U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

# UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

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# The DEA Researcher

A Review of Federal Rules and Regulations

# Goals and Objectives

- What is the DEA Diversion Control Division
- The DEA Registrant
- Federal Rules and Regulations
- Pre-Registration Inspection
- Responsibilities:
  - Record Keeping
  - Initial Inventory
  - Security
  - Handling
  - Reporting

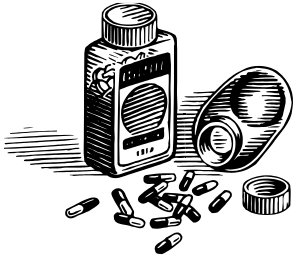
# DEA Diversion Investigators


**Who we are…**

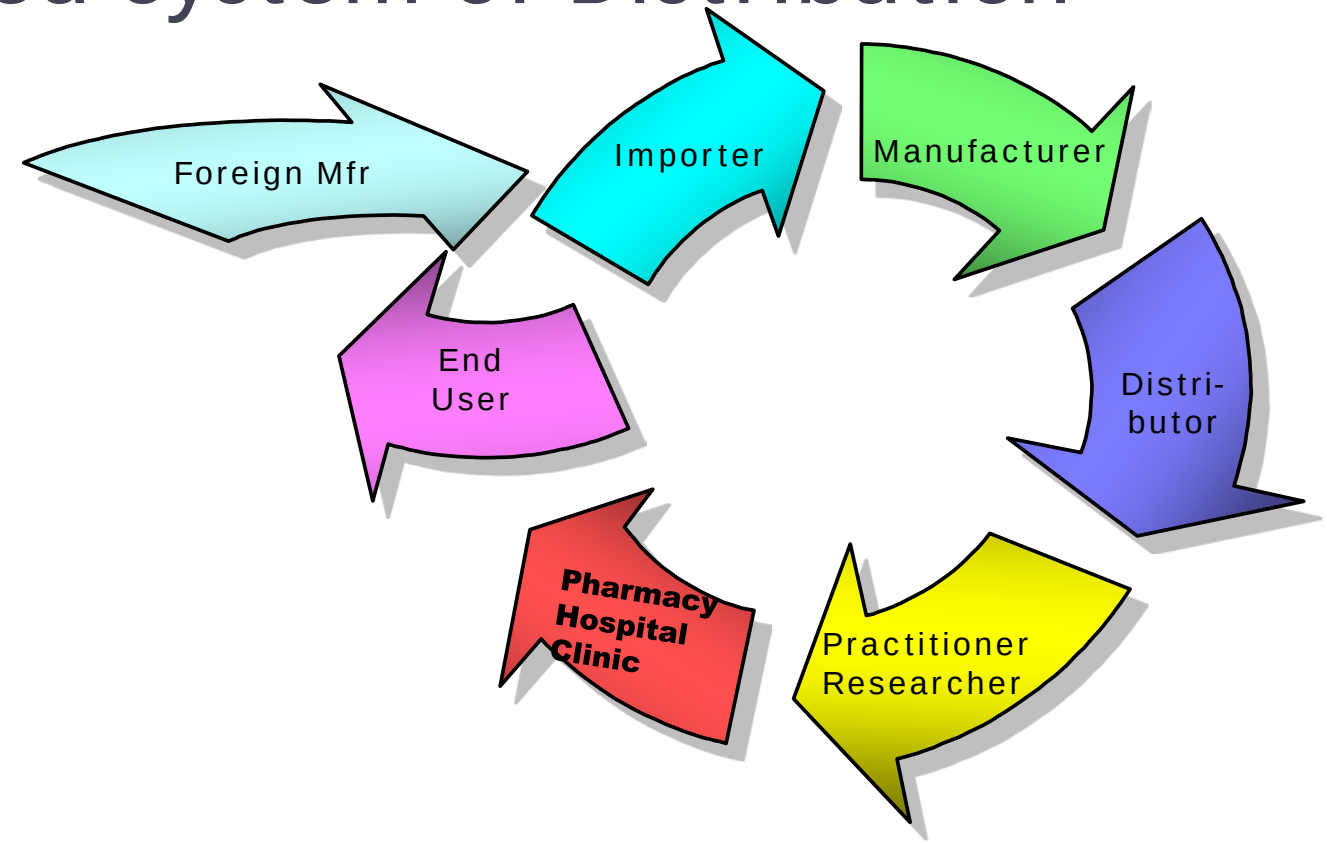
**What we do…**


# DEA Office of Diversion Control Mission Statement

The mission of DEA's Office of Diversion Control is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and **scientific needs**.



