

Baxa Corporation

USP 797 Training Requirements

A Case Study

A summary of the process used by
Swedish Medical Center to meet the personnel training
and evaluation requirements for USP <797>



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Abstract

This paper summarizes the process used by Swedish Medical Center in Seattle, WA to comply with the personnel training and evaluation in aseptic manipulation skills required by the United States Pharmacopeia (USP) Chapter <797>. Given the multiple requirements for USP 797 compliance, Swedish pharmacy management quickly made the decision not to build a new process from scratch. Instead, they enhanced their existing program by purchasing the commercially available Valiteq products. The conclusion through the Swedish experience is that a quality USP 797-compliant training and evaluation program can be implemented with minimal effort when built around commercially available products.

Introduction

USP Chapter <797> was released in January 2004, creating a new (US) national standard for sterile preparation. This standard is intended to describe the current best practice for quality assurance in sterile compounding in an effort to improve patient safety and reduce the number of adverse events related to sterile compounding activities.

The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has adopted these standards for use after July 1, 2004. Individual State Pharmacy Boards are also including the standards in their inspections.

USP 797 is an evolving document that is subject to continuous refinement and updates. Refer to the USP Web site¹ and the *JCAHO Perspectives* newsletter² for current guidance on the regulations.

Facility Overview

The Swedish System³ in Seattle, WA includes 697 licensed beds on the main First Hill campus, 163 beds at its Ballard campus and 436 beds on the Medical Center's Providence campus, as well as a large Home Care Services division.

Internationally recognized specialties at the Medical Center include many types of surgery, cancer treatment through the Swedish Cancer Institute, and cardiac care at the Seattle Heart and Vascular Institute. Swedish is affiliated with more than 2,000 physicians representing every medical and surgical specialty and sub-specialty. Last year, more than 39,000 surgical procedures were completed at Swedish Medical Center.

USP 797 Training and Evaluation Requirements

The following section is the full USP 797 text regarding: PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATION SKILLS.

Personnel who prepare CSPs must be provided with appropriate training from expert personnel, audio-video instructional sources, and professional publications in the theoretical principles and practical skills of aseptic manipulations before they begin to prepare CSPs. Compounding personnel shall perform didactic review, and pass written and media-fill testing of aseptic manipulative skills initially; at least annually thereafter for low- and medium-risk

level compounding; and semi-annually for high-risk level compounding. Compounding personnel who fail written tests, or whose media-fill test vials result in gross microbial colonization, must be immediately re-instructed and re-evaluated by expert compounding personnel to assure correction of all aseptic practice deficiencies.

Media-Fill Challenge Testing — The skill of personnel to aseptically prepare CSPs may be evaluated using sterile fluid bacterial culture media-fill validation, (i.e., sterile bacterial culture medium transfer via a sterile syringe and needle). Media-fill testing is used to assess the quality of the aseptic skill of compounding personnel. Media-fill tests represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare particular risk level CSPs and when sterilizing high-risk level CSPs.

Commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium (see Sterility Tests (71)), shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to CSPs from the compounding personnel and environment. Media-filled vials are incubated at 25° to 35° for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days.

Example of a Media-Fill Test Procedure — Perform the test as directed in the section “Quality Assurance of Low-Risk Level CSPs.”

Starting the Compliance Process

Before beginning the process of USP 797 compliance, Swedish already had a good aseptic technique training and evaluation program in place – similar to other peer institutions. However, the USP 797 Gap Analysis identified a number of deficiencies that needed to be addressed at the Medical Center.

The first decision by pharmacy management was whether to address the identified gaps using internal resources, or by purchasing a commercially available program. Given the numerous other USP 797 gaps to fill, it was an easy decision to buy the best ready-to-use solution to save the facility time and money.

There are a number of high-quality training resources available to aid in compliance. Many journal articles describe these solutions, but probably the best is the Eric Kastango article⁴ published in the *American Journal of Health-System Pharmacy* in June 15, 2005 entitled, “Blueprint for implementing USP Chapter 797 for compounding sterile preparations.” Kastango provides an excellent description of the issues and a more detailed description of the USP 797 requirements on training and evaluation than will be described in this paper.

Excellent training and evaluation products are available from professional⁵⁻⁸ and commercial organizations. Swedish choose the Valiteq⁹ system because they felt it provided the most complete solution for their needs. The written and video training aids complemented the existing Swedish training program to fulfill the didactic and written requirements. The media fill products completed the process required by USP 797.

A side note is that it was also important to consider compliance with the NIOSH Alert¹⁰ in the development of any sterile compounding training program. While not the focus of this paper, NIOSH compliance is covered in

the Swedish training and evaluation program. Further assistance is also available through Valiteq.

