



**SOCIETY OF QUALITY ASSURANCE  
REGULATORY FORUM**

**EPA REGULATORY UPDATE**

**Linthicum Heights, Maryland**

**January 24, 2008**

**Robert Cypher**

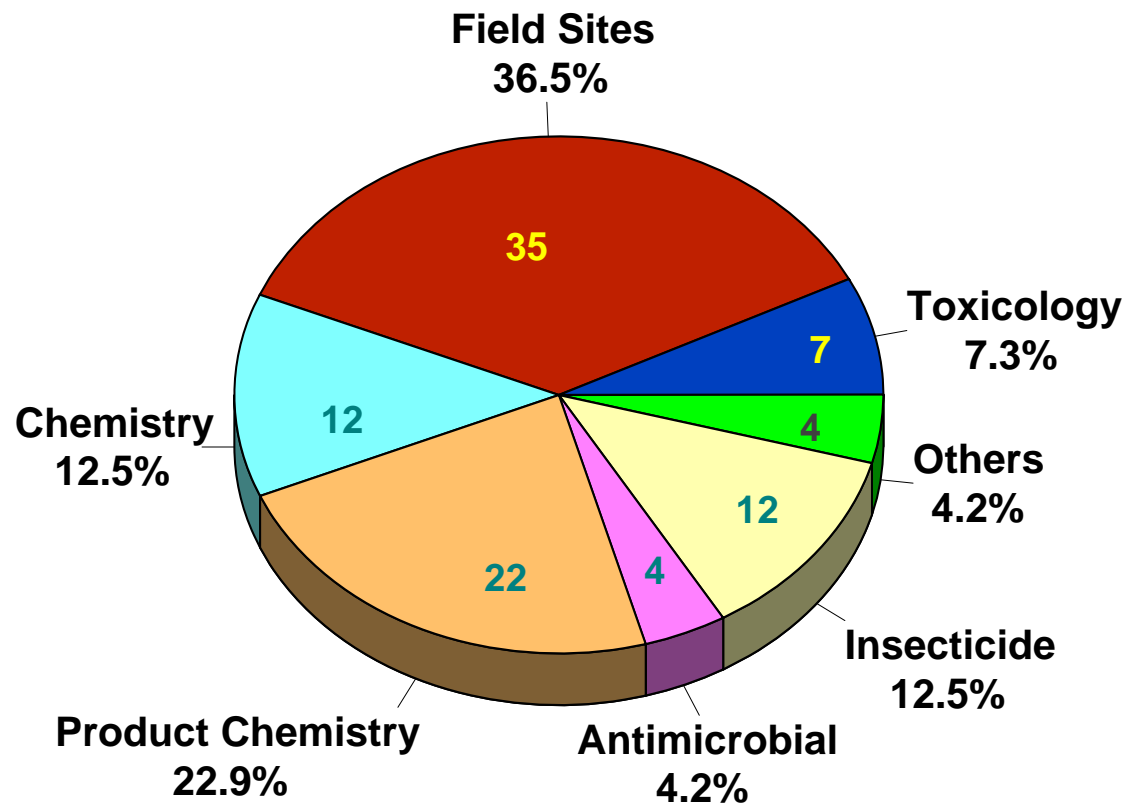
**United States Environmental Protection Agency**



