



# Choosing a Vial Processing Line for Aseptic Compounding: Part 1

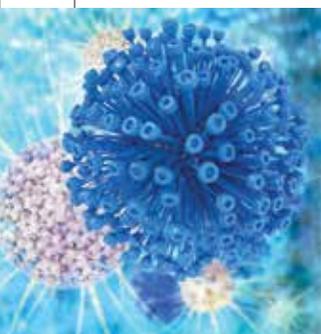


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*This article on the topic of choosing a vial processing line for aseptic compounding is part 1 of a 2-part series. In part 2 of this series, the success of our choice of a vial processing line and its effect on sterile compounding in our facilities will be discussed.*

## ABSTRACT

Equipment systems that enable compliance with stringent state and federal compounding requirements are a topic of increasing interest to U.S. pharmacists. Of those equipment types, an aseptic vial processing line offers unique benefits (especially to 503B compounding pharmacies and small contract manufacturers of aseptic pilot-size batches) if the volume of sterile preparations dispensed offsets the cost of purchase, installation, and maintenance. In this article, the reasons for and the process of selecting an aseptic vial processing line for use in 2 independent 503B compounding pharmacies are presented, the operation of our choice of equipment is described, and specifications for the components of that line are listed. In part 2 of this series, the success of our choice and its effect on sterile compounding in our facilities will be reported.



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The value of a current good manufacturing practice (CGMP)-compliant sterile vial processing line has long been recognized by U.S. compounders and small contract manufacturers of aseptic pilot-size batches, but the footprint and cost of that equipment often render it inappropriate for use in many pharmacy settings. In this article, we describe our reasons for deciding that such equipment would be essential to our newly expanded 503B compounding facilities, the selection of an aseptic vial processing line, the installation of that line, and its operation. Specifications for the components of that line are also listed. The second article in this 2-part series will reveal the success of our choice and its effect on our sterile compounding output, accuracy, efficiency, and cost.

After rigorous due diligence, we both selected the PennTech (PennTech Machinery Corporation, Warminster, Pennsylvania) (Figures 1-4) aseptic vial processing line. That equipment is, in our opinion, unique because it is designed for use in smaller compounding pharmacies and 503B facilities, and its versatility and options for customization yield a CGMP-compliant sterile vial processing line that can be configured to meet specific compounding needs. We both found that having professional assistance for even minor aspects of installation of the line is immeasurably helpful. PennTech can refer customers to a variety of experts who can provide that assistance.

## Shaun Noorian

EMPOWER PHARMACY // HOUSTON, TEXAS

Empower Pharmacy specializes primarily in hormone replacement therapy and age- and weight-management medications. At the time of this writing, we are building a 15,000-square-foot CGMP-compliant 503B outsourcing facility. In our earliest stages of planning that construction, we realized that purchasing new and upgraded types of equipment would be necessary, especially for processing the glass vials used in aseptic compounding. In the past, we manually washed nonsterile vials with sterile water for injection (SWFI) and depyrogenated them in a convection oven. We then removed the depyrogenated vials from their wrappings and manually filled, stoppered, and capped/ crimped them under a laminar flow hood. Because we were dissatisfied with that labor-intensive process, we decided to purchase, for use in our new facility, an automated CGMP-compliant aseptic vial processing line, the results of which can be validated and qualified to meet our exacting standards.

As part of due diligence before that major purchase, we considered aseptic vial processing equipment from several vendors across the globe. We found that some of the lines we evaluated were too expensive for us, had too large a footprint for our facility, or were inferior. Ultimately, we chose the PennTech CGMP-compliant standard compounding vial-processing line, all components of which are constructed of American

Iron and Steel Institute (AISI) stainless steel. In our 503B sterile compounding pharmacy, that equipment will be used to wash (the RW-250 unit) (Figure 1), depyrogenate (the PST-30/160 unit) (Figure 2), and fill, stopper, and cap/crimp (the FSC-1R unit) (Figure 3) our borosilicate glass serum vials that range in size from 2 mL to 30 mL. The installation process of the line is described later in this section of the article. A complete PennTech aseptic vial processing line is shown in a cleanroom in Figure 4.

## ADVANTAGES AND DISADVANTAGES OF AN AUTOMATIC STERILE VIAL PROCESSING LINE

If the volume of sterile preparations processed is high enough, the advantages of purchasing an automatic aseptic vial processing line are many, but caveats also exist.

