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# GLPS: EPA vs OECD

*Worlds apart?*

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# OECD: *Who are you?*

- **Organization for Economic Co-operation and Development (OECD)**

Intergovernmental Organization  
29 Industrial Countries  
>200 Specialized Committees

- **Focus**

Coordination/Harmonization of Policies  
Discuss Issues of Mutual Concern  
Respond to International Problems

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# EPA vs OECD

## **US EPA Good Laboratory Practice Standards** (FIFRA;40 CFR Part 160)

- GLP Advisories (75 Advisories to Date)

## **OECD Principles of Good Laboratory Practice** (1997)

- Application of GLP Principles to Field Studies
  - Application of GLP Principles to Computerized Systems
  - Application of GLP Principles to Multi-Site Studies
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# SCOPE

## EPA

- studies that support or intended to support applications for research or marketing of pesticide products regulated by EPA
- intended to assure the quality and integrity of data submitted

## OECD

- apply to all non-clinical health and environmental safety studies required to register or license pesticides, unless exempted by legislation
  - intended to promote the development of quality test data
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EPA	OECD
<p>160.1 This part prescribes good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by EPA. This part is intended to assure the quality and integrity of data submitted pursuant to sections 3,4,5,8,18 and 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136a, 136c, 136f, 136q and 136v(c)) and sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a, 348).</p> <p>This part applies to any study described by paragraph "a." of this section which any person conducts, initiates, or supports on or after October 16, 1989.</p>	<p>Section I (1) These Principles of Good Laboratory Practice should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment. Non-clinical health and environmental safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory, in greenhouses, and in the field. Unless specifically exempted by national legislation, these Principles of Good Laboratory Practice apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.</p>

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# COMMON GROUND

- Definitions
  - Organization and Personnel
  - Facilities
  - Equipment
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# COMMON GROUND

- SOPs
  - Study Conduct
  - Reports
  - Archives
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# SEPARATE ROADS

- Organization and Personnel
    - Testing Facility, Testing Facility Management, Study Director and QAU *versus Testing Facilities, Test Sites, Testing Facility Management, Test Site Management, Study Director, Principal Investigator(s), and QA Programme*
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# SEPARATE ROADS

## ■ Terminology

- Protocols *vs* *Study Plans*
    - Changes & Deviations *vs* *Amendments & Deviations*
  - Study Initiation & Completion *plus* *Experimental Start/Completion*
  - Equipment *vs* *Apparatus*
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# SEPARATE ROADS

- Equipment / Apparatus
    - EPA
      - Calibration & Maintenance Logs
      - SOPs
        - Designate Person Responsible
        - Routine & Non-routine Maintenance
    - OECD
      - Validated Computerized Systems
      - Test System Interference
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# SEPARATE ROADS

- SOPs
    - EPA
      - Deviations *authorized* by Study Director and PI
    - OECD
      - Deviations *acknowledged* by Study Director and PI
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# SEPARATE ROADS

- Quality Assurance

- EPA – QA Unit

- Inspections conducted at intervals adequate to ensure study integrity
      - Inspections are reported to Study Director & Management
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# SEPARATE ROADS

- Quality Assurance

- OECD – QA Programme

- Inspections designated as one of three types:

- Study Based

- Facility Based

- Process Based

- Inspections are reported to Management, Study Director, Principal Investigator (s), and respective management

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# COMMON GOALS

- Quality Data which is both Valid and Reproducible
  - Protection of Human Health and the Environment
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