**ANY UNITED STATES  
GLP FIELD TRIAL MAY  
BE SUBMITTED TO  
OTHER COUNTRIES IN  
THE WORLD**



# FY2007 - INSPECTIONS BY DISCIPLINE

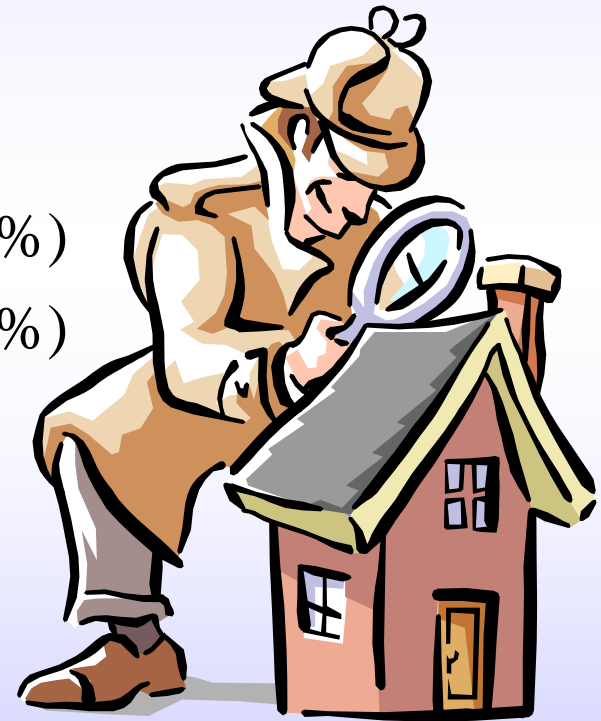


<b>Total Inspections</b>	<b>96</b>
<b>Total data audits</b>	<b>304</b>
<b>Human studies</b>	<b>11</b>

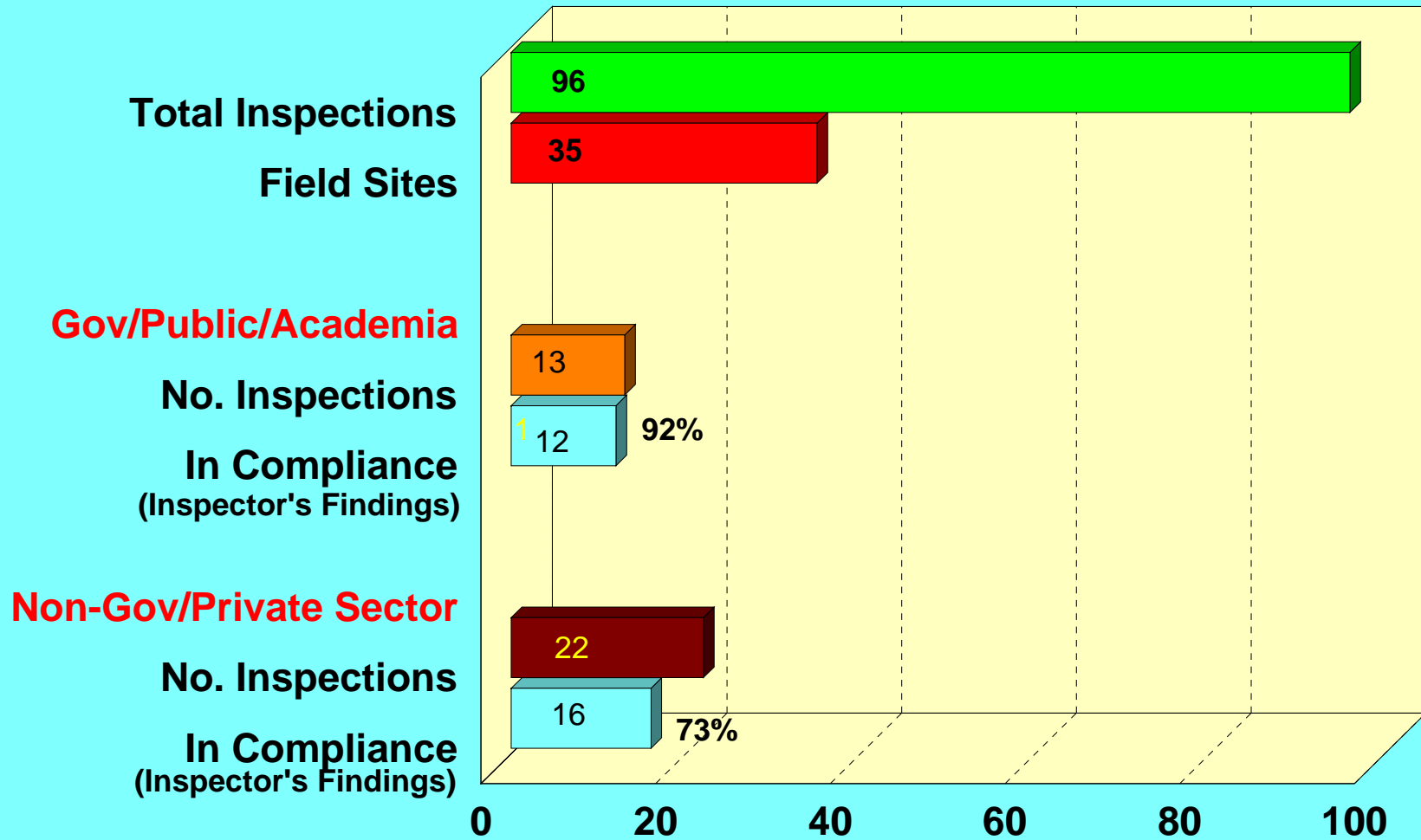


# FIELD SITES INSPECTED - FY2007

- Total field sites inspected 35
  - IR-4 field sites 13 (37%)
  - Non IR-4 field sites 22 (63%)



