

Baxa Corporation

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**Pharmacy Considerations for Syringe Batch Processing**

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Technical Paper

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Applying the available resources,  
regulations, guidelines, and procedures  
to the process of automated syringe filling.

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## Introduction

Cost containment issues and new technologies such as syringe pumps and patient-controlled analgesia have placed increasing demands on the hospital pharmacy to provide large quantities of pre-filled syringes. This task has been carried out typically by hand-filling each syringe with pump assistance. Automated syringe filling equipment will help pharmacists meet these growing demands, while reducing the risks associated with sterile filling techniques.

Pharmacists should begin planning for the projected increase in demand for automated sterile syringe filling. They should apply the key information resources, regulations, guidelines, policy and procedures on the topic, and familiarize themselves with the terminology and requirements for preparing sterile products. Pharmacists should also understand how automated syringe filling machines meet key requirements and plan for the training and evaluation of the pharmacy technicians who will be involved in sterile syringe product filling.

## Information Resources

Any pharmacy preparing sterile products must give top priority to quality assurance practices that ensure the safety and therapeutic efficacy of its extemporaneously prepared products. Each pharmacy must apply the current practice standards to their own unique requirements, maintaining the integrity of the end product using appropriate operator qualification and process validation.

The practice of sterile-product compounding changed with the publication of professional guidelines issued by the American Society of Hospital Pharmacists (ASHP), the *ASHP Principles of Sterile Product Preparation*, Revised 1<sup>st</sup> Edition (2002); the United States Pharmacopeia (USP) <1206>"Sterile Drug Products for Home Use" (2002); and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards. These standards serve as the basis for preparation and process validation addressing the varying degrees of risk that the resulting products represent.

These standards were issued to provide guidance to pharmacists on the quality assurance and quality control activities necessary for the safe preparation of sterile products. Although these standards do not have legal status, their status as benchmarks of professional practice can be upheld in a court of law. Therefore, any system presented for the use in preparing these products should be consistent with these principles.

## Guideline Scope

The ASHP principles apply to sterile-product preparation in various pharmacy practice settings. The USP general chapter <1206>, however, is intended for pharmacists who prepare sterile products in a pharmacy; however these products are typically administered in settings other than a professionally staffed healthcare facility. JCAHO-accredited facilities utilize standards to help ensure that medications are safely and accurately prepared. All three guidelines provide a classification scheme to match the type of quality assurance activities needed, to the potential risks posed to patients by the various types of sterile products that are compounded, as well as the types of

operator qualification and compounding process validation needed to ensure the quality of the sterile products prepared.

## Risk Factors

The ASHP and USP guidelines both classify sterile products into three risk levels, as determined by the potential risk for the introduction of contamination. Although the risk levels vary slightly, they are essentially the same in that they are divided into low-, medium-, and high-risk compounding. Some product types in the USP chapter do not match the corresponding level in the ASHP. The ASHP considers the amount of storage time between compounding and administration of the final product, the temperature at which the product is stored and whether or not the product contains any preservatives.

The ASHP classifies sterile products into three different risk levels, with risk levels 1 and 2 requiring the product to be compounded from sterile ingredients and solutions, using sterile equipment and in an area that has sterile surfaces. Alternatively, the USP guidelines classify sterile products according to low-risk level and high-risk I and II levels. A condensed summary of the ASHP and USP sterile product guidelines appears in Table 1.

