EMORY UNIVERSITY

How to be Inspection Ready!

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EMORY UNIVERSITY

Research Compliance and Regulatory Affairs

Research Administration

In this presentation

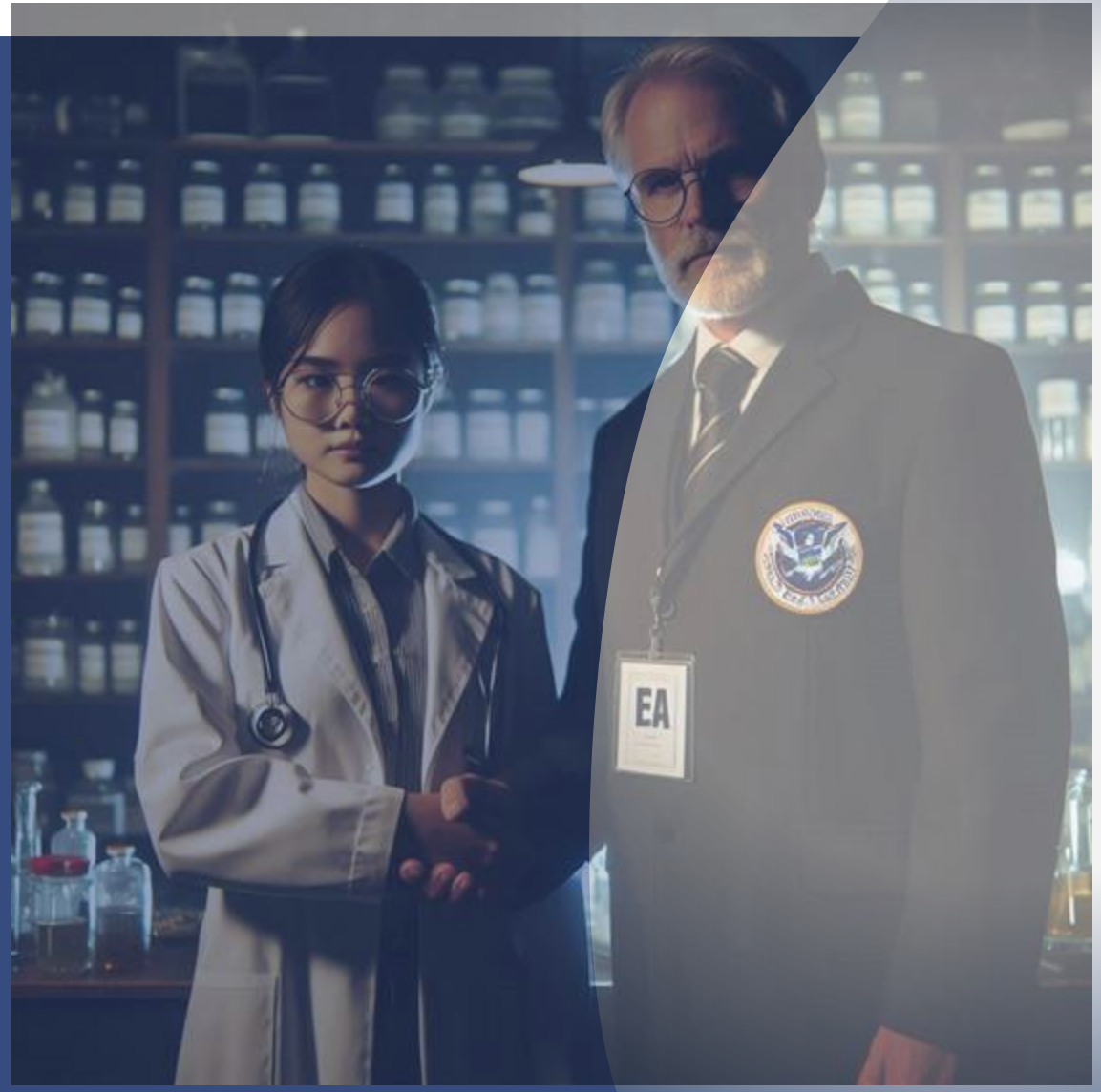
- What does it mean to be "inspection ready"?
- How should I evaluate my program?
- I found issues- what should I do?
- What to Expect When Inspected
- Q & As

What does it mean to be "Inspection Ready"?