# ***FY2007 FIELD SITES INSPECTIONS***





# ***COMPLIANCE PROFILE FY 2007***

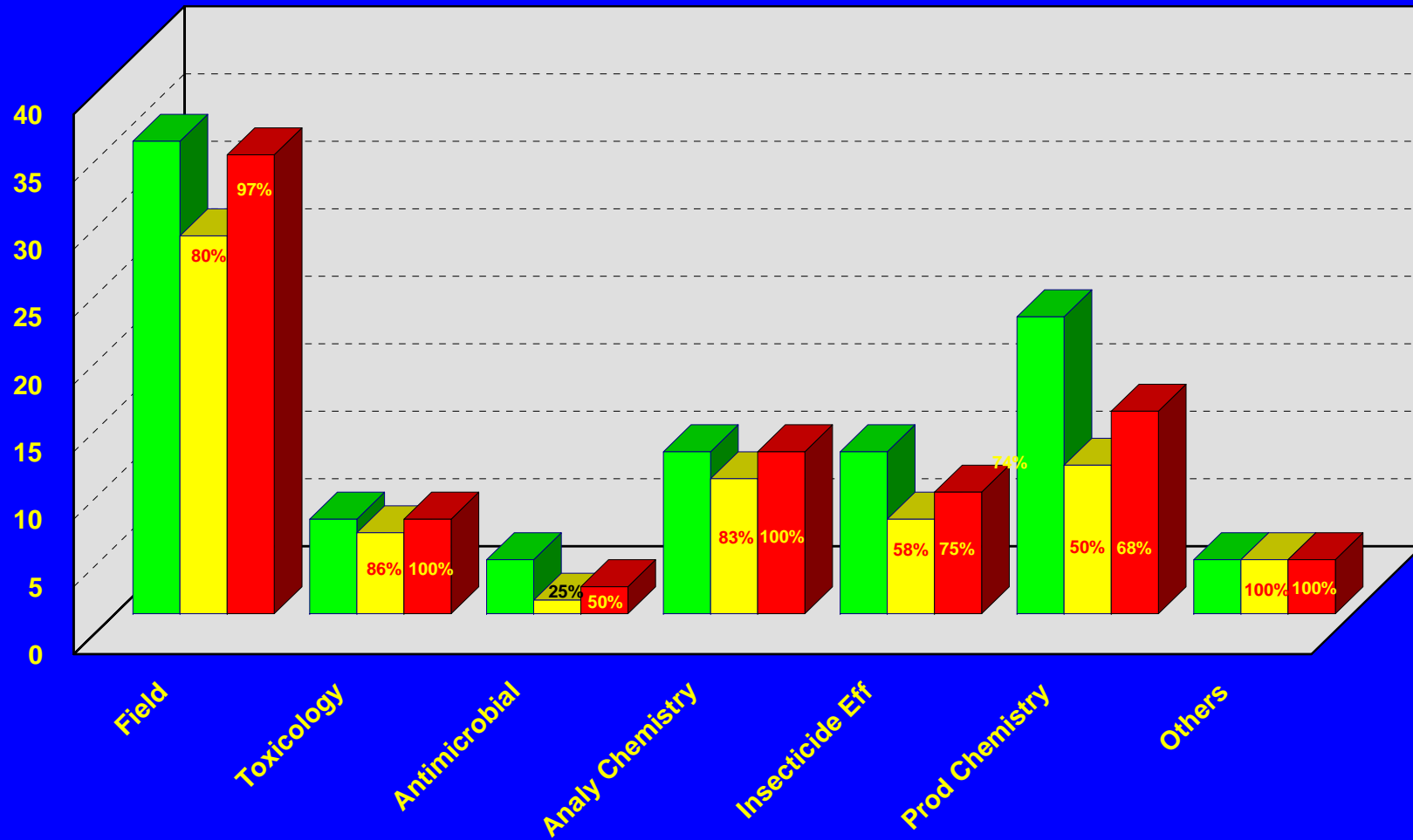
## ***High Level Violations***

### ***FIELD SITES***

<b>Total GLP Inspections</b>	<b>96</b>
<b>Inspections</b>	<b>35</b>
<b>In Compliance</b>	<b>34 (97%)</b>

