

Managing Controlled Substances in Research: An Integrated Approach

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Background

- DEA and DOJ governance over certain hazardous chemicals that are classified as drugs. (Title 21, 1300-1399)
- Material is used for many applications in the research community.
- DEA requirements for full control:
 - Licensing
 - Inventory
 - Diversion (loss)
 - Transactional History
 - Biennial Inventory



Discussion Outline

- Provide an overview of DEA Regulations for controlled substances
- Review of findings from our SWOT analysis
- Summary of our integrated approach based on the SWOT analysis
- Lessons learned from the process improvement.



Picture from the Caltech/JPL Spitzer Satellite



Controlled Substances List



- All drugs split into five categories known as "Schedules"
- Lists are classified by medical usability and addictiveness.
- CS-I has the highest level of control: no medical usability, highest level of addiction potential.
- Same material can be on different list (based on dosage/concentration)
 - Example: Sodium Pentobarbital appears a CS-II, CS-III, and CS-V



Gap? What gap?



- DEA conducted a routine audit
- Determined there were several gaps in our existing process.
- Asked us to look at potential process improvements.



Level of Scrutiny

- The main focus of the DEA regulations is to prevent diversion of controlled substances into the general population.
 - Many chemical companies produce controlled substances for sale for research purposes.
 - Each company follows a rigorous purchaser prescreen, but onus is on the purchaser to maintain proper controls and compliance.




DEA Inspections

- On a DEA inspection, one can expect:
 - A walkthrough of each laboratory of processes and procedures to verify controls.
 - A visual inspection of the material verified against inventory logs
 - Explanations for any missing material.
 - Ask for an inventory of controlled substances on any given day in with the last 24 months.
 - Copies of Biennial Inventory





Key Focus Solution Areas


- Coordination of Stakeholders
 - Role Definitions
- Training Program
- Centralization of CS Processes and Operations to improve efficiency and controls.
- Leveraging Technology



Looking at the Previously Existing Program



- One institutional license for approximately 24 researchers
- Mostly handwritten program with records on a "card system".
- Purchasing documentation separately filed by the researcher.
- Training done on a researcher by researcher basis.





Stakeholders

- Principal Investigator – Faculty Member
- Laboratory Researchers
- Purchasing
- Security
- Operations (General oversight and Disposal)
- Division (Faculty Administration)





SWOT Analysis



Coordination and Compliance

REGULATORY REQUIREMENT	STAKEHOLDER
CS Inventory Control Operations (Procurement, Storage, Disposal)	Researchers Operations Purchasing
Inspections	Researchers Operations Division (Faculty Administration)
Diversion	Researchers Operations Division (Faculty Administration) Security





Training of Operations and Researchers

- Initial training when personnel who will be handling CS have completed HR checks and approval.
- Provides basic information on:
 - CS identification
 - Recordkeeping Requirements
 - Organizational Sturcture
 - Diversion Procedures



Role of Security

- DEA regulations give an opportunity to resolve issues in 24 hours prior to reporting to minimize risk of false positives.
- Operations and Security work with Researcher
 - Utilization of electronic resources
- In case of diversion, Security, Operations, and if necessary, local law enforcement, will jointly notify DEA.

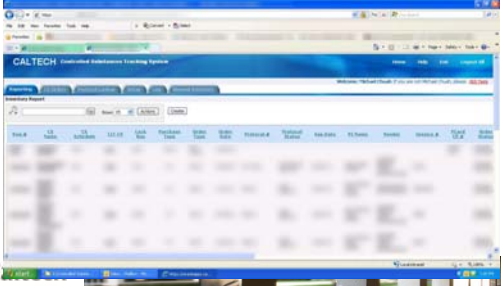




Purchasing and Controls


- Centralized electronic system that pulls data from multiple sources to ensure proper purchases are made.
- Integrated with Operations by performing hourly checks on all transactions.
- Library updates to coincide with DEA updates.

Leveraging Technology





Operations (as a part of EHS)



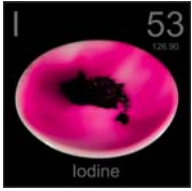

- Work with Purchasing to check against the proper datasets .
- Processing CS into electronic system
 - Digital Recordkeeping
- Inspection of lab
- Management of disposal

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Precursor Material

- Related to a large set of common chemicals (solvents, iodine, etc.)
- Purpose is to restrict the manufacture of CS
- If regulation not read carefully, it can be mistakenly applied.
 - Precursor controls are only applicable when you have a process in house that will manufacture a controlled substance.
- Title 21, Sections 1309-1312

Key Lessons Learned

- Flexibility in your procedure
 - Like other methods of hazmat management you want flexibility
 - What the regulator will hold you to
- What looks good on paper may not work practically/operationally
 - Flow chart the process... helps to delineate issues



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Key Lessons Learned



- Leverage Technology
 - Instead of creating duplication of information, look at ways to centralize your data
 - Training records with HR database
 - Inventory with PI locations
 - Inspections with a centrally mapped database
- DEA inspections follow a strict protocol
 - Have operational people assist.



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Summary

- Integrated approach provided a balance for both research and risk/liability management.
 - Looked at technology as a potential way to reduce work to all parties.
- Important to weigh stakeholder concerns and work in a consultative role to generate a program that works for everyone.



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