A Culture of Inspection Readiness

Real-time inspection readiness refers to maintaining the quality of inspection readiness without preparation. This is the level we should strive for, ALWAYS!

Any research activities under a GBP or DEA licenses are open to unannounced inspections at any time, so we should operate with an inspection ready state of mind.



Inspection readiness refers to the ability of an organization to operate at a level that allows for effective preparation for an inspection.

Typically, the less time it takes to prepare, the more inspection ready you are considered.

A Culture of Inspection Readiness

How should I evaluate my program?

Are your records in order?

CREATE A DEA AND/OR GDNA READY BINDER

You are required by law to have records that are readily retrievable. CI-II records should be separate from CIII-V records. Dangerous Drug records should be separate from CS records.

Your READY BINDERS should always be well organized and available during an unannounced inspection. All records must be stored at the registered location unless written consent is given from the agency.

Find it at GDNA/DEA Ready Binder

DEA READY BINDER

Find the forms listed below at our website

***Controlled Substance (CS) I and II records should be kept separate from CS III to IV records**

Registration Information Section	In Binder (Yes/No)
Current DEA Registration	
Any and all State/Local licenses (Georgia Board of Pharmacy license, Certificate of Occupancy if applicable)	
Emory University Employee and Agent Screening Statement (Form 3)	
Controlled Substance Authorized User Signature Log (Form 4)	
Supplier List (Name, DEA #, Address, Phone Number)	
Destruction Company Info (Name, DEA #, Address, Phone Number)	
Due Diligence Policy (SOP for detecting, preventing, reporting drug	

GDNA READY BINDER

Find the forms listed below at our website

***Dangerous & Prescription Drug records should be kept separate from Controlled Substance records**

Registration Information Section	In Binder (Yes/No)
Copy of your current Georgia Board of Pharmacy License	
Copy of your protocol	
Emory University Employee and Agent Screening Statement (form 3)	
Supplier List	

Security Section	In Binder (Yes/No)
Room Floor Plan (drawing/layout of room)	
Written description of room security (room access)	
Dangerous Drug Authorization Log (Form A)	
Any safe/cabinet information (dimensions, Lock info, picture of	

Available tools on RCRA/ORIC Website!

You can self-audit your program using the following forms:

- For Controlled Substances: Form 1: Controlled Substances Self-Inspection (DOCX)-
- For Dangerous Drugs: Dangerous Drugs Self-Inspection (DOCX)

These forms have been created to help ensure that all aspects of your program are considered when self-inspecting your drug use. But don't just check the "yes" box. Review that you have all the records, and they are in order

Controlled Substances:

- DEA Schedule I Pre-inspection checklist
- SOP for the Report of Loss or Theft of Controlled Substances (Due Diligence Security Process) PDF
  - Please save this with your records before your pre-inspection
- Investigator Checklist for the Use of Schedule (DOCX)1 Controlled Substances
- Form 1: Controlled Substances Self-Inspection (DOCX)- **UPDATED 8/27/24**
- Form 2: Controlled Substance Access and Key Log (DOCX)- **UPDATED 8/26/24**
- Form 3: Emory University Employee and Agent Screening Statement (DOCX)- **NEW 1/30/24**
- Form 4: Controlled Substance Destruction Log- **NEW 1/30/24**
- Form 5: Controlled Substances Discrepancy and Incident Report Form (DOCX)- **NEW 1/30/24**
- Form 6: Controlled Substances Inventory (DOCX). - **NEW 1/30/24.** This form contains the following forms:
  - 6A- Initial Inventory before receiving drug but after receiving the DEA license
  - 6B- Annual or Biennial Inventory
  - 6C: Prescription Controlled Substances Inventory (Buprenorphine ER/SR)
- Form 7: Controlled Substance Current Use Log (DOCX) **UPDATED 1/30/24**
- Form 8: Order/Receipt Log for Schedules I & II Controlled Substances (DOCX)
- Form 9: Order/Receipt Log for Schedules III - V Controlled Substances (DOCX)
- Form 10: DEA Power of Attorney (PDF)
- Form 11: Controlled Substance Dilution Use Log (DOCX)- **UPDATED 1/30/24**
- Form 12: Chain of Custody (DOCX)
- Form 13: Use and Disposition Log Prescription (DOCX)
- **Internal Transfer Requests- Use this form and contact oric@emory.edu to discuss your internal transfer plan.**