**Table 1. Condensed Summary of the ASHP and USP Sterile-Product Guidelines.\***

<b>ASHP</b>	<b>USP</b>
<b>Risk Level 1</b>	<b>Low Risk</b>
1. <i>Products</i>	Commercial, <b>sterile</b> components
a. Stored at room temperature and completely administered within 28 hours	
b. Stored refrigerated, seven days, used within 24 hours	
c. Stored frozen, 30 days, and administered within 24 hours	
2. <i>Products</i>	Compounded with basic, few, quick, good aseptic practices
a. Unpreserved, <b>sterile</b> products intended for only one patient, or	
b. Batch prepared with preservatives, intended for multiple patients	
3. Made by closed-system, aseptic transfer of <b>sterile</b> nonpyrogenic components, into a <b>sterile</b> container	Closed-system transfers
<i>Examples</i>	
Single-patient ophthalmic/preserved	TPN compounding via gravity transfer
Batch-prefilled syringes with preservatives	Transfer from vials or ampoules via needle/syringe
Single-patient, batch-filled syringes with preservatives, used within 24 hours	
<b>Risk Level 2</b>	<b>High-Risk I</b>
Products stored longer than time periods in Nos. 1 and 2 above	Compounding involves the pooling of <b>sterile</b> components.
Batch compounding without preservatives, intended for use by more than one patient	Compounding involves complex or numerous manipulations over a relatively long period of time
Multiple <b>sterile</b> ingredients combined via septic, closed transfer, given to multiple patients	Product administered over several (multiple) days subdivided into multiple units
<i>Examples</i>	
Injection for use in a portable infusion pump or reservoir	Automated TPN compounding
Batch-reconstituted antibiotics without preservatives	Ambulatory pump reservoirs
TPN for administration over more than seven days	
Batch-filled syringes without preservatives	
<b>Risk Level 3</b>	<b>High-Risk II</b>
Compounded with nonsterile ingredients, containers or equipment	A bulk or nonsterile drug substance used to compound inhouse
Made by combining multiple ingredients ( <b>sterile</b> or nonsterile) in an "open system," followed by sterilization, filtration and aseptic filling, and subdivided into multiple units	Open systems used in compounding
<i>Examples</i>	
Morphine injection from powder or tab	Injectable morphine solutions from nonsterile powders
Alum bladder irrigation	TPN from nonsterile starting components
Autoclaved IV solutions	
TPNs from nonsterile amino acid powders	
TPNs sterilized by final filtration	

### Key Differences

#### Risk Level 1

Related to storage conditions and number of patients

#### Risk Level 2

Longer temperature and time requirements than 1 and 2  
Dispensed to multiple patients using multiple ingredients

#### Risk Level 3

None

\*Adapted from: Avis, KE.

#### Low Risk

Related to process **technique**

#### High-Risk I

Related to complex **technique** or compounding manipulations  
Administered over the course of several days

#### High-Risk II

None

## Table 2. ASHP: Facilities and Equipment Guidelines.

#### Risk Level 1

Sink for hand washing  
Refrigerator and freezer  
Controlled area with nonporous, washable floors  
Class 100 hood, recertified every six months  
Calibrated automated compounders  
Suitable waste disposal and area disinfection  
Order processing and documentation outside the hood

#### Risk Level 2

*Risk Level I plus* Class 100,000 cleanroom with positive pressure  
Methods for cleaning all surfaces of cleanroom and hoods  
Environmental monitoring program with threshold limits  
Anteroom separate from cleanroom

#### Risk Level 3

*Risk Level II plus* Class 10,000 cleanroom with Class 100 hood or class 100 cleanroom without hood  
Anteroom at Class 100,000  
Microbiologic monitoring of the environment  
Detailed methods of equipment sterilization

## Table 3. Comparison of ASHP and USP Process Validation Requirements.

#### ASHP

##### Risk Level 1

Process simulation for each operator

##### Risk Level 2

Process simulation for all types of products

##### Risk Level 3

Process simulation required for each different product

#### USP

##### Low Risk

Process simulation for each operator, initially, three media fill runs, then one media fill run quarterly

##### High-Risk I

Each different compounding process requires three media fill runs initially, then one media fill run annually

##### High-Risk II

Same as Category I

## Table 4. Comparison of ASHP and USP Environmental Control Guidelines.

#### ASHP

##### Risk Level 1

Separate controlled area

##### Risk Level 2

Class 100 LAF, etc., in a class 100,000 cleanroom with a separate anteroom

##### Risk Level 3

Class 100 LAF in a Class 10,000 cleanroom, or a Class 100 cleanroom with a Class 100,000 anteroom

#### USP

##### Low Risk

Class 100 laminar airflow hood (LAF) in a Class 100,000 cleanroom with an anteroom

##### High-Risk I

Class 100 LAF in a class 10,000 cleanroom with an anteroom

##### High-Risk II

Same as High-Risk I

## Table 5. Comparison of ASHP and USP End-Product Testing Requirements.

#### ASHP

##### Risk Level 1

Visual and physical inspection of final product

Compounding accuracy verification  
(Observation, calculation checks, documentation)

##### Risk Level 2

End-product sterility sample testing to supplement media fills; formal, statistically valid sampling plan; acceptance criteria; recall mechanism

#### USP

##### Low Risk

Visual and physical product inspection; (check for particulates, precipitation, leakage)  
Double-checking of compounding accuracy, prescription labels and correct amount of preparation ingredients

