

Date:
 PI Name:
 Location:

Controlled Substance (CS) Audit Checklist



1 Administration					
#	Check list Item	Explanation/Criteria	Yes	No	N/A
1.1	Is DEA registration/license current and a copy available?	Controlled substances can only be attained and stored by those with DEA license/registration.			
1.2	Are laboratory specific DEA CS SOPs available?	Protocols need to be available to employees for the use, PPE, recording, disposal, and discrepancies of controlled substances.			
1.3	Is a copy of DEA CS guidelines available?	Guidelines need to be available for all authorized users.			
1.4	Is there a designated route of disposal of any unused CS?	Guidelines need to be available for all authorized users; Is there a designated route of disposal for any unused CS?			
2 Physical Security					
2.1	Is access to controlled substances limited by lock?	Controlled substances must be stored with limited access in a locked cabinet or a double locked safe for Schedule II-V drugs or a drug safe with an alarm for Schedule I drugs.			
2.2	Is the storage safe or cabinet adequately sized?	The storage safe or cabinet must be large enough to maintain stock containers and waste materials.			
2.3	Are locks and cabinets in good condition?	Self explanatory.			
2.4	Does the area for use of CS have limited access?	Only trained personnel should be in the area of use of controlled substances.			
2.5	Do each CS container have original label?	Controlled substances must not be transferred from original containers for inventory purposes and labels must not be removed. If the substance is converted or diluted, the new container must be labeled properly.			
2.6	Do each CS container have a unique ID # on label?	Each CS container must have a unique ID # for accurate records.			
3 Inventory Control					
3.1	Are the handwritten records for purchase, distribution/dispensing, and disposal of the CS present and up to date?	Must maintain a copy of the purchase (DEA Form 222) and handwritten records of use and disposal of the controlled substance, up to date and remain in the lab with the controlled substance for at least 2 years from the final use.			
3.2	Do the forms for records of use have details for an accurate audit?	Records should include: Name of the substance, Source of the substance, Date of expiration of the substance, Date of receipt, unique identification number for the bottle, Starting quantity of controlled substance, Date of use, Protocol (or project) for which it is being used, Animal (or group of animals) for which it is being used, Person dispensing the medication from storage, Person administering the medication to the animal(s), Quantity (cc/ml/grams) of agent dispensed, administered and wasted, Quantity remaining in the vial/bottle/box			
3.3	Do you have schedule II CS and records?	Schedule II substances must be listed on a separate form or separately from schedule III-V.			
3.4	Are initial and biennial inventories on record?	DEA requires an initial inventory and additional inventories every 2 years.			
4 Personnel Security					
4.1	Are the records of personnel access present?	Only users authorized by the registered/licensed PI are allowed access.			
4.2	Is a screening process/background check done for authorized users?	All authorized users should be screened before given access to controlled substances. (21 CFR 1301.9)			
4.3	Are completed questionnaires for authorized users in a secure location?	All employee personal information should be in a secured location.			
4.4	Is training for CS use in lab documented?	All lab personnel should be trained in the use of controlled substances and authorized personnel should be trained in the use, PPE, recording, disposal, and discrepancies of controlled substances.			
5 Personnel Exposure and Contamination Control					
5.1	Is the fume hood operational and inspected within 12 months?	Inspection date _____			
5.2	Is general housekeeping maintained?	Self explanatory.			
5.3	Is PPE available?	PPE must be available to all employees using controlled substances.			
5.4	Are any uncontained CS observed?	All controlled substances should never be left unattended when removed from locked containment.			

Notes: _____