Dangerous Drugs:

- Dangerous Drugs Self-Inspection (DOCX)- **UPDATED 8/27/24**
- Form A: Dangerous Drugs Access and Key Log (DOCX)- **UPDATED 3/13/2024**
- Form B: Dangerous Drugs Order/Receipt Log (DOCX)-**UPDATED 1/30/24**
- Form C: Dangerous Drugs Use (DOCX)-**UPDATED 1/30/24**
- Form D: Isoflurane Current Use Log (DOCX)**UPDATED 3/13/2024**
- Form E: Dangerous Drugs Discrepancy and Incident Report Form (DOCX)- **UPDATED 1/30/24**
- Form F: Dangerous Drug Dilution log-**UPDATED 1/30/24**
- Form G: Meloxicam* (Stock Bottle) Use Log- **UPDATED 3/13/2024**
- Form H: Meloxicam* Dilution Use Log- **UPDATED 3/13/2024**
- Form I: Dangerous Drugs Destruction Log- **NEW 1/30/24**
- **Internal Transfer Requests- Use this form and contact oric@emory.edu to discuss your internal transfer plan.**

I Found Issues during a Self-Inspection.

What Should I do?

Don’t Panic!

Errors happen!

- Even in the best of circumstances, errors happen.
- Don’t backtrack info or correct if info cannot be verified
- Document Incidences on Form 5 or Form E (an incident is not a discrepancy.
  - An incident is: I made a mistake on a record and corrected the error, or a spill occurred, and I documented it on a DEA 41 form)
- Discrepancies in inventory should be reported upon awareness, not after an investigation. DEA FORM 106 Form E.
- Work on a Corrective and Preventive Action (CAPA) Plan, and make sure to check its implementation
- Contact ORIC for help

CAPA PLANS

- Every Incident or Discrepancy Report should have a CAPA
- Ensure your CAPA is up to date, and that it is working
- Take CS/DD trainings, attend webinars
- Inventory your drugs
- Ask for help!

What To Expect When Inspected

Remain *CALM* and only answer the questions you are asked.

Then contact us at ORIC@emory.edu and let us know you are being inspected

What to Expect When Inspected

DEA and GDNA are looking for three main things when they inspect:

1. Security – Are your drugs secured?
2. Recordkeeping – Are you records in accordance with state and federal regulations?
3. Drug Accountability – Can you account for your drug inventory?

Items Generally Reviewed During an Inspection

Controlled Substances	Dangerous Drugs Only
All receiving records for 2 years	All receiving records for 2 years
All dispensing records for 2 years	All dispensing records for 2 years
All Destruction records for 2 years	All Destruction records for 2 years
Initial Inventory (if w/in 2 years of DEA license startup)	Temperature logs for refrigerated/frozen drugs
Biennial Inventory (must include expired and dilutions)	Drugs stored in location listed on license
Personnel Access List	Are drugs secured in appropriate and approved cabinet/safe?
Temperature logs for refrigerated/frozen drugs	Are you logging all Dangersous Drugs?
Drugs stored in location listed on license	License is active and Registrant is at registered location
Are drugs secured in appropriate and approved cabinet/safe?	Theft/Loss Reports are appropriately reported to GBP
Drug accountability (using your records they will complete accounting of your inventory)	Personnel Access List
License is active and Registrant is at registered location	
Theft/Loss Reports are appropriately reported to DEA, GBP, and GDNA	

Keep in Mind

- While we are reviewing the general scope of what to expect during an inspection, every inspection and ***inspector*** varies.
- Inspectors have checklists which define the elements they must review. They also have the authority to go beyond those elements and look more closely at any area of concern.
- However, the inspector can't look at everything so there's always the possibility that although you are is not in compliance with the regulations, you might not be cited.

Don't take a chance!

After An Inspection

Emory Policy requires that you contact RCRA/ORIC when you have been inspected and you notify us of the outcome.

If an inspection report is provided by GDNA, the results should be emailed to ORIC@emory.edu

If you are issued a Letter of Admonition (LOA) or Memorandum of Agreement (MOA) by DEA for violations found during an inspection, you are required to report that to ORIC@emory.edu

Questions?