##### High-Risk I

Same as low-risk classification

**Risk Level 3**

Outside laboratory determination of conformity with specifications, to include microbiologic testing for sterility and pyrogens; chemical stability testing; quarantine product pending results; recall procedure testing; conditional release if recall procedures in place

**High-Risk II**

Low risk plus: sterility and pyrogen testing, and chemical potency testing for products that require terminal sterilization; should not release products prior to completed growth

## Policy and Procedures

The ASHP has a specific section in each risk level for policies and procedures. Similarly, the USP document lists requirements for policies and procedures under the major heading, "Environmental Quality and Control" and in the section titled, "Standard Operating Procedures." Additional topics covered in each of the guidelines include personnel training, product storage, facilities and equipment, operator garments, aseptic processing, operator and process validation, environmental monitoring and control, expiration dates, product inspection, end-product evaluation, and quality control after products leave the pharmacy. A full discussion of each subcategory is beyond the scope of this paper.

## Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards

The JCAHO standard revisions applicable to automated syringe filling equipment are described below, with an explanation of their operational intent.

**Standard:** TX.3.8 Medications are prepared safely and under proper conditions  
Whenever medications are prepared within the organization, the organization develops and uses processes to help ensure that medications are safely and accurately prepared. These processes include:

- Preparing medications and products using appropriate pharmaceutical and aseptic techniques;
- Preparing the medication according to approved directions;
- Using the metric measurement system;
- Visually inspecting ingredients and final products for inappropriate particulate matter or signs of deterioration or signs of microbial contamination; and
- Visually inspecting ingredients, calculations, and final products to prevent dosage and formulation errors.
- Using accepted quality control systems to ensure that appropriate processes and procedures were followed in the preparation of medications;
- Using processes for packaging medications that ensure the safety of personnel and prevent packaging error; and
- Preparing and packaging medications (including labeling and expiration dating) according to *United States Pharmacopeia (USP)* standards and all applicable laws and regulations.

The organization ensures that sterile medications are prepared under proper conditions, in accordance with law and regulation and accepted standards of practice. These conditions include:

- Clean, uncluttered, and functionally separate areas for sterile product preparation that minimize the possibility of particulate and microbial contamination;
- Using a laminar airflow hood, or other Class 100 environment for preparing sterile products, where feasible;

- The availability of adequate safety equipment (e.g., biological safety cabinets) to protect personnel preparing cytotoxic or hazardous medications; and
- Keeping work surfaces clean, disinfected, and free of materials, paper and equipment (e.g., computer printers) unnecessary for preparing a given medication or total parenteral nutrition (TPN) therapy solution.

When pharmacy services are provided, all sterile medications, intravenous admixtures, or other drugs that require compounding, mixing, manipulation or admixing should be prepared and labeled by the pharmacy, except in emergency situations when time does not permit (including during surgery and other procedures), or when the product stability is so short that pharmacy preparation of the product is not feasible. This includes splitting tablets, mixing solutions from powder, and other pharmaceutical manipulations to drug products.

**Standard:** TX.3.9 All medications are appropriately labeled.

All medications dispensed to, or otherwise prepared for use, in-patients are appropriately and safely labeled using a standardized method according to applicable law and regulation, accepted standards of practice, and organizational policy. At a minimum, all medication labels should include: drug name, strength, amount (if not apparent by the container – e.g., gradations on a syringe), and expiration date. If dispensed for administration by another individual, then any applicable cautionary statements must be included on the medication label or attached as an accessory label (e.g., requires refrigeration, for IM use only, etc.). In addition, all compounded intravenous admixtures and TPN solutions must be labeled with the scheduled date, time, and rate of administration, when appropriate. All labels for infusion products (including plain IV's) must have the label on the container that is being hung for a patient (i.e., not the overwrap).

The only medications that do not need to be labeled are those drawn-up for immediate administration to the patient, or those already appropriately labeled. Any time one or more medications are drawn up or prepared for later use, the container (e.g., syringe, bottle) must be appropriately labeled. In addition, every drug must be labeled during any intermediate step of the preparation process if the medication could possibly be confused or mistaken for another. When a commercial label is on the medication container, the organization label should not cover it. Information on the commercial label does not need to be duplicated on the organization's label.

When the organization provides pharmacy services, and medications are prepared, dispensed, or distributed by departments other than the pharmacy, including physician offices, the organization must assure that the labeling requirements and information on the label are equivalent throughout the organization.

## **Pharmacy Standards**

These references are essential starting points for any pharmacist or pharmacy staff member who is contemplating setting up an automated sterile syringe filling service in a hospital.

