



# Controlled Substance Inspection Self-Audit Checklist

Annual Inspection

Follow-up Inspection

Inspection Date: \_\_\_\_\_

Registrant Name: \_\_\_\_\_ Registration #: \_\_\_\_\_

Department: \_\_\_\_\_ Building: \_\_\_\_\_ Room Storage Location: \_\_\_\_\_

| Yes                      | No                       | N/A                      | Checklist Items  |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 1. Are DEA Registration and FL Exemption Letter in the CS Manual? Are they current?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 2. Are Employee Questionnaire on file for all Authorized Users?<br>List of users: _____  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 3. Are CS inventories up to date, and details of the use have been documented?   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 4. CS inventory on hand matches the quantity stated in the Biennial Inventory Log?   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 5. Is recordkeeping maintained for the last 2 years only?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 6. Are order and receipt records available for each purchase?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7. DEA Form 222 are available for all Schedule I and II Drugs? Are the forms secured?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8. Does the registrant have an SOP for the use of CS and for detecting loss or diversion?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 9. Schedule I and II records and storage are separate from Schedule III- V, and other prescription drugs?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 10. Are disposal records and DEA 41 Form (if applicable) available?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 11. Are prepared solutions of CS labeled, locked and secured? Is a separate log sheet used?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. Are all CS logs and receipt forms maintained?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 13. Are all losses or discrepancies in recordkeeping (if any) and promptly reported to EHS?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 14. Are the physical security controls adequate for CS?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 15. Is access to CS restricted at all times to only individuals authorized to work with CS?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 16. Are all Authorized Users including the registrant are up to date with training and have reviewed the Possession of Prescription Drugs and Controlled Substances Procedure? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 17. A CS Authorization Update form has been submitted to EHS each time an addition or deletion change of authorized user has been made?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 18. SDSs for CS being ordered are printed and available for inspection?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 19. Are all expired drugs being disposed of within 60 days of expiration?  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20. Has the CS Spill Record and DEA 106 Form been used for loss or diversion?  |

### Follow-up Actions:

| Item # | Description of Problem | Corrective Action |
|--------|------------------------|-------------------|
|        |                        |                   |
|        |                        |                   |
|        |                        |                   |
|        |                        |                   |

### Additional Comments:

Researcher's Signature: \_\_\_\_\_

Date: \_\_\_\_\_