OBP/DEA Lab Self-Assessment Checklist

This checklist is a self-evaluation tool to help your laboratory remain inspection-ready for an Ohio Board of Pharmacy (OBP) and/or Drug Enforcement Administration (DEA) audit.

Registrant/Authorized Agent(s) - UC Resource Knowledge

☐	UC policy: "Individual Investigator Use of Controlled Substances in Non-Therapeutic Research"
☐	UC forms for controlled substance acquisition, inventory, and use.
☐	UC training: "Controlled Substance Procurement and Use"
☐	Know who to contact with questions: • General Inquiries: Associate Dean for Research for your college, or department chair • Compliance/Training: Office of Research Integrity (UCORI) integrity@uc.edu

Use the above QR code to access UC resources.

Registrant/Authorized Agent(s) - General Knowledge

☐	Know how to identify which drugs are considered controlled substances by the OBP and DEA. • OBP Controlled Substance Reference Table • DEA List of Controlled Substances
☐	Know how to dispose of controlled substances safely and securely. • OBP Drug Disposal Resources • DEA Drug Disposal Resources
☐	Know how to report theft and loss of controlled substances to the OBP, DEA, and UCORI.
☐	Know how to document the addition/removal of trained, security cleared individuals as Authorized Agents acquiring/using controlled substances with approval of the Registrant.

Drug Storage and Security

☐	All controlled substances are stored behind at least 2 differently keyed locks.
☐	Schedule I and II substances are stored in a safe or steel cabinet with an inner and outer door that are keyed differently.
☐	Schedule I and II substances are not stored with Schedule III, IV, and V substances.
☐	Refrigerated controlled substances have a lock present on the refrigerator door.
☐	Non-controlled substances are not stored with controlled substances.
☐	Lockbox keys are not stored by the lockbox or together in the same location.
☐	Expired and/or contaminated drugs awaiting disposal are clearly labeled "do not use" and stored separately from active/non-contaminated drugs.

Drug Labelling

☐	Stock containers/solutions are assigned and labeled with a unique identifier.

Diluted or "cocktail" solution labels include the:

☐	unique identifier of the stock containers/vials it was made from
☐	final dilution concentration/strength
☐	date the dilution/cocktail was made
☐	date of expiration
☐	initials of the individual who created the dilution

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Drug Ordering, Usage, and Inventory

	The Registrant or Authorized Agent(s) perform inventory of new drugs at the time of initial receipt.
	The Registrant or Authorized Agent(s) perform inventory of all controlled substances annually (OBP requirement) and/or biennially (DEA requirement).
	Copies of completed DEA Form 222s used to acquire Schedule I and II substances are on file with controlled substance records.
	Drug usage forms are kept up to date (all drug usage can be accounted for, no backlog of entries).

Recordkeeping

	All controlled substance records are retained for 5 years to meet institutional and federal recordkeeping requirements.
	Registrant is able to quickly produce copies of their active OBP/DEA registration(s). • Print and keep a paper copy with related controlled substance records, OR • Keep an electronic copy on file in an accessible area (e.g. laboratory shared drive)
	Records for different DEA registrations are kept separate from one another.
	Schedule I and II drug records are maintained separately from all other laboratory and/or administrative records.
	Schedule III, IV, and V drug records are maintained separately from all other records OR are easy to quickly separate out from other laboratory and/or administrative records.
	The Registrant retained copies of Registrant Record of Controlled Substances Destroyed (DEA Form 41) for controlled substances destroyed within the last 5 years.