### Advantages

In our opinion, the PennTech aseptic vial processing line, when compared with similar equipment, offers several advantages, including:

### CUSTOMIZATION

The PennTech line can be configured in a variety of ways to meet the unique needs of a specific compounding facility. For example:

- The line can be configured to process glass vials as small as 2 mL and as large as 100 mL.
- The vial output speed can range from 20 to 70 vials per minute, according to vial size.
- The vial washer can be networked with a printer to output logged batch results.
- The vial washer has the option to be manufactured with a special tank that is attached to hold SWFI, or a separate water supply skid is available.
- The RW-250 can be mounted on casters to facilitate repositioning if purchased as a standalone unit.
- Validation documentation and testing include functional requirements specification, design specifications, installation qualification, operational qualification, factory acceptance test (FAT), and site acceptance test (SAT).
- An optional electronic log can track any out-of-specification events that occur during the production cycle in any component of the vial processing line (this renders the processing line compliant with *Code of Federal Regulations [CFR] Title 21*).
- The depyrogenation chamber entrance can be adjusted for each vial height to minimize heat loss.
- The filling weights of vials can be automatically check-weighed and adjusted by the FSC-1R.
- The FSC-1R can be mated to an International Organization for Standardization (ISO) Class 5 restricted access barrier system so that the FSC-1R can be placed in an ISO Class 7 room instead of an ISO Class 5 room.

**FIGURE 1. The PennTech Rotary Vial Washer Model RW-250.**

PHOTOGRAPH COURTESY OF PENNTECH MACHINERY CORPORATION, WARMINSTER, PENNSYLVANIA.



### PennTech Rotary Vial Washer Model RW-250

Vials processed in the PennTech vial washer model RW-250 meet *United States Pharmacopeia* standards and comply with CGMP regulations stipulated by the U.S. Food and Drug Administration (FDA). The RW-250 has 8 vial holders that are made of AISI 316L stainless steel and hold each vial at the neck. Depending on the vial format, up to 6 vials can be placed in the vial holder. There are no springs, grippers, or other moving parts that generate particulates. The throughput of the RW-250 is usually 20 vials/min to 70 vials/min, and the usual batch size processed ranges from 1000 vials to 8000 vials. The size of vials that can be processed in the RW-250 ranges from 2 mL to 100 mL (glass or plastic), but change parts are required. The RW-250 has 6 stations for water (deionized/reverse osmosis, water for injection [WFI]) and sterile-air blowing. If bagged WFI is used, a WFI skid with an 80-L tank is available with a heating element that can increase the WFI temperature as high as 80°C. The skid includes a sanitary centrifugal pump that provides the vial washer with 73 psi (5 bar) of water pressure. Clean vials are discharged from the RW-250 onto a tray for further processing.

### SPECIFICATIONS

**DIMENSIONS:** 1139 mm × 1270 mm  
44.8" × 50" (tray-size dependent)

**WASHING CHAMBER:** 600 mm × 600 mm (23.6" × 23.6")

**WORKING SURFACE HEIGHT:** 900 mm (approximately 35")

**PLC:** Allen-Bradley (Rockwell Automation, Inc., Milwaukee, Wisconsin) MicroLogix 1400

**HMI:** Allen-Bradley PanelView C400

**VIAL RANGE:** 2-100 mL, glass or plastic

**MAIN-DRIVE:** Servomotor

**OUTFEED MECHANISM:** Air cylinder

**WASHING CHAMBER COVER:** Transparent acrylic

**CONTACT PARTS:** Electropolished AISI 316L steel

**SANITARY PIPING:** Electropolished AISI 316L stainless steel

**MACHINE FRAME:** 1½"-AISI 304 stainless steel

**PANELS AND COVER:** AISI 304 Stainless steel

**INFEED:** Semiautomatic

**\*RTD:** Chicago Stainless (Chicago Stainless Equipment, Inc., Palm City, Florida)

**\*PRESSURE TRANSMITTERS:** Dylux (Dylux Corporation, Grand Island, New York).

**WATER CONSUMPTION:** 5-10 L/min (approximately 1.5-2.5 GPM); vial-size dependent (subject to selected washing program)

**UTILITY REQUIREMENTS:** USA: 120-V AC, single-phase, 60-Hz (receptacle plug provided), 2-kW, 20-amp dedicated circuit

**International:** 240-V AC, single-phase, 50-Hz, 2-kW, 10-amp dedicated circuit (requires field wiring)

Instrument air @ 8-bar, 120 psi; regulated point of use, 70-80 psi; 8-mm tube instrument air connector (A pressure regulator is provided on the equipment for regulating the instrument air pressure.)

