

REGULATORY INVESTIGATIONS, WHAT TO EXPECT



Drug Enforcement Administration
Pharmaceutical Training Seminar
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www.dea diversion.usdoj.gov

Scheduled Investigations

- * Preparation
- * On-Site Inspection
- * Report Writing
- * After Action, if needed

Preparation

- * Review previous Reports of Investigation & Computation Charts
- * Determine who was last in Charge of the Firm
- * Be Familiar with Controlled Substances handled
- * Be Familiar with Abused Controlled Substances

Preparation

(Continued)

- * Try to determine when physical inventories are completed
- * Check with ARCOS section
- * Check with Quota section
- * Check with Local, State, and other Federal agencies.

On-Site Inspection

- * Procedural & Background Information
- * Accountability
- * Recordkeeping
- * Security

On-Site Inspection

Procedural & Background Information

- * Signing of the Notice of Inspection
- * List of controlled substance handled
- * A production schedule
- * Decision of what to audit

On-Site Inspection

Procedural & Background Information

- * Tour of the facility
- * Background
 - * Incorporation, State of Incorporation, & Officers of the Corporation
 - * License, registrations, & permits
 - * History, experience handling controlled substances
 - * Overview of the companies

On-Site Inspection

Accountability

- * Calibration of scales
- * Closing Inventory
 - * Must be accurate, will inventory more than audited
 - * Gross, Tare, Net for each bulk substance
 - * Count everything
 - * Raw Material, In-process, finished goods, morgue, returns, retention samples, & stability samples
- * Beginning Physical Inventory

On-Site Inspection

Accountability

- * Several Separate Accountabilities in One Investigation
 - * Raw Materials Accountability
 - * Granulation OR Formulation Accountability (In-Process)
 - * Tableting OR Filling Accountability (In-Process)
 - * Labeling & Packaging Accountability (In-Process)
 - * Samples Accountability
 - * Finished Goods Accountability

On-Site Inspection

Accountability

Raw Material and Finished Goods:

Initial Inventory

+

Receipts (saleable returns, samples returned)

= Total Accountable For

Closing Inventory

+

Distributions (Samples, Sold, Charged to Batch, Etc..)

= Total Accounted For

On-Site Inspection

Accountability

In-Process:

Initial Inventory

+ Amounts Material Added (Charged) to Batch

x ? Conversion Factor ?

x Assay (%)

= Total Accountable For

Closing Inventory

+ Good Materials

+ Wastes

+ Samples

x Assay (%)

= Total Accounted For

On-Site Inspection

Recordkeeping

- * Inventories
- * Receiving Records
- * Distribution Records
- * DEA Forms, 41, 106, etc..

On-Site Inspection

Security

- * Review for changes since the last inspection
- * Test security system components
- * Test for response time
- * Obtain information on independent testing, prior alarms, and police responses to firm (to be followed up on)

Report Writing

- * Separate Reports for separate registration
- * Dosage Unit Manufacturer, Two reports
- * Follow-up conversations with firm

After Action, If Needed

- * Letter of Admonition
- * Memorandum of Understanding
- * Civil Case
- * Criminal Case

Contact Information



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