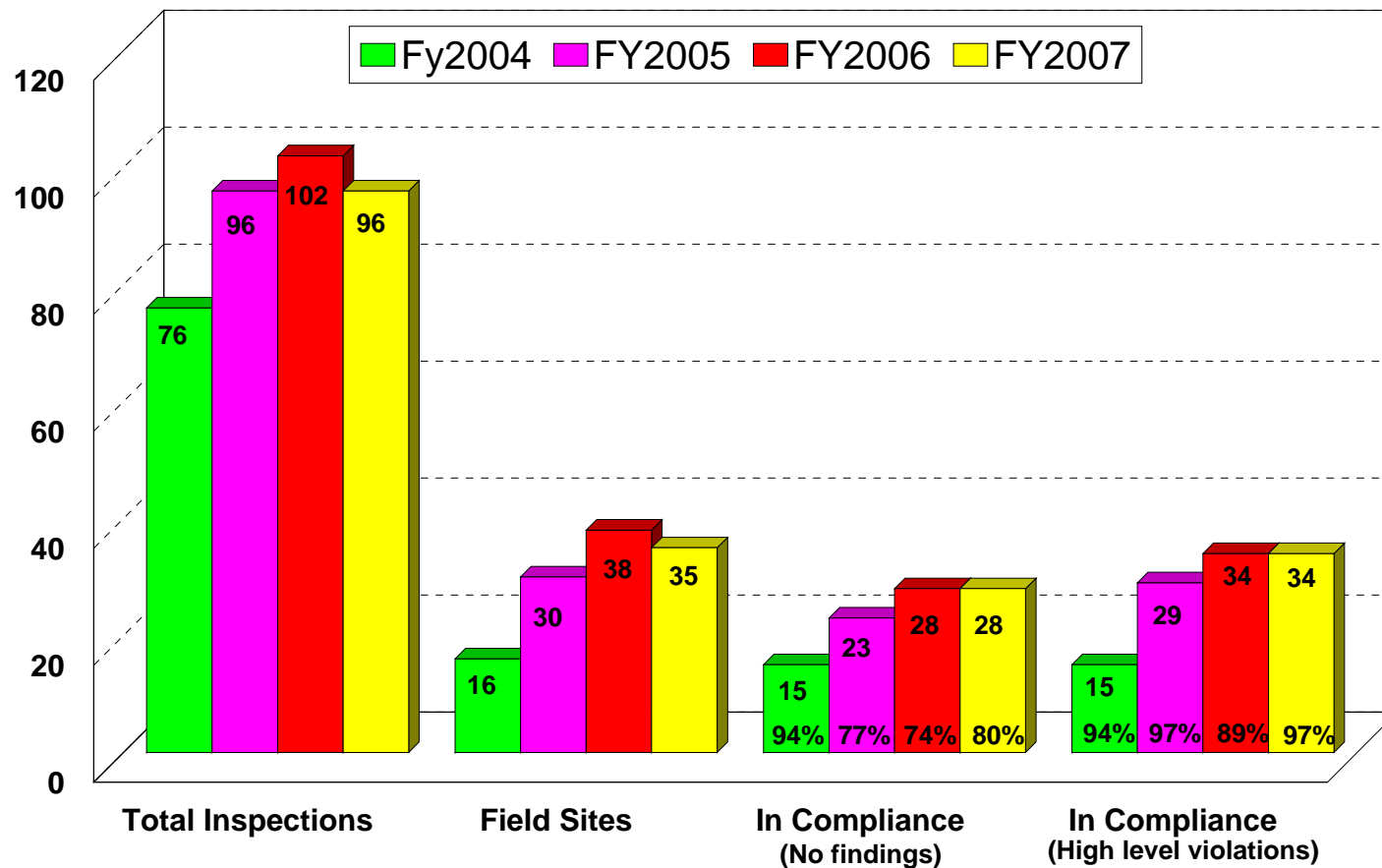
# GLP COMPLIANCE RATE - FY2007

■ Inspections ■ Compliance Rate (No findings) ■ Compliance Rate (High Level Violations)