**HEAT REJECTION:** 80°C for RO and WFI, 6000 BTU/hr max

**RO/WFI DRAIN:** Machine flushing is performed only at the beginning of the batch for 15-30 sec. Instantaneous flow rate, 7.5 GPM when flushing machine  
Average flow rate, 3.0 GPM (The average flow rate is based on 15 indexes/min, 1.5-sec spray time per index.)  
A 2" sanitary triclamp connector is provided.

**WEIGHT:** 300 kg (approximately 660 lb)

**MADE IN:** Warminster, Pennsylvania

\*Subject to change

AISI = American Iron and Steel Institute; HMI = human-machine interface; PLC = programmable logic controller; RO = reverse osmosis; RTD = resistance temperature detector; WFI = water for injection

- The output tray of the FSC-1R can be mated to an automatic lyophilization loading/unloading system to enable handsfree operation.

Before the initial payment for the equipment is made, all customizations needed at the time of purchase—and those that will be required in the future—should be identified.

## COST

Because CGMP-compliant aseptic processing equipment requires a large initial investment, its total cost should be considered before purchase to determine its cost-benefit ratio in a specific sterile compounding facility. Although a complete uninterrupted sterile processing line is the preferred method for processing aseptic dosage forms, the RW-250 and FSC-1R can be purchased as separate standalone units if space or funds are limited. If funds are not available at the time of purchase, PennTech offers financing to reduce the amount of the initial payment and defer the remaining payments over time.

## READILY AVAILABLE EXPERT HELP

The purchase price of the PennTech line includes a 2-year maintenance plan, and expert help from that manufacturer is readily available. When the maintenance plan is in effect, PennTech will, at its expense, send a technician to the facility biannually to inspect all equipment and ensure that it is functioning

**FIGURE 2. The PennTech Sterilizing/Depyrogenation Tunnel Model PST-30/160.**

PHOTOGRAPH COURTESY OF PENNTECH MACHINERY CORPORATION, WARMINSTER, PENNSYLVANIA.



## PennTech Sterilizing/Depyrogenation Tunnel Model PST-30/160

The PST-30/160 consists of a preheating chamber, a sterilizing chamber, and a cooling chamber. Vials are fed into the sterilizing/depyrogenation tunnel from the vial washer via a sanitary conveyor before they are gently pushed into the tunnel by an oscillating pusher. No format parts are required, and no operator intervention is necessary.

## SPECIFICATIONS

**DIMENSIONS:** 1550 mm × 1239 mm × 2245 mm; 61”L × 48.8”W × 88.4”H

**WORKING SURFACE HEIGHT:** 900 mm (approximately 35”)

**PLC:** Allen-Bradley (Rockwell Automation, Inc.) CompactLogix

**HMI:** Allen-Bradley PanelView Plus 1000

**BELT WIDTH:** 300-mm (approximately 12”) AISI 304 stainless steel

**BELT DRIVE:** Frequency-controlled AC motor

**AIR FLOW IN CHAMBERS:** Automatically adjusted

**AIR PRESSURE IN CHAMBERS:** Monitored and automatically adjusted

**DOP IN BOTH CHAMBERS:** Included

**VIAL CONTACT PARTS:** AISI 304 Stainless steel

**MACHINE FRAME:** AISI 304 Stainless steel

**PANELS AND COVER:** AISI 304 Stainless steel

**ELECTRICAL CABINET:** Enclosed in the machine frame

**DOOR HEIGHT SETTINGS:** Manual

**DISCHARGE LAST ROW OF VIALS:** Manual

**HEATING ELEMENTS (10X):** 1.5 KVA each; silicone-controlled rectifier

**TIME TO HEAT TO 300°C:** Approximately 30 min

**WORKING TEMPERATURE:** 290°C-320°C (max, 350°C)

**PRESSURE TRANSMITTERS:** Duwei (Hefei Duwei Instruments S&T Co., Ltd., Hefei, Anhui, China)

**UTILITY REQUIREMENTS:** USA: 480-V AC, 3-phase, 60-Hz (field-wired by customer), 20-kW, 50-amp dedicated circuit 208-V AC, 3-phase, 60-Hz (only if requested, 20-kW, 70-amp dedicated circuit

International: 400-V AC, 3-phase, 50 Hz (field wired), 20-kW, 50-amp dedicated circuit

**HEAT REJECTION:** 55,000 BTU/hr, max

**EXHAUST:** Max flow rate, 1650 cfm  
Average exhaust temperature, 30°C  
Exhausted into room within footprint of machine (no external connection needed).

