**Sterility Monitoring: Confirmation of System Performance**

Product sterility monitoring is an essential component of the compounding process monitoring system, upon which the release of Pharmacy-prepared sterile products is justified.

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**STERITEQ™ Concentrate**

The STERITEQ™ Concentrate provides a “spot-check” of sterility for canceled, or returned sterile products. In this challenge, the entire product and its container become the aliquot test. Following aseptic introduction of the STERITEQ™ growth-medium concentrate into the product container to produce a destructive, 100% aliquot test of the subject, it is incubated at room temperature (20°-25°C) and read periodically for clarity, without the need for an incubator. The STERITEQ™ Concentrate can also be used to routinely monitor the sterility of compounder source bags, tubing, and reconstitution equipment. (Patient Pending)

**P/N: VM-ST**

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**STERIQUOT™ Spot-Chek**

The STERIQUOT™ is a sterile Trypticase-soy Broth USP, concentrate, to which a 10 mL aliquot sample of sterile product may be added following compounding, and prior to the product being delivered to the patient. It is a non-destructive monitor of final product sterility, and may be carried out quickly and easily by the compounding operative.

**P/N: VM-SQ**

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**CHEMOTEQ™**

**Hazardous Compounding Technique Validation System**

The CHEMOTEQ™ Hazardous Substances Compounding Validation Kit provides evaluation of both the aseptic, and containment technique of personnel who compound antineoplastic and other hazardous products. CHEMOTEQ™ products are double-strength, sterile Trypticase-soy broth USP, and also contain a non-inhibitory color tracer, used to visualize any leakage that occurs during the compounding process. These products are of particular value as practice subjects for skills development, because they allow operators to immediately identify practices which lead to the release of drug product into the environment. Includes standardized Qualitative Residue Recovery, Manipulated Product Sterility, and a Practical Skills Evaluation form and grading system. (Patient Pending)

**P/N: VM-1001CM**

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**Do your IV and Chemo Admixtures Programs give you the warm-fuzzies?**

Hospital, clinical, and home healthcare pharmacies must demonstrate and document control of their aseptic compounding processes and facilities, yet the diversity, and extremely small batch sizes of Pharmacy-produced sterile products make it impossible to validate Pharmacy aseptic processing operations through the use of “classical” Quality Assurance Validation Practices.

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** Operator Knowledge**

1. Selection, training, and evaluation of all operatives within a closed-loop, outcome-producing Quality Assurance Validation system, including a period of supervised clinical experience, (60-90 days),

2. A structured aseptic technique compounding curriculum,

3. Completion of a comprehensive, written test of knowledge,

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**Operator Skills**

4. A comprehensive and hazardous products Media-fill Compounding Validation Exercise to verify skills,

5. An observed Assessment of Aseptic Technique, carried out during the Media-fill exercise,

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**Process Verifications**

6. Ongoing monitoring and documentation of equipment and facility parameters,

7. Software documentation of training, testing status, and scheduling of all operatives,

8. Periodic sterility monitoring of compounded sterile products,

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**finally: CQI**

Use of the VALITEQ®, CHEMOTEQ™, and STERITEQ™ Systems will allow you to establish your program quality compliance levels, and to identify and assess your Continuous Quality Improvement (CQI) efforts.
Tools for successful outcomes:

**Education: The Foundation for Success**

COMPOUNDING MANUAL

The Compounding Manual is organized in accordance with accepted educational principles, and includes self-assessment exercises to assist the participant in identifying problem areas. The manual provides both theory and the practical application of concepts in: 1. QUALITY ASSURANCE RELEASE OF PHARMACY-PREPARED STERILE PRODUCTS; 2. ENGINEERING CONTROLS AND LAMINAR AIRFLOW THEORY; 3. BARRIER CONTROLS & ASEPTIC MANIPULATIONS; and 5. PHARMACEUTICAL COMPOUNDING CALCULATIONS. Pkg. of 3. P/N: V1001T

5-PART TRAINING VIDEO

Because many concepts and techniques are most effectively presented visually, the VALITEQ™ system incorporates a five-part training video. The video parallels the training manual, and is designed to reinforce the training concepts and procedures presented in the manual. Available on 3 VHS cassettes, or a fully-audible 1-hour, 53 min., double-sided DVD. Part No. V1001V or V1001D

**Evaluation: The Key to Improvement**

Although “classical” validation of pharmacy sterile compounding personnel and processes is not possible due to the extemporaneous nature of pharmacy practice, and the general lack of identifiable batches, it is essential that both the knowledge and practical skills of compounding personnel be periodically evaluated.