# The CSA's
# Closed System of Distribution



# A DEA Registrant's Responsibility


**To comply with regulatory requirements relating to drug security and recordkeeping**

# Federal Rules and Regulations

- The Controlled Substances Act
- Title 21 of The Code of Federal Regulations

# Pre-Registration Investigations

For Researcher's

# Pre-Registration Investigations

- Apply for your DEA Registration on-line at http://www.deadiversion.usdoj.gov/

- Two types of Researchers
  - Researcher (I)
  - Researcher (II-V)

# Pre-Registration Investigations Cont.

The primary purpose of conducting a pre-registrant investigation is to determine the applicant's ability to operate consistent with the public health and safety

# Pre-Registration Investigation

## Who?

**Interviews will be conducted with:**

- the Researcher's Supervisor,
- the Researcher responsible for the overall operations,
- and those who will be maintaining the records and handling the controlled substances.

# Pre-Registration Investigation Cont.

## What?

**DEA will review and verify:**

- State Licensure (if applicable)
- Accuracy and Completeness of each application
- Identification of responsible individuals
- Identification of the Applicant

- DEA will make a determination of compliance regarding security and record-keeping

# Pre-Registration Investigation Cont.

## When?

The Applicant must have submitted all requested supplemental application information prior to the pre-registration investigation

# Pre-Registration Investigation Cont.

## Where?

The investigation will either be conducted at the registered location (where the controlled substances are to be stored) or telephonically at the discretion of the DEA Diversion Investigator assigned.

# Record Keeping Requirements

For Researcher's

# Record Keeping Requirements

"The intent of the Administration is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled substances used in any activity."

# Record Keeping Requirements Cont.

- Records maintained in one consolidated record system
- Maintained in written, typewritten, or printed form at the registered location
- A separate inventory shall be made for each registered location and each independent activity registered

# Record Keeping Requirements Cont.

- When a researcher manufactures a controlled item, he/she must **keep a record of the quantity manufactured**
- When he distributes a quantity of the item, he must use and **keep invoices or order forms to document the transfer**
- When he imports a substance, he keeps as part of his records the **documentation required of an importer**
- And when substances are used in chemical analysis, he need **not** keep a record of this because such a record would not be required of him under a registration to do chemical analysis

# Initial Inventory

Every person required to keep records shall take an inventory of all stocks of controlled substances on hand...In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

****ZERO****

# Biennial Inventory

- At least every two years take inventory of <u>all</u> items on hand
  - Substances manufactured in the lab
  - Imported
  - Purchased Domestically
  - Substances administered to subjects
  - Distributed to other researchers
  - Substances destroyed during chemical analysis

# SAMPLE INVENTORY

University of Colorado **Denver | Anschutz Medical Campus**

ENVIRONMENTAL HEALTH AND SAFETY | HAZARDOUS MATERIALS

**DEA Initial/Biennial Inventory**

DEA Registration Holder:_____ DEA Registration Number: _____

☐ At the start of the business day on : _____

☐ At the close of the business day on : _____

| Substance name | Finished Form (tablet, conc) | Unit/vol per container | Batch/Serial Number | No. of Containers |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

# Purchasing Controlled Substances Schedules I & II

- Schedules I & II controlled substances are purchased with a DEA Form 222
- DEA Form 222s may be obtained by signing in online at www.deadiversion.usdoj.gov
- Only the person who signed the original application for the DEA registration may sign the DEA Form 222, unless a power of attorney form has been given to an authorized user
- An example of power of attorney can be found in Title 21 Code of Federal Regulations section 1305.05
- DO NOT PRE-SIGN 222 Forms

# Purchasing Controlled Substances Schedules III thru V

- Controlled Substances Listed in Schedules III-V
  - Should be purchased by an invoice identifying exactly what is purchased.
  - The date received and quantity received must be indicated on the invoice.

# Security Requirements

## For Researcher's

# Physical Security Controls

- Building Security
  - Access to the building
  - Access to the area where controlled substances will be stored
  - Private or Campus Security

# Physical Security Controls

- Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

- Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.

# Handling Procedures

- Those with Access to Controlled Substances
  - Full name
  - Home Address
  - Home Telephone Number
  - Date of Birth
  - Social Security Number
  - E-mail address
- Day-to-day handling of controlled substances
  - Storage
  - Transit
  - Drug destruction

# Reporting Requirements

- Change of Schedule I Protocol
- Change of Address
- Change in Security
- Theft and Loss of Controlled Substances (DEA Form 106)
- Destruction of Controlled Substances (DEA Form 41)

# Web-Based Resources

- The Code of Federal Regulations – www.eCFR.gov
  - Title 21 – Food and Drugs
  - Volume 9, Chapter II, Parts 1300 – 1399

- The Controlled Substances Act – http://uscodebeta.house.gov
  - Title 21 “Food and Drugs”
  - Chapter 13 “Drug Abuse Prevention and Control”
  - Subchapter I “Control and Enforcement”

# www.deadiversion.usdoj.gov

# DEA Contacts

- Registration Support
  - Call: 1-800-882-9539 (8:30 am-5:50 pm ET)
  - Email: DEA.Registration.Help@usdoj.gov

- Denver Field Division 720-895-4234

# QUESTIONS?