**WEIGHT:** Approximately 1300 kg (2870 lb)

**MADE IN:** Warminster, Pennsylvania

AISI = American Iron and Steel Institute; DOP = dispersed oil particulate testing of filter systems; HMI = human-machine interface; PLC = programmable logic controller

properly. PennTech staff also have Internet access to the components of the line during its operation; this facilitates troubleshooting.

After the initial maintenance plan has expired, we'll purchase an additional maintenance agreement because, in our opinion, PennTech staff are best able to ensure the correct operation, maintenance, and repair of the equipment.

### CGMP COMPLIANCE

Using an automatic aseptic vial processing line yields CGMP-compliant results that can be quantified and validated and helps ensure the sterility and effectiveness of the compounds prepared, all of which are indispensable aids for best practice.

### ACCURACY AND SPEED OF OPERATION

Large batches of vials can be cleaned, depyrogenated, and filled, stoppered, and capped/crimped more quickly and accurately than hand processing allows, and the safeguards of automated operation reduce the likelihood of contaminating medications. In addition, pharmacy technicians are free to perform the compounding tasks for which they are trained, and staff time can thus be better spent.

### GUARANTEES

PennTech warrants its equipment for 2 years against material or manufacturing defects or for 4000 production hours, whichever occurs first. Before shipping the line, PennTech will also perform, at PennTech headquarters and in the presence of the purchaser, an FAT to validate the function of each component and will assume the responsibility for crating, shipping, and

*“... pharmacy technicians are free to perform the compounding tasks for which they are trained, and staff time can thus be better spent.”*



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**FIGURE 3. The PennTech Filling, Stoppering, and Capping/Crimping Machine Model FSC-1R.**

PHOTOGRAPH COURTESY OF PENNTECH MACHINERY CORPORATION, WARMINSTER, PENNSYLVANIA.



## SPECIFICATIONS

**DIMENSIONS:** 940 mm × 1296 mm × 2508 mm; 37" L × 51" W × 98.8" H with a 24" (laminar air flow unit optional)

**WORKING SURFACE:** 900 mm (approximately 35")

**PLC/HMI:** Allen-Bradley (Rockwell Automation, Inc.) CompactLogix, PanelView Plus 600

**VIAL RANGE:** 2-100 mL, glass or plastic

**MAIN-DRIVE:** Servomotor

**SAFETY ENCLOSURE/RABS:** 0.25" Thick safety glass

**LAMINAR AIR FLOW HOOD:** 280-W, Single source, 120-V, 60-Hz  
Magnehelic differential pressure gauge (Dwyer Instruments, Inc., Michigan City, Indiana); speed controller on blower box

**CONTACT PARTS:** AISI 316L stainless steel

**MACHINE FRAME:** 2" AISI 304 stainless steel

**PANELS AND COVER:** AISI 304 Stainless steel

**ELECTRICAL PANEL:** Included in machine base

**UTILITY REQUIREMENT:** 208/240-V AC, 3-Phase, 60-Hz (field-wired by customer), 3.5-kW, 30-amp dedicated circuit

Sterile-air 8-bar (120 psi) regulated point of use; 50 psi/flow rate, 0.25 scfm

8-mm Tube instrument air connector

(A pressure regulator is provided on the equipment for regulating the instrument air pressure.)

**WEIGHT:** Approximately 544 kg (1200 lb)

**MADE IN:** Warminster, Pennsylvania

AISI = American Iron and Steel Institute; HMI = human-machine interface; PLC = programmable logic controller; RABS = restricted access barrier systems

insurance during transit. After all equipment has been delivered and installed in the purchaser's compounding facility, PennTech technicians will perform an SAT to confirm the correct setup and function of the equipment, utility connections, selected vial format(s), safety guards, and the emergency shutoff and will also ensure that each component's construction meets its specified (and needed) requirements. If a repair is needed, PennTech will send technicians to repair the unit on site.

