

Endocrine Disruptor Screening Program: Validation Issue

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Endocrine Disruptor Screening Program: Validation Issue: Questions

- **Validation shows that a method gives the correct toxicological result, so that a sound regulatory decision can be made.**
- **What is the regulatory decision that will be made?**
- **What is the purpose of the assay in supporting the decision?**

Endocrine Disruptor Screening Program: Validation Issue: Questions

- Are the measurements/scores relevant for the purpose? (biologically based and plausible)
- Is the assay sufficient for the purpose and straightforward? (KISS - method will be a guideline)

Endocrine Disruptor Screening Program: Validation Issue

Reproducibility & Prediction

- **Assess within labs (over time) - *keep purpose in mind***
- **Assess across labs (over time) - *keep purpose in mind***
- **Assess the method's prediction and use *for regulatory decisions***
- **Is the protocol workable and successful?**

Endocrine Disruptor Screening Program: Validation Issue – A Note

Sample should be coded this will insure that:

- **Investigator bias is removed.**
- **Inter-laboratory comparisons are possible and logistically easy to perform.**



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