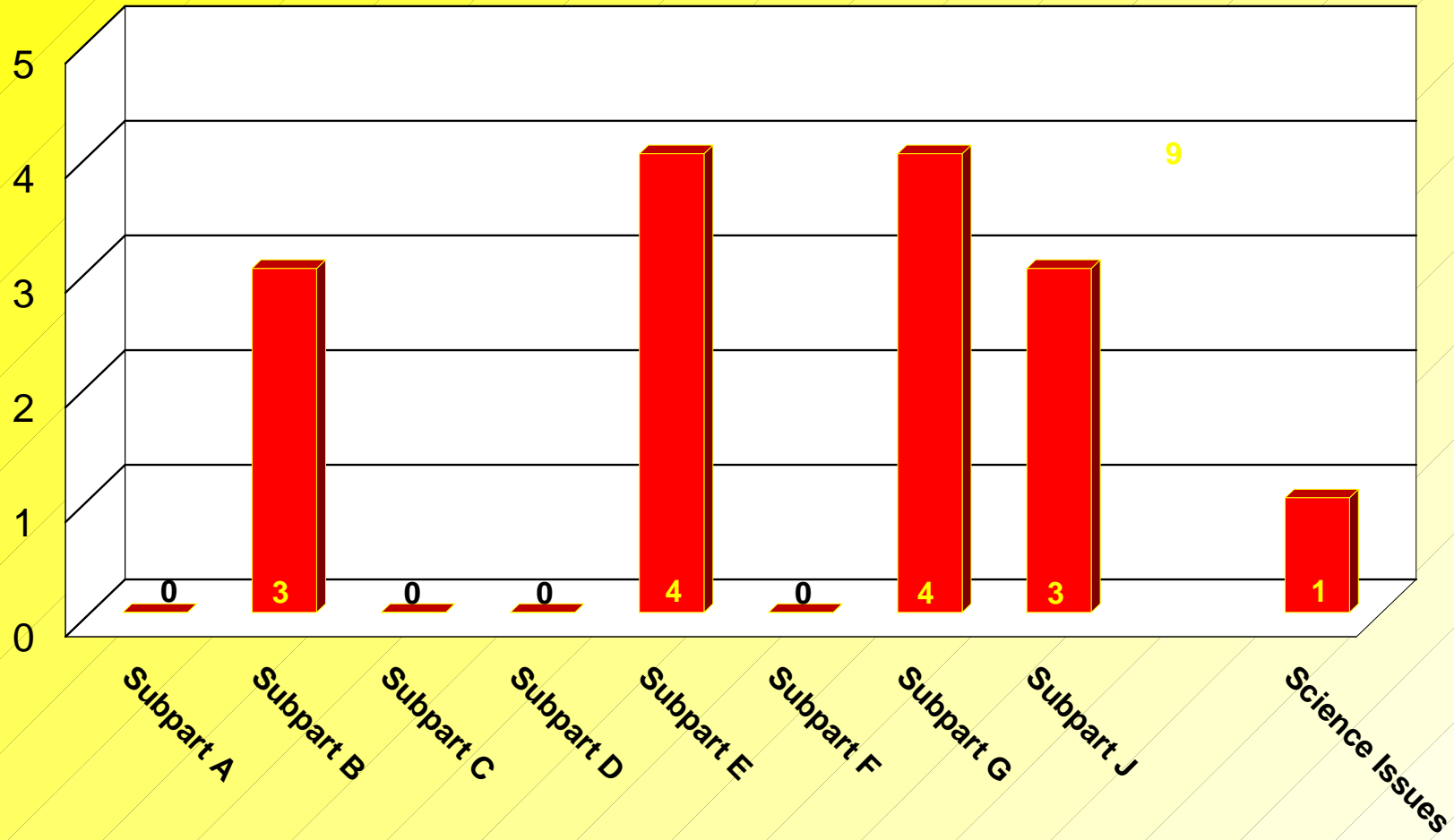


# FIELD SITES FY2004-FY2007 COMPLIANCE STATISTICS





# FY 2007 GLP VIOLATIONS FIELD SITES





# **GLP FIELD SITE VIOLATIONS** **BY CITATION FY2007**

- Subpart B
  - Training records, experience and job descriptions not available
  - Final report does not reflect raw data



