

ICHP Position Statement - Quality Sterile Products

ICHP supports the concepts of safety and quality assurance for pharmacy-prepared sterile and non-sterile products described in United States Pharmacopeia (USP) chapters <795>, <797>, and <800>. Health care organizations must comply with these USP chapters and develop policies and procedures in their practice settings appropriate within the state law and applicable accrediting bodies for each sterile and non-sterile product compounded by their organization.

If an organization chooses to outsource the preparation of sterile products, as allowed under section 503B, individual vendors should be assessed for compliance with applicable regulations and GMPs.

Reference - pharmacy practice act

ASHP 503B checklist <https://outsourcing.ashp.org/>

Illinois Administrative Code: **SECTION 1330.640 PHARMACEUTICAL COMPOUNDING STANDARDS**

Revised 3/2023