## Aseptic Technique

The word aseptic originates from the Greek words *a*, meaning without, and *sépsis*, meaning decay. The contemporary definition of aseptic technique refers to handling procedures that preclude microbial or particulate contamination of the raw materials and/or the final product. Training guidelines and videos for good aseptic techniques are available from ASHP, CHP, and various solutions manufacturers.

Over the years, specific techniques have been developed to handle items introduced into the controlled environment of the hood. These are:

1. All manipulations at least 6 inches from front of hood.
2. Hood operates continuously; otherwise run for 30 minutes before using.
3. All surfaces within hood should be cleaned thoroughly before and during use.
4. Nothing should touch the HEPA filter.
5. Hood should be away from other traffic and out of disruptive air flows.
6. No jewelry should be worn by technicians.
7. Talking, coughing, etc should be directed away from the hood.
8. Objects that are not directly involved in the sterile operations should be not be left in the hood.
9. Hoods should be tested on a regular basis.
10. No food or drink should be permitted in the aseptic preparation area.

In addition, all objects should be at least six inches from the side of the hood, and there should not be any object upstream of the critical area that could be a source of contamination.

*Techniques are specifically mentioned in the ASHP guideline that addresses the use of syringes. It is recommended that syringes be opened within the hood, and that any over-wrap or trays not be allowed to remain within the hood.*

## Contamination

Contamination of a final preparation can occur by two means: first, by poor aseptic technique, and second, by the use of contaminated raw materials. Repeated manipulation of the same product (such as multiple punctures of a vial or bag) also increase the risk of contamination. One of the main, but often overlooked, sources of contamination is the person preparing the syringe. An average healthy adult constantly sheds particles such as skin flakes, saliva and sweat, as well as head, facial and body hair. Clothing and cosmetics also generate particles. Pharmacists and pharmacy technicians must not only protect themselves from product exposure, but also protect the product from themselves.

Techniques that minimize the presence of people in the filling process will reduce the introduction of these potential contaminants. This reasoning has permitted the presence of automated compounding devices in the laminar flow hood, even though they are known to disrupt the airflow within the hood.

## Contaminants

Contaminants fall into two broad categories: micro-organisms (including pyrogens) and particulate matter. Pyrogens are products of micro-organisms, and can cause a febrile reaction in human beings. Only sterile, certified non-pyrogenic products should be used for syringe filling unless terminal sterilization (gas sterilization or autoclaving) is available. (Note: filtration will not remove/kill pyrogens.) Product-inherent particulate matter includes plastic, lint, rubber stopper particulate, glass ampoule chips and crystals. A simple visual inspection in front of a bright light can detect particles in a solution. Non-sterilizing filters (e.g., 5 micron) can be used to remove particles from solutions before they are given to a patient. When breaking glass ampoules, a filter or filter-needle is recommended to reduce the risk of glass fragment contamination.

## Sanitization

All working surfaces in the syringe filling area must be cleaned on a regular basis. The working surface and the sides of the laminar airflow hood must be cleaned and sanitized before any manipulations start. A germicidal detergent (containing quaternary ammonium as the active ingredient) is recommended as a cleansing agent. Sanitization should be done with isopropyl alcohol 70%. Some institutions clean the hood with sterile water or a water-based solution before sanitization with isopropyl alcohol. Detergents and cleansing agents should be changed periodically to minimize the development of resistance by the possible contaminating organisms.

## Controlled Environment

Sterile products should be prepared in a Class 100 environment, i.e., no more than 100 particles of 0.5 micron size or larger per cubic foot of air. Vertical and horizontal laminar air flow hoods (LAFHs) provide a Class 100 environment by producing a continuous flow of air that passes through a high-efficiency particulate air (HEPA) filter.

## Operator Preparation

Several steps must be followed to protect the sterile product from human contaminants. Hand washing and gloving: A sufficient quantity (3-5 mL) of topical antimicrobial (e.g., chlorhexidine gluconate) is required for proper hand washing, and the washing process should last at least 10 seconds to be effective. Gloving does not replace hand washing; microorganisms multiply rapidly inside a warm moist glove, and a puncture or tear of the glove will free the contaminants. Controversy exists as to whether the operator should or should not wear gloves, and if gloving, whether the gloves should be sterile or nonsterile. For automated sterile syringe filling, ASHP guidelines recommend sterile gloves; nonsterile gloves are acceptable for low-risk syringe filling activities such as cleaning the hood.