# **GLP FIELD SITE VIOLATIONS** **BY CITATION FY2007**

- Subpart E
  - SOP deviations
  - Reagents were not labeled according to GLP
  - Experimental dates were determined arbitrarily





## **GLP FIELD SITE VIOLATIONS** **BY CITATION FY2007**

- **Subpart G**
  - **Changes to protocol were not signed by the Study Director**
  - **PI do not have a complete protocol**
  - **Activity and observations were not recorded**



# *GLP FIELD SITE VIOLATIONS* *BY CITATION FY2007*



- Subpart J
  - Test facility (Study Director) did not have a copy of the final report
  - Final report does not reflect raw data



# FY2007 STUDY REJECTIONS



- **Product chemistry**
  - **Five (5) studies**
  - **One (1) laboratory**



# EPA INTERNATIONAL ACTIVITIES

## OECD – MUTUAL ACCEPTANCE OF DATA (MAD)

<b>Chair of OECD GLP Working Group</b>	<b>EPA</b>
<b>Full members of OECD MAD</b>	<b>27</b>
<b>Members of MAD (non OECD members)</b>	<b>3 (South Africa, Slovenia, Israel)</b>
<b>Provisional members of MAD (non OECD members)</b>	<b>4 (India, Singapore, Brazil, Argentina)</b>
<b>Guidance document – Archives</b> <b>“Establishment and Control of Archives that Operate in Compliance with Principles of Good Laboratory Practice”</b>	



# **GUIDANCE DOCUMENTS RELEVANT TO FIELD RESEARCHERS**

- No. 1 The OECD Principles of GLP**
- No. 4 Quality Assurance and GLP**
- No. 5 Compliance of Laboratory Suppliers with GLP Principles**
- No. 6 The Application of the GLP Principles to Field Studies**
- No. 8 The Role and Responsibility of the Study Director in GLP Studies**
- No. 10 The Application of the Principles of GLP to Computerized Systems**
- No. 11 The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP**
- No. 13 The Application of the Principles of GLP to the Organization and Management of Multisite Studies**
- No. 15 Establishment and Control of Archives that Operate in Compliance with Principles of Good Laboratory Practice.**