## Disadvantages

There are disadvantages to purchasing an aseptic vial processing line, one of which is the substantial initial investment. Dispensing a certain volume of sterile compounds must be guaranteed so that continual operation of the equipment is ensured and its cost is justified. For relatively smaller sterile batches, using an automatic vial processing system is more expensive and time consuming than performing necessary tasks by hand. Also, the performance of each component of an automatic line must be observed and verified by an operator. Processing different vial sizes requires a changeover of parts, which, if the PennTech line is used, usually requires about 15 minutes. In addition, the amount of electricity used to operate the line and the waste heat from the sterilization tunnel that is released into the cleanroom during vial processing must be carefully considered when the viability of that equipment in an existing or future cleanroom is determined.

### PennTech Filling, Stoppering, and Capping/Crimping Machine Model FSC-1R

The FSC-1R is an intermittent-motion filling, stopper-inserting, and capping/crimping machine designed for aseptic applications in a Class 100 environment. The size of vials processed ranges from 2 mL to 100 mL, and the average output is 15 vials/min to 30 vials/min. The FSC-1R has 1 filling nozzle, a stopper-inserting station, and a capping/crimping head for aluminum caps. It is equipped with an Allen-Bradley (Rockwell Automation, Inc.) programmable logic controller and human-machine interface.

**FIGURE 4.**  
The complete  
PennTech  
aseptic vial pro-  
cessing line in a  
cleanroom.

PHOTOGRAPH  
COURTESY OF FUSION  
IV COMPOUNDING  
PHARMACY, LOS  
ANGELES, CALIFORNIA.



## Fail-Safes and Alarms

The PennTech line is equipped with sensors on every component involved in processing vials from the beginning to the end of the cycle. If any of those sensors indicates a value that is out of specification, the operator is immediately notified by a display on the unit and an audible warning. If a major problem is identified, the entire line will shut down before damage to the equipment occurs or the vials in process are compromised.

## Technical Support from the Manufacturer

At the time of this writing, all PennTech commitments to us have been fulfilled, and their response to our questions and problems that rarely occurred has been excellent. We are looking forward to purchasing additional equipment from PennTech as our new compounding facility increases its output.

## INSTALLING THE PENNTECH LINE AT EMPOWER PHARMACY

Our water, sterile-air, and electrical hookups were in place and ready before our PennTech line was delivered. The installation and testing of the line required 2 weeks. During that time, PennTech staff performed the SAT, the first step of which involved validating the sterile vial washer. We supplied water, scales, and riboflavin (which, during the SAT, was used to contaminate the test vials processed in the washer), and the PennTech staff brought their own testing equipment. Postwash examination of the test vials under an ultraviolet light revealed no remaining riboflavin.

The next step involved validating the depyrogenation tunnel. Temperature probes positioned in test vials and in the tunnel showed that the temperature was uniform throughout. Then the depyrogenated test vials were processed in the filling, stoppering, and capping/crimping unit, and each of those functions was tested for each

## OTHER PREPURCHASE CONSIDERATIONS

Other factors that should be reviewed before an aseptic vial processing line is purchased include the staff training required, ancillary purchases, space requirements, maintenance, the fail-safes and alarms provided, and accessibility to technical support from the manufacturer.

### Necessary Staff Training

Because the training required to run an automatic aseptic vial processing line is complex, only operators who are technically competent must be selected to perform that task. PennTech offers training during the FAT and again during the SAT when PennTech experts are installing and validating the equipment. Intermittent training is provided as needed. PennTech staff can be easily reached by phone during working hours to help find a solution to problems that might arise.

### Ancillary Purchases

Installing an aseptic vial processing line requires ancillary equipment such as a water purification system and a clean

dry air compressor. PennTech referred us to other vendors for those purchases, which were seamlessly integrated with the PennTech components. We bought a type 2 reverse osmosis water system, which supplies a grade of water that is economical and validatable, to supply the preliminary spray in our vial washer, and we decided to use bagged SWFI for the final rinse, which is supplied from a tank attached to the washer. We also bought a JUN-AIR (JUN-AIR/Gast Manufacturing, Inc., Benton Harbor, Michigan) clean dry air compressor. Those additional purchases will enable us to achieve online operation of our vial processing line.