ASHP guidelines suggest that all personnel performing aseptic syringe filling should wear clean, low-particulate material (e.g., polyester) gowns or coveralls over street clothes, a head and facial hair cover and a mask.

## Expiry Date

It is important to determine the stability and expiry date of a product once it is reconstituted, diluted and/or transferred from its original container into an intravenous bag, syringe or cassette. In many instances, published data is available on the stability of IV medications, especially if they are commonly administered. The automated system used for this process should enable and encourage correct labeling.

## Documentation

In order to prevent error, pharmacists and other staff members are recommended to prepare a master worksheet describing the particular syringe filling procedure. Following a written procedure while syringe filling is a key component of quality assurance. Each syringe filling should be accompanied by a worksheet, listing the ingredients and quantities, syringe filling instructions, expiry date, storage conditions, and identification of personnel involved in syringe filling.

## The Pharmacist's Role

Pharmacists' skills and knowledge of automated sterile syringe filling make them the most qualified health practitioners to prepare sterile medications for the patient. Pharmacists must be constantly aware of the risks associated with sterile preparation. They should analyze the sterile preparation practices of all staff involved in automated sterile syringe filling on a routine basis, in order to identify deficiencies and take corrective action.

## Summary

ASHP, USP and JCAHO guidelines all contain valuable information for pharmacists involved in the preparation of sterile products for subsequent administration in either the healthcare system or alternate-site setting. However, each document contains unique information not contained in the others. Pharmacists who prepare sterile products are encouraged to read all guidelines and determine the appropriate risk level for the sterile products that they prepare. Pharmacists should ensure that the products they prepare are categorized into categories based on multiple compounding breaks, complexity of compounding, high-risk administration sites and any extenuating circumstances. *As always, professional judgment should be exercised when applying these guidelines to specific pharmacy practice settings in order to ensure the highest level of product quality.*

## Conclusion

Pharmacists in hospitals settings must take ownership of the automated sterile syringe filling of medications, because they are the most skilled and knowledgeable healthcare providers for this task. To fill sterile syringe products safely, pharmacists must understand the guidelines discussed or referred to in this article. Before filling a sterile syringe, at least the following must be in place: a proper facility with validated equipment; personnel who are trained in automated sterile syringe filling; and access to reference sources which specify stability, incompatibilities, expiry date and storage conditions. In addition, pharmacists must understand the risks associated with automated sterile syringe filling, and use professional judgment in deciding whether or not to fill a prescription.

## References

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APPENDIX I.

<b>ASHP, USP and JCAHO Evaluation of Baxa Corporation's Rapid-Fill Automated Syringe Filler (ASF)</b>			
<b>ASHP - Risk Level 2</b>	<b>USP - High-Risk Level I</b>	<b>JCAHO Revised Stds</b>	<b>Syringes Produced by the Rapid-Fill ASF</b>
<b>Product:</b> Batch compounding without preservatives to be stored greater than 24 hours and used by more than one patient.	<b>Product:</b> Compounding involving the pooling of sterile components.	<b>Product:</b> Prepare according to <i>USP</i> and applicable laws and regulations.	<b>Product:</b> Baxa Corporation filled syringes encompass many configurations of filled syringes, which fall within ASHP, USP and JCAHO standards.
<b>Facilities and Equipment:</b> 1. Sink for hand washing 2. Refrigerator and freezer 3. Class 100 hood 4. Class 100,000 cleanroom with positive pressure 5. Environmental Monitoring Program 6. Anteroom separate from cleanroom	<b>Facilities and Equipment:</b> 1. Sink for hand washing 2. Refrigerator and freezer 3. Class 100 hood 4. Class 100,000 cleanroom with positive pressure 5. Environmental Monitoring Program 6. Anteroom separate from cleanroom	<b>Facilities and Equipment:</b> Prepare according to <i>USP</i> and applicable laws and regulations	<b>Facilities and Equipment:</b> Baxa Corporation recommends: 1. Sink for hand washing 2. Refrigerator and freezer 3. Class 100 hood for use with Rapid-Fill ASF. 4. Class 100,000 cleanroom with positive pressure. 5. An Environmental Monitoring Program 6. Anteroom separate from cleanroom
<b>Validation Requirements:</b> Process simulation for types of product.	<b>Validation Requirements:</b> Each different compounding process requires three media fill runs initially, then one media fill run annually.	<b>Validation Requirements:</b> Use accepted quality control systems.	<b>Validation Requirements:</b> Baxa recommends following the ASHP, USP and JCAHO standards to validate the process prior to using the Rapid-Fill Automated Syringe Filler.
<b>Environmental Control Guidelines:</b> Class 100 LAF, in a class 100,000 cleanroom with a separate anteroom.	<b>Environmental Control Guidelines:</b> Class 100 LAF, in a class 100,000 cleanroom with a separate anteroom	<b>Environmental Control Guidelines:</b> Prepare products using appropriate pharmaceutical and aseptic techniques.	<b>Environmental Control Guidelines:</b> Baxa Corporation recommends a Class 100 LAF, in a class 100,000 cleanroom with a separate anteroom.
<b>End Product Testing Requirements:</b> End-product sterility sample testing to supplement media fills; a formal, statistically valid sampling plan; acceptance criteria; recall mechanism.	<b>End Product Testing Requirements:</b> Sterility and pyrogen testing, and chemical potency testing for products that require terminal sterilization. Should not release products prior to completing procedures in place.	<b>End Product Testing Requirements:</b> Test according to <i>USP</i> and applicable laws and regulations.	<b>End Product Testing Requirements:</b> Baxa Corporation recommends following the ASHP, USP and JCAHO standards for End Product Testing.

