USP just released the revised General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. While the regulations were initially introduced in 2004, this is only the second revision to the rules, which have been widely adopted by various regulatory bodies as the safety standards for compounded sterile preparations (CSPs). Many of the standards remain and were further clarified, and regulatory bodies are expected to enforce the updated standards. In addition to ensuring compliance with the existing chapter, review the checklist below to help as you prepare for the impact of the recent revisions. USP <797> section references are provided, and key changes are emphasized.

**Have you:**

**Facility**

- Determined if any existing compounding areas need to be reclassified based on facility requirements or engineering control (hood) limitations? *<Section 4>*
  - Standards are now based on a full clean room suite (classified area) or a segregated compounding area (SCA).
  - Compounding aseptic isolators (CAI, aka glove boxes) may only use limited beyond use dating (BUD) if placed in a room that does not meet full clean room standards. *<Sections 1.5 and 14.3>*
- Assessed capabilities and procedures for pressure, temperature and humidity monitoring in compounding and storage areas? *<Section 4.2>*

**Categories of CSPs and Beyond Use Dates (BUDs)**

- Reviewed and understand the new categories and beyond use dates for immediate use, category 1 and category 2 CSPs? *<Section 1.5>*
- Assessed the impact changes to BUDs will have on your pharmacy IV room production workflow and staffing? *<Section 14>*
- Considered BUD implications related to clarification of preparation per approved labeling? *<Section 1.4>*

**Environmental and Personnel Monitoring**

- Developed a sampling plan for all classified compounding areas and decided who will complete the monthly surface sampling? *<Section 6>*
- Determined which personnel will need to be tested *every 6 months* with a gloved fingertip and media fill? *<Section 2.2>*

2019 USP <797> Preparation Checklist

Updates were just published. Will you be ready for the Dec. 1, 2019, anticipated compliance deadline?
Environmental and Personnel Monitoring (continued)

☐ Discussed the new incubation standards with your lab or certification vendor? <Sections 6.2 and 6.3>
☐ Developed corrective action procedures and documentation? <Sections above and Section 20>

Policies and Procedures

☐ Reviewed existing policies and procedures for compliance with USP <797> revisions and required components?
☐ Established a quality assurance (QA) and quality control (QC) program for CSPs that includes procedures for recalls, complaint handling and adverse event reporting? <Section 18>

Master Formulation and Compounding Records

☐ Created and/or validated Master Formulation Records for any batch compounded preparations and preparations made from nonsterile components? <Section 11>
☐ Reviewed documentation requirements for Compounding Records? <Section 11>

Staff Training and Competency

☐ Identified and provided clear expectations for a designated person to oversee compliance with all aspects of USP <797>? <Section 1.1>
☐ Reviewed your staff training and competency policies, procedures and documentation? <Section 2>
  - Some elements, including hand hygiene and garbing competency testing, are now expected to be performed every 6 months.

Compliant Supplies

☐ Assessed supplies and procedures for compliance with cleaning, disinfecting and sporicidal agent application? <Section 7>

Hazardous Drugs

☐ Prepared for USP <800>?
  - Hazardous drug references have been removed from USP <797> and cross-referenced to USP <800>.

December 1 is quickly approaching. Whether you need to assess your organization’s compliance, leverage Premier® GPO contracts on related products and services, or accelerate your organization’s readiness, reach out to be connected with a Premier expert at Solutioncenter@premierinc.com.

Please consult the USP website for up-to-date and complete USP requirements and FAQs.

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