NATIONAL ALLIANCE OF INDEPENDENT CROP CONSULTANTS

WHAT EPA WANTS FIELD QUALITY ASSURANCE TO KNOW

Memphis, Tennessee

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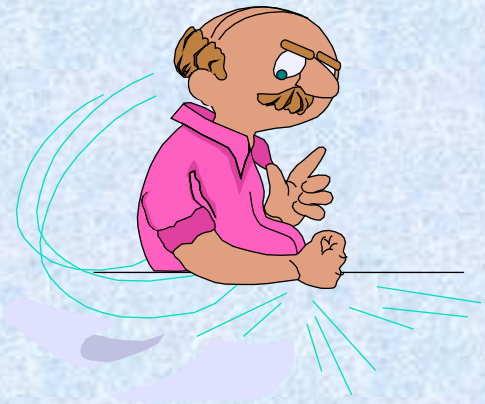
WHERE HAS THE TIME GONE?

- **May 2, 1984 EPA GLP Regulations 40CFR160**
  - **Health effects studies**
- **October 16, 1989 EPA GLP regulations 40CFR160 amended**
  - **All studies (Including field trials)**

20th Anniversary of GLP in Field Trials – QA Inspections

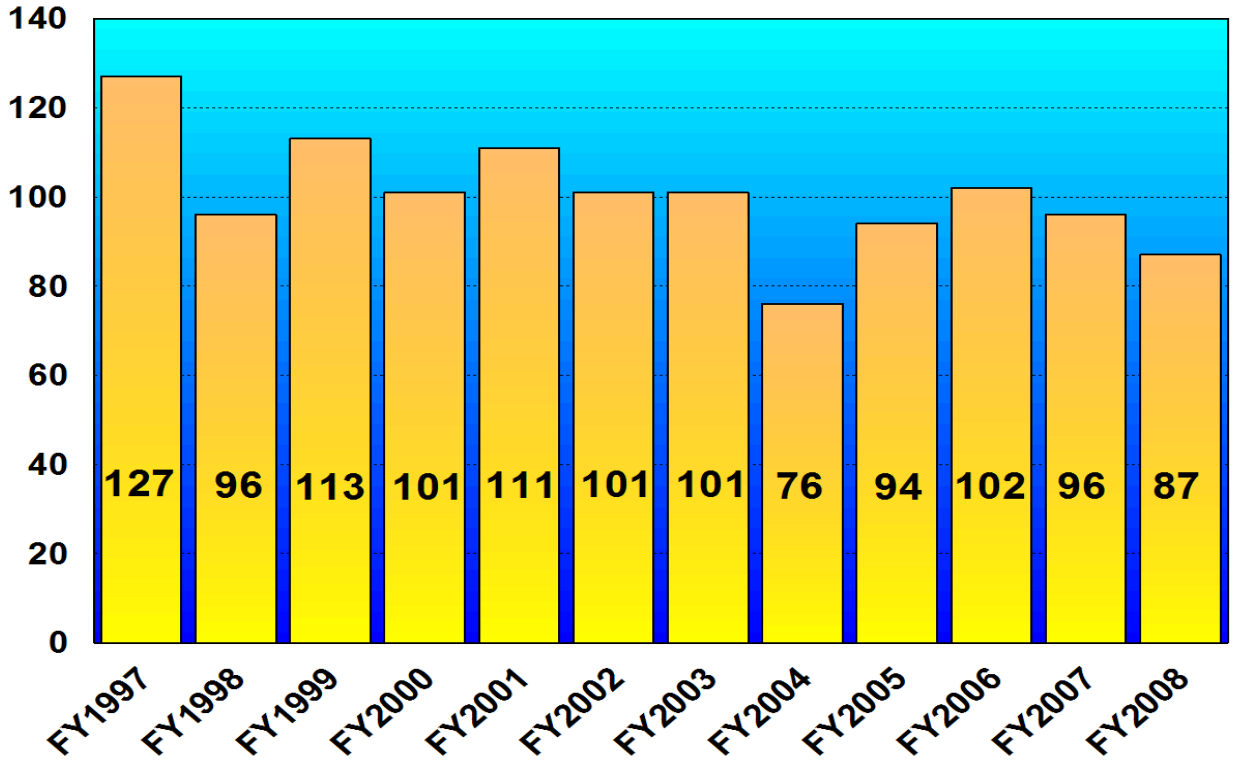
GLP IN FIELD TRIALS



- Five stages of grief
  - Denial
  - Anger
  - Bargaining
  - Depression
  - Acceptance

GLP INSPECTIONS

FY1997 - FY 2008



CASE STUDY #1 – FIELD TRAIL

- Residue study consisting of 20 trials
- One trial – phytotoxicity – not reported in final report
- GLP violation referred to OPP
- OPP decision
  - Phytotoxicity should have been reported
  - The deficient trial was part of a 20 trial study
  - The deficient trail was not used in the decision making
  - Study survived because of the other 19 non-deficient trials

CASE STUDY #2 – FIELD TRIAL

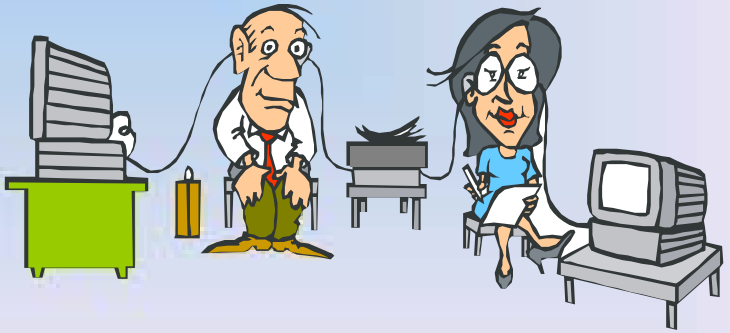
- Electronic data in Field Notes were not recorded directly, promptly – up to 6 months later

CASE STUDY #3 - CHEMSITRY

- **Chromatograms stored electronically**
- **The best peak is printed out**
- **All other e-data (chromatograms) are deleted**

GLP ALERT #1

- **Sponsor must notify a contractor that the study must be conducted in compliance with FIFRA GLP**



GLP ALERT #2

- **Good Agriculture Practices are not GLP requirements, but EPA encourages researchers to follow**

GLP ALERT #3

- **Contract archives**
  - **Must be GLP compliant**
  - **Will be inspected by EPA**

GLP ALERT #4

- **GLP compliance statement vs. QA statement**
  - **No compliance status on QA statement !!**

GLP ALERT #5

- **Pathology report must be reviewed by QA**
- **Peer review of Pathology report must be reviewed by QA**
- **Peer review of Pathology report must be included with the study final report**

GLP ALERT #6

- Memoranda, e-mail (printout), notes of study must be signed and dated and kept with the study records

GLP ALERT #7

- QA reports to study director and management must not be delayed

GLP ALERT #8

- **QA must not:**
  - **Write laboratory's final study report**
  - **Write laboratory's SOPs**

GLP ALERT #9

- Translated final report must include signature of
  - Study Director
  - Translator (notarized)