APPENDIX II.

<b>Aseptic Analysis Table for the Rapid-Fill ASF Used in a Standard Class 100 Laminar Flow Hood</b>	
<b><i>Aseptic Issue Concerning Rapid-Fill ASF</i></b>	<b><i>Design Features and Clarification</i></b>
The Rapid-Fill ASF is placed in a Class 100 hood and can cause an interruption of Laminar Flow. ASHP defines this as the shadow effect of a large machine.	The Rapid-Fill ASF is designed to minimize interruptions of laminar flow. The outer case of the machine has contoured lines and air vents, which help direct the laminar flow toward the front of the hood and the sterile filling operation. This also minimizes any eddy airflow effects.
The interior of the Rapid-Fill Syringe has the potential to be contaminated when opening the syringe case outside the hood and loading the machine. The back end of the barrel is open and may be exposed to a contaminated airfield.	Rapid-Fill Syringe Strips are packed in a syringe holder to minimize access to environmental air. Potential exposure to a contaminated airfield is limited to the time that the container is accessed and the Rapid-Fill ASF loaded. During loading, the syringes are inside the laminar flow. Exposure time should be limited to several seconds, and is controlled by user technique. The syringes remain capped during the entire process.
Rapid-Fill Syringes can be filled with any drug solution. Solutions and disposables should be handled using aseptic technique in order to maintain sterility and minimize exposure to contaminants.	The Rapid-Fill System uses only terminally sterilized disposables. With proper sterile technique, sterility should be maintained during the loading of disposables and solutions onto the machine.
Once the solution has been set up there is a potential to contaminate the exposed solution port to be contaminated. The solution port is at the end of the Rapid-Fill Tube Set.	The Rapid-Fill Tube Set transfers solutions from the fill bag to the syringe. The Tube Set spike is capped, maintaining sterility until it is removed for usage. The tube set should be opened in the laminar flow and loaded onto the Rapid-Fill ASF just prior to the start of the filling operation. Using aseptic technique within the laminar flow will maintain fluid path sterility during tset up.
There is a potential for contamination when the Rapid-Fill ASF removes and replaces the syringe tip cap during the filling process.	Rapid-Fill Syringes are provided capped and sterilized – a closed system until the filling process begins. The Rapid-Fill ASF removes the syringe cap and fills in a direct laminar air flow path. Syringe sterility is maintained throughout the filling and capping process. An added benefit of the automation is that it eliminates the potential for touch contamination. The only unfilled syringe that is touched by human hands in each 200-unit run is the one used during the loading process.
The hood can become contaminated from non-sterile product packaging.	The syringe case is bagged. This outer bag is removed before the syringe case is brought to the hood to prevent packaging contamination from being brought to the hood. The syringe box holder is then put in place before the sterile syringes are exposed. Careful handling of the syringe strips and box holder should prevent any contamination of the hood.
If contaminated air moves over the machine before crossing the fill area, it is possible to contaminate the solution during filling.	The Rapid-Fill ASF is designed to maximize laminar flow in the filling area and limit flow interruptions. The outer case of the machine is contoured to direct laminar flow toward the front of the hood and away from the fill area. Sterile filling should be maintained throughout the process.