### Space Requirements and Maintenance

The PennTech vial processing system has a very small footprint (50% to 75% of that required by the next most compact similar equipment), which is ideal for our new facility. Little maintenance is required because the PennTech line has very few moving parts, which are servomotor driven rather than gear driven. When our line is fully operational, appropriate intervals for all other scheduled maintenance will be determined.

size vial. Only 2 problems occurred during the installation of the line, and both involved the filling, stoppering, and capping/crimping unit. During the 10-mL fill-volume test, the fill was, on average, within 1%, but PennTech standards require a standard deviation of no less than 0.5%, so the unit was recalibrated. Also, that unit had to be recalibrated to seal the lyophilization stoppers properly (a problem likely due to the use of sterilized stoppers, which were not available at the FAT). PennTech staff quickly resolved those problems.

PennTech has an excellent staff of support personnel and engineers who will help a compounder select needed equipment and provide advice about how to get those machines working. To complement that assistance, we engaged Kamy Behzadi, a regulatory, quality, and CGMP consultant, to help us integrate the delivered equipment into our facility and confirm that the plumbing and wiring had been correctly installed.

## USING THE PENNTECH ASEPTIC VIAL PROCESSING LINE

During sterile vial processing in our new 503B facility, nonsterile glass vials will first be placed by the operator into the RW-250 vial washer, where the interior and exterior of each vial will be rinsed multiple times. The cleaned vials will then be automatically pushed onto the belt of the PST-30/160 unit, which will move them through the depyrogenation tunnel at a temperature that ensures depyrogenation within minutes. The depyrogenated

batch will be cooled by forced air and conveyed from the belt of the PST-30/160 onto the FSC-1R feed turntable and then into a star wheel that will move each vial to each of the several consecutive stations for filling, weighing (optional), stoppering, and capping/crimping. Appropriately processed capped/crimped vials will then be automatically pushed out onto a collection tray, and any vials that were out of specification during that cycle will be deposited into a “reject area.”

The capping/crimping process can be skipped for vials destined for lyophilization. In that case, trayed vials will be loaded into the lyophilizer by the operator. After lyophilization, those vials will be placed back into the FSC-1R for final capping/crimping. After the capping/crimping process is complete, lyophilized or liquid-filled vials will be placed into a bin for removal from the cleanroom, after which they will be labeled and must pass our quality-control procedures before being dispensed to the end user.

We've determined that this automatic process is faster, more effective, and more accurate than manually processing sterile glass vials.

## PROJECTIONS FOR THE FUTURE OF ASEPTIC COMPOUNDING

In the compounding industry, it is always wise to think of the future. I suggest that all sterile compounding facilities and 503B outsourcing facilities move away from United States Pharmacopeia (USP) Chapter <797> standards and toward

CGMP compliance to ensure a stable practice because U.S. sterile compounding restrictions are likely to become more stringent over time. In my opinion, state boards of pharmacy and federal agencies will continue to investigate sterile compounding facilities with increasing vigor, and compounding pharmacists will face ever-greater challenges in complying with evolving regulations. Purchasing an aseptic vial processing line is just 1 piece in the puzzle of achieving that compliance, but it is a very important piece. The risk of not investing in such equipment is greater than the cost of doing so.

At Empower Pharmacy, we want to ensure that our patients and practitioners receive only the highest quality medications, and the purchase of our aseptic vial processing line is essential to achieving that goal. PennTech has been a great partner in helping us find solutions to new and current challenges in sterile compounding, and I will definitely purchase future upgrades from them.

Readers who are interested in viewing the assembly, installation, and operation of our PennTech vial processing line in a real-time working pharmacy environment are invited to visit the Empower Pharmacy website<sup>1</sup> to access professionally filmed videos of those events as well as the complete construction of our new outsourcing facility from the ground up. In those videos, we'll highlight the equipment, facilities, and processes required to ensure that a 503B compounding facility is CGMP compliant.

