ENSURING DATA QUALITY FOR IN VITRO TESTS AS ALTERNATIVES TO ANIMAL STUDIES

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- In Vitro Performance Standards
- Seeking to incorporate these Performance Standards so that validated in-vitro methods for corrosivity can be added into OPPTS Corrosion / Irritation guideline

Legal Considerations

Government Employees May Not Endorse a Commercial Product

- Office of Government Ethics regulations prohibit endorsements of commercial products (5 CFR 2635.702)

Performance Standards Solve the Endorsement Problem

- Performance standards set forth desired descriptive and functional attributes of the test method
- Stating that a specific PTM satisfies a specific performance standard is allowed

In-Vitro Corrosivity Test Methods

- Corrositex®,
- EpiDerm™ / EPISKIN™
- Transcutaneous Electrical Resistance Assay (TER)

Proprietary Test Methods

- CORROSITEX® is a registered trademark of In Vitro International, Inc.
- EPIDERM™ is trademark of MatTek Corp.
- EPISKIN™ is trademark of L'OREAL.

Essential Test Method Components

- Each proposed test method would include these elements from the validated method:
  - Structural
  - Functional
  - Procedural
- Comprised of unique characteristics, critical procedural details, and QC measures.

Reference Chemicals will be used?

- Reference chemicals were used to validate the original test system in Lab
- Used to assess the accuracy and reliability of the proposed mechanistically and functionally similar test method.
  - Represent range of responses
  - Consistent results
  - Reflect accuracy
  - Well defined chemical structure
  - Readily available

What are Performance Standards?

- A way to communicate the basis by which a new proprietary (i.e., copyrighted, trademarked, registered) and non-proprietary test methods have been determined to have sufficient accuracy and reliability for specific testing and regulatory purposes.

Agency Approaches

- Draw on current GLP regulations to ensure in vitro test systems used for regulatory purposes are reproducible, credible, and acceptable.
- Draw on Performance Standards developed by US agencies through ICCVAM when writing generic Agency guidelines for PTMs

Agency Approaches (cont'd)

- Ensure that guidelines incorporating in vitro methods used as alternatives to animal testing conform to Agency Quality Assurance guidance
- Identify quality control measures for in vitro methods in Agency test guidelines

Agency Approaches (cont'd)

- Identify appropriate controls, including benchmarks, in Agency test guidelines so that the potential hazards of chemicals can be reviewed and reliably assessed.
- Work with national and international organizations to promote policies and "standards" for scientific practice to promote quality in implementation of in vitro methods performed for regulatory purposes