for Skin Irritation (+PR)
  - TG 431 on Reconstructed Human Epidermis TM for Skin Corrosion
  - TG 432 on 3T3 NRU for Phototoxicity Testing

NEW PROJECTS APPROVED

- **17 New Projects Approved**
  - 6 Manufactured Nanomaterials Projects
  - 2 Ocular Toxicity Projects
  - 2 Skin Sensitization and 1 Dermal Exposure Projects
- **4 Projects Not Approved**
  - NL Proposal to delete Beuhler Test (BT) from TG 406
    - US opposed the proposal for several reasons:
      - LLNA not appropriate for all types of test materials
      - Potential for false positives with LLNA
      - US regulations allow registrants to select any appropriate method

OUTCOME OF DISCUSSIONS

- **Performance Standards Development:**
  - WNT agreed PS are not/should not be developed for the purpose of avoiding situations of monopoly abuse
    - Signature of the fair, reasonable and non-discriminatory (FRAND) declaration avoids monopoly abuse
  - WNT agreed PS should be developed on a case-by-case basis after evaluating the need and utility
- **Cloud-based Predictions:**
  - WNT agreed reviewers and regulators need to have access upon request
  - Regulators are to check their policy about signature of non-disclosure agreement
  - Versioning and GLP issues:
    - Recent input received by OECD Secretariat will be clarified and shared to help delineate policy and principles

OUTCOME OF DISCUSSIONS

- **Ethical Issues w/Use of Human-derived Products in TGs:**
  - WNT supported check-list, informed consent model and future development of a traceability scheme (SPSF to be developed)
- **Dose Selection in Chronic Studies:**
  - WNT did not approve US SPSF: *"Review and Evaluation of Case Studies for Possible Approaches to Top-dose Selection"*
  - A steering group will be formed to discuss organization of a workshop
    - Objective: review regulatory needs and share viewpoints regarding dose selection

PATH FORWARD ON THE FOLLOWING PROJECTS

- **AOP Development Program:**
  - WNT supported proposed work on the AOP Development Program
  - WNT supported June 2019 joint session with WPHA/EAGMST/WNT
  - WNT agreed streamlining the process is challenging due to scientific review
- **Outcome of ICATM Validation Workshop:**
  - WNT expressed interest to stay informed of progress among ICATM partners
  - WNT noted the importance of clarifying regulatory needs across jurisdictions in OECD countries when starting work in new areas

MANUFACTURED NANOMATERIALS

- **Issues Related to Manufactured Nanomaterials:**
  - The use of references that are not freely available (e.g., ISO) and ways to keep the references updated and in line with the TGs
  - Guidance on the number and types of NMs needed for confirming the applicability and validity of the test method evaluated
    - There are TGs for NMs that are validated with only 1 manufactured NM
    - What other information is needed to consider if a test method validated for 1, 2 or 3 NMs will be applicable for all NMs?