

## **BEST PRACTICE: COMPOUND RECORD AND MASTER FORMULATION RECORD**

USP Chapter 797 requires a compound record to be created and maintained, however, does not define the specific elements to be included in the compound record. Upon unanimous recommendation of the Sterile Compounding Task Force and adopted by the Kentucky Board of Pharmacy at the December 16, 2015, Board Meeting, the following is a Best Practice recommendation on the elements of a compound record. (This is the same requirement as in the proposed revision of USP Chapter 797 published September 2015.)

### **COMPOUND RECORD**

- Name, strength, and dosage form of the compounded sterile preparation (CSP)
- Master Formulation Record reference for the CSP, when used
- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription or lot number)
- Signature or initials of individuals involved in each step (e.g., technician or pharmacist)
- Name, vendor or manufacturer, lot number, and expiration date of each ingredient and container-closure system
- Weight or measurement of each ingredient
- Documentation of the calculations, made to determine and verify quantities and/or concentrations of components, if appropriate
- Documentation of quality control procedures in accordance with the SOP (e.g., filter integrity, pH, and visual inspection)
- Any deviations from the Master Formulation Record, if used, and any problems or errors experienced during the compounding of the CSP
- Total quantity compounded
- Assigned Beyond Use Date
- Duplicate container label if prepared in a batch

A master formulation record is recommended when performing batch or high risk compounding. The following is a Best Practice recommendation on the elements of a master formulation record. (This is the same requirement as in the proposed revision of USP Chapter 797 published September 2015.)

### **MASTER FORMULATION RECORD**

- Name, strength, and dosage form of the CSP
- Physical description of the final preparation
- Identities and amounts of all ingredients and appropriate container-closure systems
- Complete instructions for preparing the CSP, including equipment, supplies, and a description of the compounding steps
- BUD and storage requirements
- Quality control procedures (e.g., pH, filter integrity, and visual inspection)
- Sterilization method, if applicable (e.g., filter, steam, or dry heat)
- Any other information needed to describe the operation and ensure its repeatability (e.g., adjusting pH and tonicity and temperature)