



DEA Inspections/ Internal Audits

- ◆ DEA Inspections: Overview
- ◆ Compliance Problems: Commonly Observed Violations
- ◆ Auditing Tools: Mock DEA Inspections
- ◆ Training Tools

DEA Inspections: Overview

- ◆ Purpose of Inspection/ Investigation
 - Verify compliance with applicable provisions of the CSA
- ◆ Type of Inspection/ Investigation
 - Periodic (Cyclic)
 - Complaint
 - Verification
 - Authentic Sample Collection
- ◆ Initiation of On-site Inspection/ Investigation
 - Notice of Inspection (DEA Form 82)
 - Administrative Inspection Warrant
 - Notice of Inspection not required or issued: Verification Investigations or Sample Collection
- ◆ Closing Inventory
- ◆ Accountability
 - Raw material, sampling, assay, cradle-to-grave accountability per lot
 - Batch accountability for theoretical vs actual yields
 - Packaging accountability
 - Distribution accountability

DEA Inspections

- ◆ **Inventory Records**
 - Biennial Inventory
 - ARCOS annual inventory
 - Other inventories
- ◆ **Review of Receipt, Distribution, and Disposition Records**
 - Purchase/ Receipt Records: DEA 222s, purchase invoices
 - Distribution/ Usage Records: DEA 222s, batch records, etc.
 - Returned Product Records
 - Destruction Records: DEA 41
 - Quota and ARCOS Records
 - Review of Physical Security and SOPs
 - Review of Licenses and Background
- ◆ **Chemical Products**
 - Compliance with applicable provisions of CSA

DEA Inspections

- ◆ Inspection is not over when DEA leaves. They return to office and review records.
- ◆ Company gets feedback in the form of:
 - adequate
 - verbal warning
 - letter with violations (which requires response within 30 days); follow-up letter from DEA and return visit
 - administrative hearing with re-inspection in 6-12 months
 - civil prosecution if patterns of violations have not been addressed (letter of intent to file suit by attorney general may allow resolution out of court)
 - violations committed intentionally are punishable by \$25,000 each (e.g., fraudulent ARCOS reports were \$25,000 per entry (line) and cost the company \$250,000)

DEA Inspections/ Internal Audits:

Compliance Problems: Commonly Observed Violations

- ◆ Wrong order forms or incomplete DEA 222s
- ◆ Batch records fail to record samples taken for quality testing; accountability not well documented
- ◆ Actual vs. Theoretical Yields: no explanation for large differences
- ◆ Incomplete biennial inventories and/or annual ARCOS reports; moved inventory date without notifying DEA regional office
- ◆ Quotas are wrong
- ◆ ARCOS reports not filed or follow-up records not addressed
- ◆ Import/ Export done under wrong registrations
- ◆ Transfer of ownership not told to DEA
- ◆ Lack of knowledge of scope and limitation of each registrant

DEA Inspections/ Internal Audits:

Auditing Tools: Mock DEA Inspections

- ◆ See attached CS Audit Checklist. By performing internal audits against the CSA (applicable sections), you can increase sensitivity to compliance.

DEA Inspections/ Internal Audits: Training Tools

- ◆ Use lots of visuals to give the big picture or snapshot of logistics in moving CS around the sites
- ◆ Delegate training to specific areas and you can customize with more in-depth information. Instead of a company-wide training program, focus on analytical or manufacturing aspects and address those procedures in detail.
- ◆ Use videotape training films for core aspects -- like handling and recordkeeping -- things that rarely change
- ◆ Trend compliance problems and train in those particular areas (e.g., proper completion of DEA 222 forms)
- ◆ Use tests to assess retained knowledge