ETPLAS EU-60: Developing in vitro methods and approaches for scientific and regulatory use

Course Contents

PART 1: CONTEXT AND NEEDS FOR RELIABLE AND RELEVANT IN VITRO METHODS

An introduction to part 1
Drivers for developing reliable and relevant non-animal methods or approaches
Legislation that calls for the use of alternatives to animal testing
Examples of alternative approaches to animal testing
The process from developing a method to its regulatory implementation

PART 2: METHOD DEVELOPMENT AND IMPLEMENTATION BASED ON GOOD IN VITRO METHOD PRACTICES (GIVIMP)

An introduction to part 2

2.1. THE PURPOSE OF GIVIMP

Aims of GIVIMPAims of GIVIMP
How and where to use GIVIMP
GIVIMP users

2.2. TEST SYSTEM CONSIDERATIONS

Test system characterisation and documentation
Quarantine and contaminant screening the test systems
Considerations for handling test systems

2.3. METHOD ACCEPTANCE CRITERIA

Selection and use of reference/control item
Define appropriate acceptance criteria

2.4. TEST ITEMS AND METHOD LIMITATIONS

Test item preparation and concentration range
Assessment of risks, uncertainties, and method limitations

2.5. DEFINING A METHOD COMPLETELY AND CLEARLY

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Determine the proper level of detail in a standard operating procedure

2.6. REQUIREMENTS FOR PERFORMING AN IN VITRO METHOD

Maintaining and calibrating equipment
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PART 3: DEMONSTRATING THE SCIENTIFIC VALIDITY OF A NEW METHOD OR APPROACH

An introduction to part 3
What is a scientifically valid test method or approach?
Information requirements to demonstrate the reliability and relevance of a method
Principles and study designs to assess the scientific validity of a test method
Understanding the principles of OECD test guidelines and guidance documents

PART 4: KNOWLEDGE ASSESSMENT

Knowledge assessment based on case study exercise