By Thomas Wheeler, BS, RPh and Mark Franklin, PharmD

Lab Safety Corporation

ADVOCATE ILLINOIS MASONIC MEDICAL CENTER, located in Chicago, is a 461-bed acute care hospital and was recently recognized as one of *U.S. News and World Reports*' top 50 hospitals in heart and heart surgery. The following article details our pre-cleanroom-build efforts to comply with the USP <797> requirements for personnel training, annual media-fill challenge, end-product sterility monitoring, and process documentation in our preparation of CSPs.

Personnel Training

The proposed revisions to USP Chapter <797> require that compounding personnel be trained via a variety of methods including instruction from expert personnel and audio-visual aids, as well as professional publications. In addition, compounding personnel must pass a test of their aseptic technique at least annually for low- and medium-risk level compounding. The initial selection of the Valiteq system was based upon its proven reliability and reputation. We have since found that the Valiteq Aseptic Technique Verification System provides the philosophy, materials, and instructional tools necessary to comply with the current and projected requirements of the USP chapter.

We use the ACPE-accredited Valiteq aseptic technique training program to meet USP's requirements for didactic training in compounding skills. The program incorporates both audio-visual and written iterations, including a five-part compounding manual and a five-part audio-visual program and learning guide. Our associates perform the 10-step verification process outlined in the Valiteq kits' literature to verify that they are proficient in and in compliance with standard operating procedures. The Web tool entitled "Technique Assessment Form" (www.valiteq.com/AssessmentForm.pdf) documents their completion of the verification lab exercise and assures that personnel are skilled in, and compliant with, established protocols. We use this tool as a systematic grading standard to improve personnel training through direct observation and real-time documentation.

Aseptic Technique Verification Kits

To verify our compounding staff's aseptic technique during the preparation of low- and medium-risk preparations (up to 400 per day), we use the Valiteq RL-2 kit and the A.T.T.A.C.K. II kit. The RL-2 kit is used by all of our associates involved in the preparation or verification of parenteral products. It contains a three-test challenge of medium-risk aseptic technique, and incorporates multi-strength trypticase soy broth USP in single- and multi-dose vials and ampoules, and sterile powders for reconstitution to simulate medium-risk aseptic compounding. The A.T.T.A.C.K. II Kit provides a three-test challenge of low-risk aseptic technique. We have also utilized the online "Verification Procedure" tool (www.valiteq.com/ instruction_sheets/procedureform.htm) to customize our verification exercises to match the tools, materials, and processes we actually use in our daily practice. Our process incorporates the pumping of a parenteral nutrition bag, using our Baxa Exacta-Mix 2400 compounder, and the preparation of a PCA syringe using an Abbott PCA cartridge. The Valiteq-recommended procedures were easily augmented to include these kinds of preparations.

Documentation Management

After using the Valiteq Documentation Management System (DMS) v1.1 software to document all of our personnel selection, training, and technique-verification and re-verification exercises, we recently upgraded to version 2.0. The new version allows us to document and schedule personnel education testing, re-testing, and monitoring, as well as document and grade our personnel's performance of critical equipment cleaning, disinfection, and pressurization checks. It also allows us to document the microbial sampling of glove tips, gowns, and work surfaces. This tool will prove very helpful with USP's anticipated expansion of fingertip and active air sampling. The DMS is managed by our quality coordinator, and the documentation itself requires only two to three hours per month.

Also, because our facility's engineering controls must support asepsis, the DMS v2.0 identifies all of our engineering controls and defines the necessary critical testing, including certifications, pressurization, particle counts, and microbial surface sampling, as well as active airborne sampling, which is required by the proposed revisions to USP Chapter <797>. It also provides complete documentation, and compares testing results to action and alert levels to assure our facility and engineering controls are functioning in accordance with their design and are properly maintained, cleaned, and disinfected.

End-Product Sterility Auditing

End-product sterility is vital to the safety of our patients. We use Valiteq's Steriteq sterility testing and Steriquot sterility monitoring systems to spot-check end-product sterility on randomly selected, returned or wasted low- or medium-risk products. The user-friendly systems contain instructions on their proper use and how to interpret the results. Each case of the RL-2, Steriteq, and Steriquot contains a certificate of performance documenting that each of the products have met USP's sterility, ph, and cosmetic standards, and that the growth medium has been tested to meet USP growth-performance standards. Our processes have been validated through our spot-checks, which have not yielded the need for an intervention.

We have found the Valiteq line of products to be easy to use, affordable, and reliable, and they are an important aspect of our ongoing training and quality assurance program. ■

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