

# Preparing for Your Compounding Pharmacy Survey

*We're with you. Every step of the way.*

*To help prepare for your pharmacy's site survey, we suggest you double-check that you are ready with the following:*

## Regulatory Compliance

- Display all current licenses, registrations and certifications as required
- Policy and Procedures compliant with USP and other applicable regulations (FDA, DEA, ADA, etc.)
- Compounding personnel demonstrate understanding of applicable USP guidelines
- Compounder ensures USP <1075> controls are established and implemented
- Standard Operating Procedures (SOPs) are established and clearly documented for equipment and formularies

## Personnel

- There is a designated Pharmacist in Charge (PIC) and Compounder, who may or may not be the same person
- Personnel licensing is up to date and required checks are documented
- Proof of OIG/GSA/SAM verification
- Staff compounder(s) are qualified and understand responsibilities
- Staff Pharmacists are qualified and understand responsibilities
- Pharmacy Technicians are qualified and understand responsibilities
- Compounder training meets USP <1075>

## Facilities and Equipment

- Drug compounding facility and equipment are appropriate for intended compounding procedures and meet USP <1075> et al
- Compounding environment and equipment are appointed for complexity and volume of compounding and meet USP <795> et al
- Maintenance of machines and equipment is appropriately conducted according to SOP's and documented accordingly

## Compounding Storage and Handling

- Bulk chemicals and compounds are stored, labeled, and handled appropriately in compliance with USP and other applicable guidelines
- Appropriate Formulation Records, Compounding Records, and prepack log are maintained and signed off on by Compounder
- Sterility in compounded preparations meet USP <795> et al
- Personal protection procedures are in place and appropriate employees are trained on proper use of personal protective equipment

## Compounding Practices

- Compounded preparations and processes comply with USP <795> requirements
- Component selection requirements meet USP <1075> at minimum
- Ingredient selection follows USP <795> guidelines
- Pharmaceutical Calculations are done in compliance with USP <1160>
- Stability criteria and beyond use dating are appropriately conducted and in compliance with USP <795>
- All labeling is put together following USP <795>
- Checklist for Acceptable Strength, Quality, and Purity meet USP <795>
- Quality Control and Verification meet USP <795> Packaging and Drug Preparation Containers meet USP <795>

## Compounding Records

- Policies and Procedures for appropriate use and retention of documentation are in place

## Quality Assurance

- Policies and Procedures for assurance of appropriately functioning equipment, processes procedures are in place to produce expected results