OECD and EPA GLP Differences

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I conduct studies in the US, so Why do I care about oecd regulations?

DUPONT

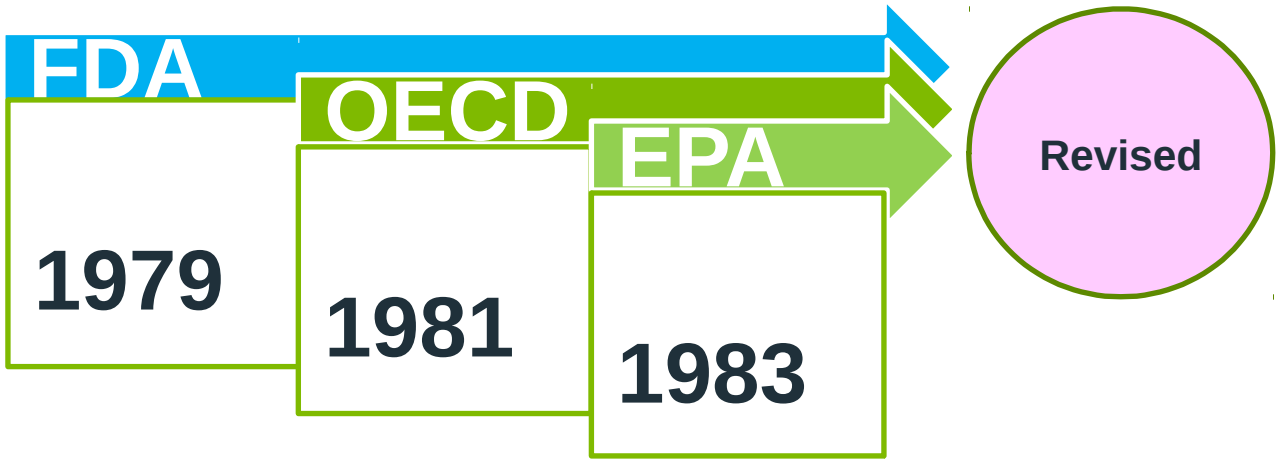
PIONEER

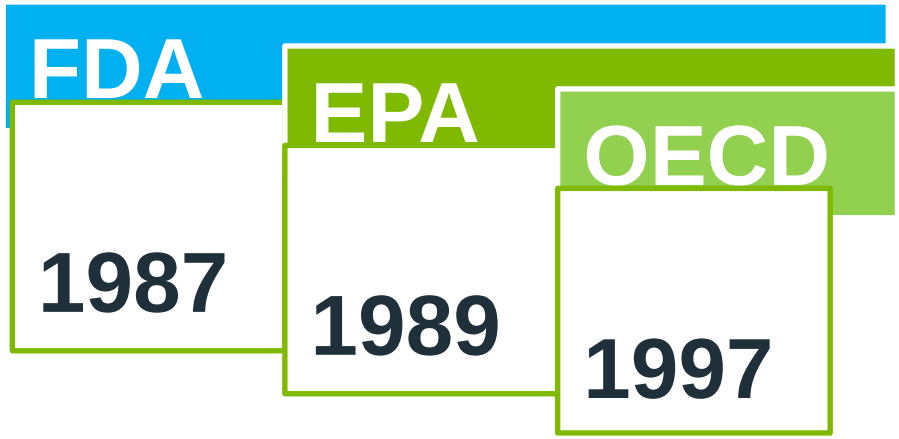
Disclaimer:

- I cannot cover all the differences in twenty minutes – I will try to cover what you may need to change

- Requirement or Industry Expectations

GLPs (FDA , EPA, OECD) based on toxicology studies





Organization for Economic Co-operation and Development (OECD)

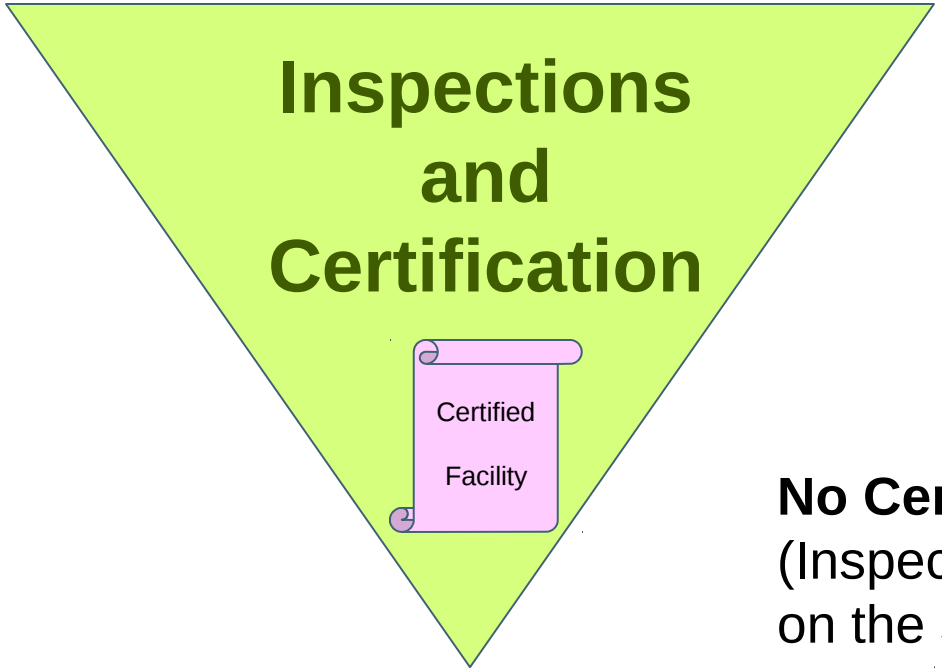
OECD has since published numerous guidance documents that give clarity to specific areas of the GLPs

