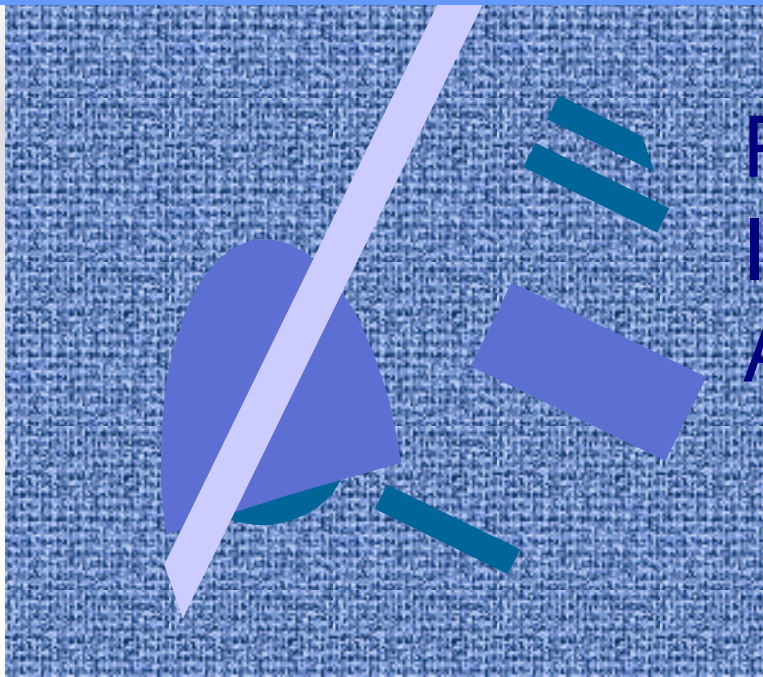


PDMA INVESTIGATIONS



Pharma Compliance
Investigations &
Audits

PDMA INVESTIGATIONS WHY?

- The FDA requires it
- Best Business Practice
- Mitigate Risks, Fines & Penalties to the Corporation
- Protect our customers (consumers)
- Resource helping develop a better organized, compliant sales force
- It's the right thing to do

WHO?

Who Do We Partner With?

- Internally:
 - Corporate Legal
 - Corporate Human Resources
 - Sample Accountability
 - Sales Territory Operations
 - Sales Management (Corporate & Field)
 - Regulatory Affairs

WHO?

Who Do We Partner With?

- External
 - FDA Regulatory
 - FDA Office of Criminal Investigations
 - FBI Health Care Fraud Unit
 - DEA
 - State Agencies ranging from Pharmacy Boards to Health & Human Services
 - Local Law Enforcement

WHEN?

- NOW

- As covered previously, when it has been determined there is reason to believe that there has been:

- Falsification of Sample Documentation
- Significant Loss or unaccounted for samples
- Theft of samples
- Diversion (of samples or product)

The FDA must be notified within 5 working days and a final report* submitted within 30 calendar days from the reporting date.

HOW?

- When an investigation is deemed warranted:
 - I. FDA Notification
 - II. Information Gathering
 - Call Reporting Information
 - Signature Cards
 - Other information on an as needed basis
 - III. Review
 - Examine information provided
 - Conduct interviews as necessary
 - Consult with internal partners

HOW?

- IV. Conduct Field Audit and Interview Representatives
- V. Document Results
- VI. Distribution of Investigative Results
 - Legal & Human Resources
 - Sales Management
 - Field Management (Disciplinary Action)
- VII. Respond to the FDA with investigative report

HOW?

- Sources providing information leading up to an investigation are extensive, but can include:
 - Sample Accountability
 - Field Sales Management
 - Sales Representatives
 - Industry Competitors
 - Domestic Contacts
 - Human Resources
 - Anonymous Calls
 - Law Enforcement Referrals
 - Random Audits
 - Other Outside Sources

Investigative Examples

- **Sample Accountability (SA)**
 - **A representative who's corporate copy of signature cards has product quantities which significantly differ from product quantities on representative's copy of cards, including signed blank signature cards.**
 - **ISSUES:** Falsification of Sample Records
Force Balancing
- **District Sales Manager**
 - **District Sales Manager observed that representative appeared unfamiliar with doctor's staff and doctor. The representative got a blank signature card signed without leaving samples and later reported samples distributed to physician on that date.**
 - **ISSUES:** Falsification of Sample Records
Possible Sample Diversion
Force Balancing

Investigative Examples

- Sales Representative
 - Sales Representative reviews another area representative's detail and call reporting of a physician who died 2 years ago.
 - ISSUES:?? ???
- Competitor
 - Sales Representative steals competitors samples.
 - ISSUES: Theft
Sample Diversion

Investigative Examples

- Domestic Contacts
 - Sales Representative was providing samples to friends and children (including representative's own child) to include writing down instructions for product use.
 - ISSUES: Sample Diversion
Falsification
Practicing Medicine without a License
- Human Resources
 - Non-sampling representative goes with District Sales Manager to 'blue-chip' doctor who appears to not recognize the representative. Investigation revealed a pattern of falsifying call-reporting
 - ISSUES: Falsification (Marquee Syndrome)

Investigative Examples

- Anonymous
 - Anonymous caller reported former sales representative at new employment was giving out 'left over' samples at new place of employment.
 - ISSUES: Sample Diversion
Falsification
Refer to FDA OCI
- Random Audits
 - Conducting inventory reconciliations and reviewing various sample documentation (including sales representative copy of signature cards) with sales representative can often turn a random audit into a 'For-Cause' audit/investigation
 - ISSUES: Falsification
Sample Diversion

Investigative Examples

- A Pharmacy Clerk reported that the Pharmacist/Owner was making him 're-package' samples into Trade Bottles. Investigation determined that sales representative was supplementing vacation travel and home projects by regularly selling product to a Pharmacist (old high school friend) @ \$.50 on the dollar.
 - Termination
 - Criminal Prosecution of Sales Representative and Pharmacist