Focus on Quality Assurance: Tips on Meeting Sterile Compounding Standards

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ROLE OF STERILE COMPOUNDING SUPERVISOR AND THIRD-PARTY EVALUATOR

A sterile compounding supervisor must:

[Refer to Sections 5.1.1.2, 5.1.2.3, 5.1.2.4 of the standards]

- be a pharmacist or pharmacy technician who has successfully completed training (i.e., courses) in the compounding of sterile preparations
- have the competency required to manage a safe, high-quality sterile-preparation compounding area
- maintain up-to-date knowledge and demonstrate the required compounding competencies for the type and level of compounding that they are engaged in
- be evaluated for knowledge and abilities by a third-party, at the same frequency as compounding personnel
- must ensure that, if assigning training and assessment of personnel to a third-party evaluator, that individual is qualified

The sterile compounding supervisor:

- develops, regularly reviews and updates policies and procedures covering all activities related to compounding sterile preparations (see Appendix 1).
- implements and maintains a training and competency assessment program for all personnel
- establishes a quality assurance program (see Appendix 12)
- oversees personnel to ensure they know and always follow policies and procedures
- establishes supervision requirements, and requirements for delegation by a pharmacist, for unregulated compounding personnel
- verifies that the facilities and equipment meet requirements and are properly maintained, calibrated or certified
- reviews and approves compounding protocols to yield high-quality sterile preparations that are safe for patients and personnel
- ensures the available, recognized scientific literature is used by a pharmacist to determine stability and to establish the beyond-use date (BUD) for each sterile preparation.
- makes available and regularly updates the mandatory and supplementary references (See Appendix 2)
- ensures all records required by the Model Standards are completed, maintained and readily available

A third-party evaluator must:

[Refer to Section 5.1.2.4 of the standards]

- assess the sterile compounding supervisor, and may be assigned the training and assessment of compounding, cleaning and disinfecting personnel by the sterile compounding supervisor
- be a pharmacist or pharmacy technician with expertise in compounding sterile preparations
- be at arm's length (fully independent) from the pharmacy or facility
- be free of any real or perceived conflict of interest with the individual(s) being evaluated which may potentially affect the ability to be impartial and unbiased
- evaluate specific policies and procedures in effect in the workplace
- have training that covers the compounding of sterile preparations (including hazardous drugs, if applicable)
- possess knowledge and skills which correspond with the type and level of the compounding practices being evaluated
- have certification that their competencies in this area are being maintained and developed
- have competency assessment that include the same elements as the competency assessment program for compounding personnel for the type and level of compounding that they are engaged in (see Appendix 3):