No. 1, OECD GLP Principles
No. 2, Compliance Monitoring Procedures
No. 3, Laboratory Inspections and Study Audits
No. 4, Quality Assurance and GLP
No. 5, Compliance of Laboratory Suppliers
No. 6, Field Studies
No. 7, Short-term Studies
No. 8, Study Director
No. 9, Preparation of GLP Inspection Reports
No. 10, Computerized Systems
No. 11, Sponsor
No. 12, Inspections and Study Audits in Another Country
No. 13, Multi-Site Studies
No. 14, In vitro studies
No. 15, Archives

OECD Document 6 and 13 are used in the US GLP communities

OECD

Application
To
Successful
Inspection
To
Awarded
Certification



EPA

No Certification
(Inspections based
on the submissions)

Recertification Inspections
To
Recertification

VERBIAGE

OECD	EPA
Test **item**	Test **substance**
Reference **item** (“control item”)	Control **substance** and reference **substance**
Study Plan	Protocol
Experimental **completion** date	Experimental **termination** date
Quality Assurance programme	Quality Assurance unit
Apparatus	Equipment
Type of study	Nature of study

VERBIAGE

OECD	EPA
Test Site Test Site Management Principal Investigator Study Plan Amendment Approved by SD Study Plan Deviation Acknowledged by SD PI Report	Contributing Scientist report i.e. statistician, pathologist, ophthalmologist etc. “Changes to the approved Protocol” Approved by the SD

OECD Management Responsibilities (more for OECD than for EPA)

- Statement identifying Management

Must Ensure:

- Study Director has approved the study plan
- Study Director made study plan available to the Quality Assurance
- Maintenance of historical file of SOPs
- Identification of Archivist
- Maintenance and availability of a master schedule – to evaluate workload and allocate resources
- Clear lines of communication for multi-site studies, including QA
- Computerized systems are suitable, validated and maintained

Assumed under EPA

OECD Study Director Responsibilities (more for OECD than for EPA)

- Ensure
  - Proper distribution of the study plan and any amendments to QA and study personnel
  - Multi-site studies; identify and define the role of any PI and any test sites in the study plan and the final report
  - Ensure personnel use a validated computerized systems
  - Final Report signature indicates acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with the GLP
  - Compliance Statement is NOT required for OECD but it is for EPA

OECD Quality Assurance Responsibilities

- SOP copies retained by QA
- Audit of the study plan
- Inspection; Study, Facility and Process based
- **“Promptly** report **any** inspection result in writing” to SD, SDM, PI and PIM and not just report “problems which may affect study integrity” as US requires
- QA page confirms the final report reflects the data along with dates of inspection, type of inspection, phase, and all reporting dates
- OECD requires QA records of inspections to be archived

Study Plan- OECD

Approval signature from Study Director

National Legislation determines if Sponsor and Management Signature is needed

Protocol- EPA

Approval from Sponsor

Signature from Study Director

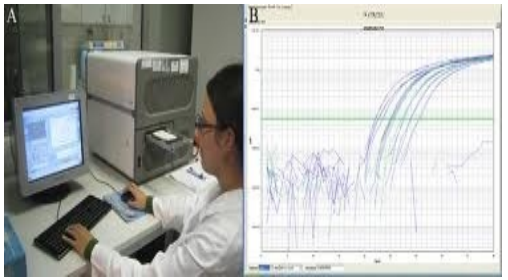
Management signature not needed

Principal Investigator → Not Covered

Not covered → include methods for the control of bias.

Amendment and deviations covered → All **changes in or revisions** of an approved protocol covered

CHARACTERIZATION



OECD

Test and Reference items can be characterized before **or** during a study

EPA

Test, control and reference substance should be characterized prior to its use in the study

Test and Reference Substance

OECD

Not Covered

EPA

Receipt and distribution documentation shall include the date and quantity of each batch returned

Storage containers shall be assigned to a particular test substance for the duration of the study

Equipment

OECD

SOP to cover use, maintenance and calibration

No specific requirements on how to record maintenance, however documenting cleaning is required

Calibration done to a National or International Standard

EPA

SOP to cover schedule for inspection, cleaning, testing, calibrations and remedial action to be taken in the event of failure or malfunction of equipment

Specific requirements on how to record routine and non routine activities

No requirement

OECD - Archived	EPA – Maintained/Retained
QA records and master schedule	QA records and master schedule
Personnel records (Curriculum vitae, job description and training records)	Summary of training, experience and job descriptions
Instrument record (log books, maintenance and calibration records)	Records of maintenance and calibration and inspection of equipment
Historical SOP file, validation deliverables and environmental monitoring records	Historical SOPs retained
Sample of test and reference item **except** short term studies	Studies **4 weeks** experimental duration, reserve samples of test, control, and reference substances

Archival

OECD	EPA
Study Plan, Data and Report is archived **after study completion**	Protocol, Data and Report is archived **on or before study completion**
Archival period is not defined *Defined by Regulatory Authorities	Approved product = life of registration Submitted but no registration = 5 years Not submitted, terminated or discontinued = 2 years

GLPs do not improve the science, but will substantiate the science

The landscape is changing ensure

Quality

Accuracy

Confidence

Trust

Thanks