



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
**The European Union Reference Laboratory for Alternatives to Animal Testing
(EURL ECVAM)**

**The EURL ECVAM
Network of Validation Laboratories
- NETVAL -**

Eligibility Criteria

January 2013

1. Human Resources

- 1.1 A team of at least four permanent staff members comprising scientists, technicians and quality assurance professionals with three or more years of experience in cell or tissue culturing and quality assurance.
- 1.2 A formal, comprehensive and documented staff competence development and training programme.

2. Quality and Safety

- 2.1 A formal quality system, preferably Good Laboratory Practice (GLP), or a system based on Good Clinical Laboratory Practice (GCLP), ISO 17025, ISO 17043, ISO 15189 or ISO 13485. The quality system should have specific provision (formal policy and related procedures) for the following;
 - 2.1.1 Drafting, reviewing, approving, versioning, distribution and archiving of Standard Operating Procedures.
 - 2.1.2 Planning and reporting of studies, including procedures for documenting deviations and amendments.
 - 2.1.3 Management and transfer of confidential information
 - 2.1.4 Handling, storage and management of test, reference and control items covering the complete life cycle.
 - 2.1.5 Handling, storage and management of test systems (e.g. cell or tissue models) covering the complete life cycle.
 - 2.1.6 An equipment calibration, maintenance and performance control programme that is fully documented.
- 2.2 A formal laboratory safety policy and related procedures.

3. Laboratory Facilities

- 3.1 At least one laboratory suitably equipped for cell or tissue culture.
- 3.2 One or more standard analytical or measurement techniques typically used in life sciences such as Fluorescence Microscopy, Flow cytometry, High Pressure Liquid Chromatography, (Capillary-)electrophoresis, Gas Chromatography, Mass Spectrometry, (Spectro-)photometry, or (Real Time) Polymerase Chain Reaction (PCR).
- 3.3 A cryo-preservation storage facility (e.g. liquid nitrogen or equivalent) together with a system for tracking and identifying cryo-stored items.
- 3.4 Experience during the last five years in implementing and performing at least five in vitro assays based on different test systems (cells, tissues) and/or standard analytical or measurement techniques.
- 3.5 Suitable equipment (e.g. glove box, chemical hood, container/plate sealer) and procedures for handling and disposing of hazardous chemicals.

Note: Documented evidence may be requested from a facility to demonstrate compliance with these eligibility criteria.