The Software Documentation Management System includes tests of the operator’s knowledge of Quality Assurance, Engineering Controls, Personal Barriers, Manipulative Technique and Calculations. The Assessment of Aseptic Technique form, used in conjunction with the media-fill validation exercise, verifies the transfer of knowledge to daily practice, and mastery of manipulative skills.

RL-2 VALIDATION KIT

Because sterile compounding involves the use of many packaging systems and tools, a skills evaluation should include all of the fundamental “core” manipulative techniques. The RL-2 kit (obverse: #1) simulates a wide range of compounding challenges, and contains materials for three, Risk Level-2 exercises. All VALITEQ™ Media products are double-strength to allow for dilution, and meet USP requirements for growth promotion in both the double-strength, and diluted forms. P/N: VM-RL2

**Documentation: Staying on Track**

DOCUMENTATION MANAGEMENT SYSTEM

The Documentation Management System software provides management of training and quality assurance activities, including Individual Training Data Records, suspense lists of personnel due for retraining or re-qualification, quality assurance reports, written tests and keys, and Observation Assessment of Aseptic Technique forms. The user may print all records, as well as document logs for compounding calibrations, hood cleaning, and refrigeration/defrost temperature. The software allows the user to input institution-specific training requirements and SOPs. P/N: V1001TS

**Practice Makes Perfect**

VM-10, Single-Use Vial

This product is used as an inexpensive practice subject in the training of operators in basic syringe/vial manipulative techniques, and for evaluation/validation of single-dose vial manipulative technique.

The VM-10 contains 10 mL of double-strength Trypticase-soy Broth, to facilitate the use of the product in more complex validations requiring further dilution and transfer. P/N: VM-10

VM-10A, Ampule

As the most vulnerable packaging form and sterile pathway, the ampule represents the greatest challenge to the routine manipulative technique of operators. The mishandling of the ampule constitutes a major cause of the contamination of compounded sterile products. Because ampules used in the admixture process require careful observance of the correct staging, disinfection, opening, and extraction procedures, as well as the use of appropriate filtration, practice that reveals sterility failures due to ampule mishandling is essential.

The VM-10A contains 10 mL of double-strength Trypticase-soy Broth, USP, and may be used to provide practice experience, and validation of ampule compounding procedures and manipulative techniques. P/N: VM-10A

VM-20R, Protein-Digest Powder for Reconstitution

The reconstitution of sterile powders requires additional skills, most especially the newer, protein-based classes of drugs, which may be destroyed by any shaking, and which have characteristic “caking” tendencies. Mastery of the reconstitution of these drugs requires considerable dexterity and practice. Use of the VM-20R provides compounding personnel with a realistic simulation of aseptic reconstitution of sterile powders, as well as a method of validating this essential manipulative technique.

The VM-20R contains sterile Trypticase-soy Broth Powder USP, sufficient to reconstitute 20 mL of double-strength Trypticase-soy Broth USP, in an amber vial as an additional challenge to operator skills. P/N: VM-20R

VM-30, Bulk Dispensing Multi-dose Vial

Regulatory and oversight organizations view dispensing of a product to more than one patient as an increased contamination risk factor. Storage of multi-dose vials, and use of dispensing devices for multiple withdrawals also present an elevated risk of contamination. The VM-30 contains 30 mL of double-strength Trypticase-soy Broth USP.

As a multi-dose vial, its contents should be dispensed into at least 3 aliquots, to simulate and validate the operator’s ability to safely manipulate multi-dose vials, appropriate dispensing devices, and their sterile caps. P/N: VM-30

VM-30, Bulk Dispensing Multi-dose Vial

Available in packages of 12 (obverse: #2).

VM-10, Single-Use Vial

Available in packages of 12 (obverse: #3).