# **OECD – MUTUAL ACCEPTANCE OF DATA WHAT IS NEW?**

# THE WORLD ACCORDING TO GDP



# **COUNTRIES DEVELOPING GLP PROGRAMS**

**Brazil**

**India**

**China**

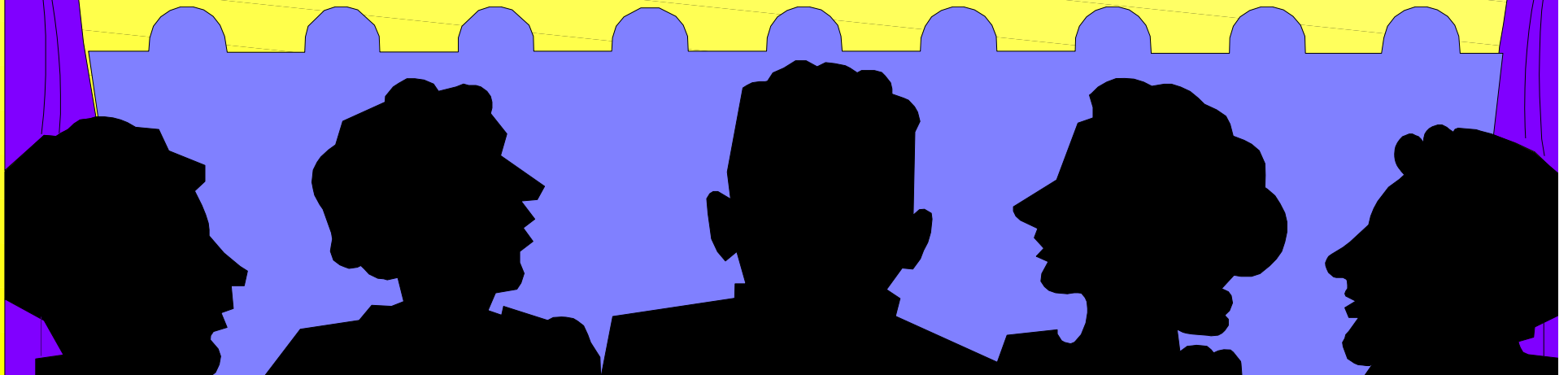
**Argentina**

**Singapore**

**Taiwan**

**Turkey**

**Malaysia**





# OECD ACTIVITIES

- No revisions of OECD Principles of GLP
- No changes of GLP affecting field research in the US
- Field studies conducted according to EPA GLP in the US will be accepted for review in other OECD Member countries
- China\*
- Turkey\*
- Malaysia\*
- Taiwan\*
- Brazil\*
- Argentina
- Other countries

\* Have visited EPA





# OECD FUTURE ACTIVITIES

- 1) OECD event with industry in April 2008 in Rome, NAICC participates
- 2) GLP inspectors training – Israel, September 2008
- 3) Evaluation of GLP compliance monitoring programs of Members of MAD
- 4) Evaluation of US EPA GLP program in 2010, FDA in 2009
- 5) Evaluation of India's GLP program in February 2008

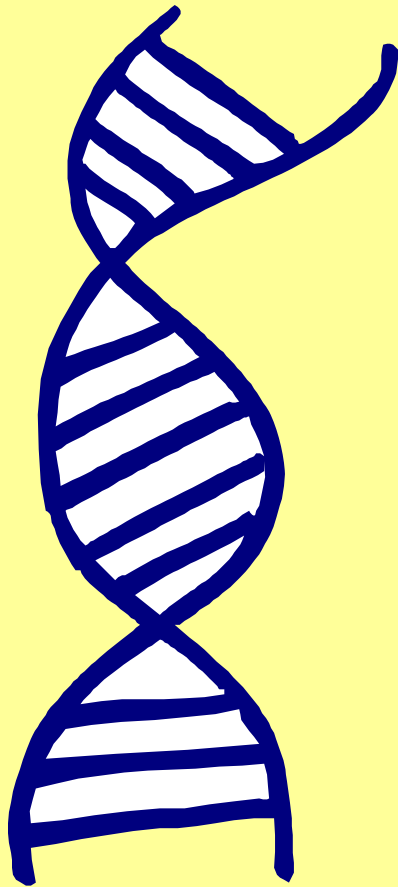


## **Foreign countries inquiring about GLP compliance status of US Field Sites and laboratories**

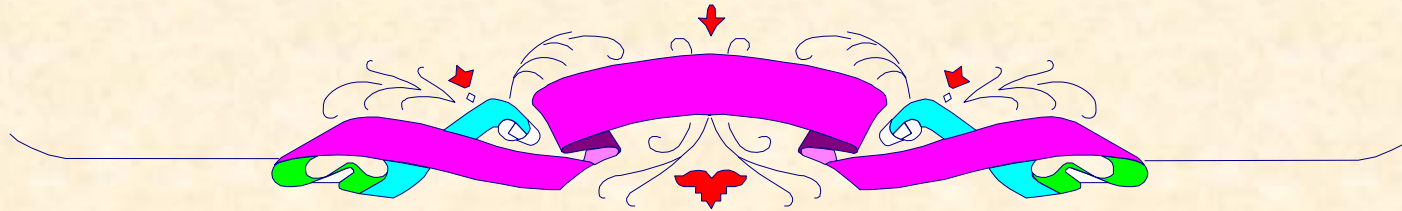
**If your facility has not been inspected for the discipline they are interested in, your study will not be accepted by foreign countries**



# FUTURE ACTIVITIES



- Biotechnology studies
- Nanotechnology
- Human testing



**Robert Cypher**  
**U.S. Environmental Protection Agency**  
**1200 Pennsylvania Ave., NW (2225A)**  
**Washington, DC 20460**

**202.564.2514 Tel                      Fax 202.564.0029**

**[cypher.robert@epa.gov](mailto:cypher.robert@epa.gov)**