## Navid Vahedi, BSc, PharmD

FUSION IV COMPOUNDING PHARMACY // LOS ANGELES, CALIFORNIA

At Fusion IV Compounding Pharmacy, we are working to become a full-service 503B-compliant facility specializing in sterile patient-specific preparations. As all U. S. pharmacists know, compounding is changing as the regulatory authority of the FDA increases, especially since the New England Compounding Center tragedy

underscored the hazards of large-scale sterile compounding performed with irresponsible oversight. The increasing state and federal compliance required of 503B facilities will ultimately help ensure a greater number of safe and effective compounds for patients. Meeting those regulations will also enable a new and potentially lucrative source of business for pharmacists interested in specialty manufacturing. Although, in my opinion, many smaller sterile compounding pharmacies will not pursue the challenging 503B business model, I welcome

it and future such challenges to better serve our clients and our physician prescribers.

To ensure that our rigorous standards at Fusion IV meet exacting FDA safety and purity requirements, we decided that an upgrade in our aseptic compounding equipment was necessary. We considered no sterile vial processing line other than PennTech because several of our compounding colleagues have purchased that equipment and are satisfied with its performance. The usual interval from the time of purchase of that line until its operation begins is 10 to 12 months, but 12 to 18 months may be needed. Our PennTech system was installed in our 503B compounding facility in February 2016, and we'll process thousands of vials each week to meet our sterile compounding volume.

I'd suggest that purchasers work with a contractor who understands their goals and objectives as well as the necessary requirements for becoming a 503B compounding pharmacy, if achieving that status is of interest. Compounders who need assistance with that or with installing the PennTech line can obtain that help from Jim Kolbet at ProPharma Group (Overland Park, Kansas).

The PennTech aseptic vial processing line is manufactured in the U.S., and we consider that one of its many advantages, in addition to the following benefits:

- Its results are superior to those of autoclaving, which does not provide dry heat at the elevated temperature necessary for depyrogenation.
- It reduces the need for human interaction with the vials and thus decreases the likelihood of error and contamination.
- Its use saves valuable staff time that would be otherwise devoted to manually processing sterile vials.
- It eliminates the expense of purchasing presterilized vials.
- It will offer a return on investment—true cost savings—if the volume of sterile compounds dispensed is high enough. (If all goes as planned, our PennTech aseptic vial processing system should pay for itself within 6 to 12 months after we begin to use it.)
- It can be purchased with an optional *CFR-Title 21*-compliant package.
- It can be customized; for example:
  - Change parts permit the processing of a variety of vials sizes.
  - The filling, stoppering, and capping/crimping unit can be programmed to insert a stopper halfway into each vial that will be lyophilized or to prepare either unstoppered sterilized vials or stoppered unfilled depyrogenated vials that can be stored for future use in an ISO Class 5 cleanroom.
  - The PennTech line is available in several sizes. We purchased the RW-250 vial washer, the PST-30/160 model depyrogenation tunnel, and the FSC-1R filling, stoppering, and capping/crimping machine because they best suit our needs.
  - The configuration of the entire vial processing line can be scaled to accommodate the space requirements and output required in a specific compounding facility.

- It can also be used to:
  - Net-weight fill-check the vials during processing.
  - Perform a nitrogen purge overlay for preparations sensitive to oxygen.

## INSTALLING THE PENNTECH LINE AT FUSION IV COMPOUNDING PHARMACY

A pharmacy's dedicated capabilities for loading and unloading equipment dictate whether the purchaser of the PennTech line must make special parking arrangements during the delivery or arrange to receive the equipment before working hours begin. (We scheduled delivery before our pharmacy opened in the morning.) This PennTech equipment must be installed by individuals who understand both machinery and computers.

Compounders can expect delivery of the 3 PennTech units via truck. The smallest and easiest unit to maneuver is the vial washer, and the most difficult is the depyrogenation tunnel. A forklift is required to lift the units, which are crated and are on pallets, from the delivery truck onto the ground. The purchaser should hire a rigging



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for All Applications**

**Laboratory Pilot Commercial**

<ul style="list-style-type: none"> <li>■ <b>LyoRenewal - Upgrades and Remediation</b></li> <li>■ <b>Innovative Technologies - Superior Design</b> <ul style="list-style-type: none"> <li>■ HyPro Condenser</li> <li>■ Rotary Disc Valves</li> <li>■ Energy Saving LN2 Refrigeration</li> <li>■ Smart Cool</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Faster Validation with Data Rich Documentation &amp; Support</b></li> <li>■ <b>Aseptic Vial Processing - Low to High Speed</b></li> </ul>
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company that specializes in the movement and placement of heavy machinery to remove the equipment from the truck and transport it into the pharmacy.

