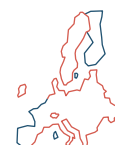


Formal validation

Formal validation is a rigorous, science-based evaluation to establish performance, i.e. robustness and reproducibility, and fitness for a given purpose, i.e. scientific validity
The validation study should be performed according to OECD Guidance on Validation³

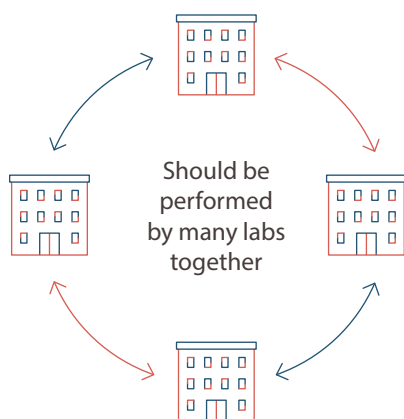


EURL ECVAM⁴ is responsible for validation within the EU

There are two steps in a validation study

Step 1

Experimental generation of quality assured data



Determines among other things:

- ✓ Within-laboratory reproducibility
- ✓ Transferability – that another lab can obtain the same results
- ✓ Between-laboratory reproducibility
- ✓ Predictive capacity – how well the method predicts the biological endpoint
- ✓ Applicability domain – what kind of samples can be evaluated with the method

Step 2



Independent scientific peer review

Publication of the results



OECD and ISO work globally to standardize and harmonize guidelines and ensure reliable data

International acceptance through adoption as OECD Guideline or ISO standard

Submission for uptake as an international guideline or standard

- ✓ Assessment
- ✓ Peer review
- ✓ Commenting



1. Good Cell Culture Practice from Coecke *et al.* 2005 ATLA and Pamies *et al.* 2021 ALTEX
 2. OECD Guidance Document No. 286 on Good In Vitro Method Practices (GIVIMP)
 3. OECD Guidance Document No. 34 on the Validation and International Acceptance of New or Updated Test Methods for Hazard Assessment
 4. EU Reference Laboratory for alternatives to animal testing