

Myocyte Working Group Break Out Session

The power of the myocytes

Consensus

- Best practices discussion- to minimize variability, allow comparison across studies.
 - Positive controls
 - Protocols – vehicle controls, drug addition methods
 - Replicates, exposure time, temperature
 - Standardizing media and drug concentrations

Role of Myocytes in CiPA

- Internal decision making:
 - Valuable and informative assay in drug discovery
- Regulatory role:
 - Consensus that myocytes are essential to balance ion channel/*in silico* study when used before FIH
 - Well-validated assay (multiple multi-site validation studies)
 - Minimal influence of site-, platform, and cell type variability
 - Confidence in sensitivity of assay provided by ability to differentiate low vs intermediate/high risk compounds
 - Detect effects not covered by simpler channel systems, higher exposures,
 - Only system integrating all native human channels (balance?) and modulatory systems

Future Directions

- White Paper on Best Practices
 - Differentiate early screening vs. regulatory purposes
 - Monitoring new technologies (3D, pacing effects)
 - Extension of protocols (longer duration, drug combinations)
 - Anticipating and validating newer preparations
 - Defining framework for validation, judging value, benefits/advantages