



Regulatory Requirements for In Vitro Systems to Meet Performance Standards During Validation and Over Time

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A recent US National Research Council report envisions humane alternative toxicological tests that are faster, less expensive, and more accurate than their animal counterparts. Currently, in vitro tissue models have been or are in the process of being validated as alternatives to animal testing for safety evaluation of cosmetics, pharmaceuticals, and consumer products. Currently available organotypic human models include dermal (EpiDerm, EpiDerm-FT), ocular (EpiOcular), ectocervical (EpiVaginal) and airway (EpiAirway). As these models become validated, regulatory agencies and users need to be assured that the models will provide consistent, high quality data over time, not just during the validation process. Recommended guidelines include "full characterization of cells or tissues, sampling of each lot ... for performance, and regular use of controls and benchmark chemicals to provide assurance of consistency of assay performance." The current poster summarizes the long-term reproducibility of EpiDerm and EpiOcular. Quality control testing of weekly production batches was performed using the MTT assay. The exposure time that reduced tissue viability to 50% (ET-50) for Triton X-100 was determined. For EpiOcular, the yearly average ET-50s have ranged from 22.0-27.3 minutes. The coefficients of variation (CV) for the negative control tissues have averaged <6% for every year since 1997; the yearly average CV has never exceeded 6.7%. For EpiDerm, the yearly average ET-50s have ranged from 5.9-7.5 hrs. The CV for the negative control has averaged <7.5% for every year since 1996. These results over the past 14 years of commercial production address regulatory concerns regarding performance standards over time.

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