In our case, the rigging company staff and I met the delivery truck at my facility. When the riggers removed the units from the truck and placed them in position on the ground, my quality assurance (QA) manager, my cleanroom staff, and I uncrated that equipment, which was then moved by the riggers into our cleanroom. My QA manager and I used a pallet jack to place each unit in its final position and assemble them together. During that process, we had a few issues that were quickly resolved by PennTech. For example, each of the 3 units was manufactured independently, and the units were not fitted together before we received them. The dead plate from the depyrogenation tunnel to the FSC-1R (the filling, stoppering, and capping/crimping unit) was not long enough and did not line up accurately enough to permit its being tightly joined to the tunnel. We also had an issue with both conveyor belts. The brackets of the first belt (which connects the vial washer to the tunnel) and the second belt (which connects the tunnel to the dead plate that meets the FSC-1R) were slotted horizontally rather than vertically, so we were not able to adjust the belts up and down as needed. PennTech responded immediately to those issues by sending us new brackets and a new dead plate, all of which were what we needed. We've found that PennTech experts, who can remotely access our vial processing line via an Internet connection and troubleshoot problems, are readily available if problems occur.

After the line was in place, we addressed electrical requirements, the water supply, and the sterile-air supply. We hired an electrician who could install 3-phase power if necessary to tie the electrical wiring in the pharmacy into the tunnel. We also hired a plumber to install the plumbing necessary to operate the vial washer and supply the deionized/reverse osmosis water required. A company like the ProPharma Group (Overland Park, Kansas), which has an alliance with PennTech, can be very helpful in ensuring that appropriate water, sterile-air supplies, and electrical wiring are correct and in place. In

retrospect, I would have hired ProPharma to undertake those tasks.

If the full aseptic vial processing line is purchased, PennTech sends staff to the facility for 2 weeks to perform the onsite SAT to ensure that everything is on line and operates correctly. To assure the best possible operation of the line, we hired an FDA consulting group; their experts (who were present during the SAT) understand laboratory construction and requirements for 503B compounding facilities as stipulated by the FDA. They helped us resolve a few issues with documentation, and our SAT had a successful result.

For me, the experience of selecting and installing a CGMP-compliant aseptic vial processing line has been very fulfilling and educational, and it has opened my eyes to a whole new world of compounding that I didn't know was possible.

## ADVICE TO COLLEAGUES

Although purchasing the PennTech line was a substantial expense, we see no disadvantage to our having done so and no reasons for which that equipment cannot be afforded by any 503B compounding facility. To ensure the safety of sterile compounds, at least the automatic vial washer should be purchased because other methods of washing vials rarely meet FDA CGMP regulations.

Before they purchase an aseptic vial processing line, my colleagues should thoroughly understand how to select, install, operate, maintain, and monitor that complex but very effective equipment. Addressing the details (electrical, sterile-air, and plumbing requirements; hiring a rigging company; designing the space for the line; installing the equipment; ensuring that the operational line meets all required state and federal standards) is very important.

I have nothing negative to say about PennTech. In spite of the effort required, I'm very happy with our purchase, and the PennTech staff are fantastic; they are wonderful to work with. My only regret is that I didn't purchase a larger line, but we'll discuss that with PennTech in the future.

## CONCLUSION

Meeting the unique challenges of aseptic compounding, which increase in scope and number as both state and federal oversight become more rigorous, requires novel solutions. The PennTech aseptic vial processing line that we describe in this article is distinctive because it can be customized to meet the preferences of the pharmacy owner and the needs of his or her compounding facility while meeting USP standards, CGMP regulations, and, if requested, CFR-Title 21 requirements. It is designed specifically for use in pharmaceutical compounding, and its

relatively small footprint, various assembly options, validatable performance, and comparatively lower cost render it one-of-a-kind equipment for use in smaller and larger sterile compounding facilities. It is our hope that the information we have provided in this article will be helpful to compounding pharmacists who want to ensure the quality and safety of their sterile preparations.

## ACKNOWLEDGMENTS

The authors thank PennTech Machinery Corporation for providing content for this article.

The International Journal of Pharmaceutical Compounding appreciates the research and assistance of Jane Vail (St. Louis, Missouri) in compiling and coauthoring this first of a 2-part article.

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