Comments to the United States Pharmacopoeia on the proposed chapter <795>.

Required format per comment forum:

Line number

Changes Requested

Rational for changes

1. Line 113
    a. If the pharmacy only has one compounder that is required to acquire training, we request that "training outside the facility" also include options that are electronically accessible.
    b. A pharmacy that only has one compounder may only have one pharmacist as well. Smaller pharmacies are more susceptible to the financial burden of hiring fill in staff and traveling for externally sourced education.
2. Line 166-168
    a. We request that the language "specifically designed for compounding" and "separated" be further clarified to give pharmacies a more specific idea of space requirements. For example, if a fully separate room with walls is required, that should be stated.
    b. A pharmacy that only performs simple, non-particulate generating compounding will not be able to justify an entire room for compounding these products, which may reduce access to medications, particularly in rural areas.
3. Line 213-214
    a. A pharmacy that only performs non-particulate generating compounding would not have the same necessity to clean walls and ceilings that a higher volume/higher risk pharmacy would. We request that lower risk/volume pharmacies be allowed to determine if this cleaning schedule is necessary for preventing cross contamination and staff safety by performing a risk assessment.
    b. A pharmacy that only compounds magic mouth wash, for example, will not have the same environmental contamination potential that a pharmacy using APIs will. The particulate is not comparable.
4. Line 226
    a. We request that the requirement for equipment to be verified annually, even if the manufacturer recommends a lesser frequency be removed.
    b. The manufacturer is the expert on the equipment it provides and is the best source of proper care and use. Additionally, pharmacies that are engaged in periodic process and staff validation could identify equipment malfunctions through that process as well. Equipment validation may result in extraneous costs that discourage pharmacies from compounding and therefore reducing medication access.

5. Line 254
    a. We request that pharmacies be allowed to conclude a vendor is qualified if it has been inspected by and remains in good standing with the FDA. We support pharmacies acquiring documentation of vendor FDA registration on a regular basis to validate this qualification.
    b. Vendors that distribute APIs are responsible to comply with Good Manufacturing Practices, a standard that is beyond what is required by USP requirements. These practices are also beyond the scope of general pharmacist education requirements. Pharmacies should be able to conclude a manufacturer is qualified if that is the conclusion of the FDA.
6. Line 333-334
    a. We support the requirement of assigning an expiration date to ingredients that do not have one from the manufacturer, but request that the 3 year requirement be retained rather than the proposed 1 year.
    b. Ingredients that do not have an expiration date are generally not APIs, but rather filler ingredients or vehicles. These ingredients are often very stable when stored correctly and often only come in large quantities. Asking pharmacies to discard these items, if there is no evidence of degradation could result in unnecessary financial costs.
7. Line 335-337
    a. We request that compounders be allowed to use their professional judgement to determine whether excess API used in compounding needs to be discarded.
    b. The amount of time that an excess component is exposed to the environment during compounding is often minimal and the proposed requirement that all powdered components be weighed in a CVE reduces the exposure to an uncontrolled environment. Requiring discarding components that have only been physically exposed to a cleaned/sanitized weighing instrument could result in unnecessary waste. This waste would cause an unnecessary increase in costs, including both disposal cost and new product acquisition costs.