Personnel Training, Evaluation and Recertification

Training, evaluation and recertification for the pharmacists and technicians are very similar, but the Swedish program incorporates differences by position. New technicians are trained by the System Lead IV Technician and pharmacists are trained by the Lead IV Pharmacist. New employee training includes the following, with the differences noted below:

1. Tour and orientation to pharmacy and hospital layout.
2. Review hospital IV admixture policies and procedures. (NOTE: the focus will be different for pharmacists and technicians.)
3. Read applicable IV admixture job descriptions.
4. Watch the Valiteq technique video series (5 parts; 1 hour and 53 minutes running time), related to quality assurance, LAF hoods, attire, hand washing and manipulation of compounded sterile products (CSPs).
5. Read the Valiteq Compounding Manual that parallels the videos. Go over key points of the manual with the trainer.
6. Watch the expert video on “Safe Handling of Cytotoxic and Hazardous Drugs” and review the workbook.
7. Read the NIOSH bulletin on antineoplastic agents and sign off that it was read.
8. Take the 30-question Valiteq test, grade and review.
9. Complete the IV Admixture Checklist Evaluation of Sterile Technique (below).
10. Complete the Valiteq media-fill testing of aseptic manipulative skills.
11. Complete the IV room orientation/observation, including all computer system training.
12. Review with the trainer the IV pharmacist training supplementary campus-specific checklist and proceed to train on all IV room equipment. Technician training is similar but focused on technician-based activities.
13. Train with an on-line pharmacist on the daily tasks and work into independent operation. Technicians work alongside senior technicians.
14. Receive final discussion, evaluation, and certification from the trainer.

Compounding personnel who fail written, didactic or media-fill tests must be instructed and reevaluated immediately. Copies of all documentation are included in the employee’s performance evaluation.

Recertification then occurs every year during the employee’s birth month. The annual recertification procedure includes:

1. Review applicable hospital and IV admixture policies and procedures.
2. Watch the four parts of the Valiteq technique video relating to quality assurance, hoods, attire, hand washing and manipulation of CSPs.

3. Read the Valiteq Compounding Manual. Go over key points of the book with the trainer.
4. Take 30-question Valiteq test, grade and review.
5. Watch the expert video on "Safe Handling of Cytotoxic and Hazardous Drugs" and review the workbook.
6. Complete the IV Admixture Checklist Evaluation of Sterile Technique.
7. Complete the PATT (Personal Aseptic Technique) media-fill testing of aseptic manipulative skills.

Once again, compounding personnel who fail written, didactic or media-fill tests must be reeducated and reevaluated immediately. Copies of all documentation are included in the employee's annual performance evaluation

IV Admixture Checklist Evaluation of Sterile Technique

Checklists for evaluation of sterile technique are unique to specific facilities. This is the list used in the Swedish System:

| IV ADMIXTURE EVALUATION CHECKLIST | | | |
|---|----------------------|-------------|-----|
| Name: _____ | | Date: _____ | |
| <u>STANDARDS</u> | <u>STANDARDS MET</u> | | |
| Removes jewelry | YES | NO | N/A |
| Ties long hair back | YES | NO | N/A |
| Washes hands to elbows | YES | NO | N/A |
| Gowns appropriately (sleeves) | YES | NO | N/A |
| Cleans hood (back to front, 70% alcohol) | YES | NO | N/A |
| Performs calculations prior to admixture | YES | NO | N/A |
| Aseptically places items in hood | YES | NO | N/A |
| Works well within hood (6") | YES | NO | N/A |
| Alcohol swipes all points of entry | YES | NO | N/A |
| Prepares IV aseptically | YES | NO | N/A |
| Places only hands and arms in hood | YES | NO | N/A |
| Uses filter needle | YES | NO | N/A |
| Caps vials with aluminum seal | YES | NO | N/A |
| Checks label prior to and after compounding | YES | NO | N/A |
| Inspects for incompatibilities, cores, particulate matter | YES | NO | N/A |
| Correctly labels product | YES | NO | N/A |
| Places proper expiration date on label | YES | NO | N/A |
| Addresses storage requirements | YES | NO | N/A |
| Initials final product | YES | NO | N/A |
| EVALUATOR: _____ | | | |
| COMMENTS _____ | | | |

Conclusion

A high-quality, USP 797 compliant personnel training and evaluation program can be implemented with minimal resources in a limited amount of time. Every pharmacy should have a robust training program in place already to meet the requirements of USP <797> for personnel training and evaluation. Commercially available products may be all that is needed to fill any gaps in USP 797 compliance in this area. The Valiteq program worked well at Swedish but there other alternatives, from a variety of sources, should be reviewed prior to choosing a vendor partner.

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