



Selecting an Incubator for Your Health-System Pharmacy

AN INTEGRAL PART OF YOUR FACILITY'S USP <797>-compliant compounding operations, an incubator is required for processing your environmental monitoring, personnel media-fill, and process-verification units. When selecting an incubator or controlled temperature chamber for a hospital pharmacy, keep in mind the following:

- USP <797> compliance
- the intended application
- temperature monitoring equipment for the incubator

These requirements should be evaluated for both the short- and long-term use of the incubator to yield a compliant, convenient piece of equipment that meets the buyer's needs.

USP <797> Compliance

USP Chapter <797> requires that pharmacy equipment be calibrated, maintained, and able to run consistently within specifications. Standard operating procedures should be written to control each of these tasks. Written procedures should include:

- how to operate the equipment
- calibration of the equipment
- checking that the equipment is running properly and what to do if it is not
- monitoring of proper operation
- preventative maintenance

While these procedures cannot be written until an incubator is selected, they should be kept in mind while choosing the right model. Look at the design of the incubator and ask the following questions:

- Will this model be easy to clean and maintain?
- Can it be easily calibrated?
- Is it easy to operate?
- Will it be able to perform within my specifications?

These questions should help find a design that meets the pharmacy's needs and achieves <797> compliance.

General Purchase Considerations

Size is the first point to consider when choosing an incubator for a

hospital pharmacy. The capacity of the incubator you choose to purchase should be determined by the materials that you intend to hold in the incubator. Think about the maximum amount of media that will require incubation at one time and whether this amount is likely to increase in the future. In addition, the shelving should be adjustable to accommodate materials of varying heights.

After the capacity needs are met, the

exterior dimensions of the incubator need to be considered. The incubator needs to be situated so that it does not hinder workflow. Many incubators require at least a 2-inch clearance from a wall that is free from strong air currents and any extreme temperatures.

The temperature range of the incubator must at least include the range of its intended use. The incubator's temperature controller should have a resolution small enough to accommodate the specified range of use. For example, if the incubator has settings in 10° increments, maintaining a temperature range of 30° to 35°C may be difficult. Digital settings will provide more accurate settings than

their analog counterparts.

A number of options are available for the type of incubator you wish to purchase. Because anaerobic incubation is not required by <797> at this point, the incubator does not need to be CO₂ capable. Both circulating or non-circulating incubators are also available. Circulating incubators blow air of the appropriate temperature throughout the incubator chamber. This method allows the incubator to reach the intended temperature more quickly and can reduce cold or hot spots in the chamber. Water-jacketed incubators surround the chamber with water to promote a uniform temperature in the chamber and may provide humidity control. The extra water weight in the water-jacketed incubator can be a disadvantage as these incubators are very heavy and difficult to move. In



Photos courtesy of Fisher Scientific

addition, the water must be maintained and monitored on a regular basis. If humidity is an issue, adding a pan of water in a regular incubator will also work. As with the water in the water-jacketed incubator, the water in the pan requires maintenance such as checking the level, cleaning, adding an antimicrobial agent, and monitoring for microbials.

The manufacturer requirements for the incubator should be considered before the purchase of the incubator. In addition to manufacturer requirements for wall clearance and placement in a draft-free area, there are also electrical requirements. Your facility's electrical capabilities should be at least equal to those needed by the incubator. Check the specified amperage, voltage, phase, and hertz for the incubator. The breaker box in your facility should indicate what is available. A three-pronged outlet is a necessity; check that one is available in the area where you will place the incubator.

The incubator's construction should be checked to make sure it is made of materials that are non-shedding, non-permeable, and will not corrode as per GMP. Incubators are not typically made of materials that shed particles or that are permeable to air or liquids, but these requirements should be kept in mind nonetheless. This will also aid in maintaining and cleaning the incubator. Check that your in-house cleaning agents are compatible with the materials the incubator is constructed of. In particular, sporocides may have corrosive properties. Follow the manufacturer's cleaning instructions to ensure the incubator will not be adversely affected.

Temperature Monitoring Equipment

USP <797> requires temperature monitoring of controlled storage areas, including incubators. The temperature needs to be recorded at least once per day in a log. A temperature device that simply displays the temperature or one that also records it may be used to check the incubator's temperature. The recorder will also need to be checked daily to ensure the temperature is still within speci-

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Compounding Operations



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USP <797> requires temperature monitoring of controlled storage areas, including incubators.

cations. That information must then be recorded on the log.

Thermometers can be recorded manually. They are inexpensive and easy to maintain, but cannot provide temperature information between readings. Continuously recording equipment is available, including chart recorders and data loggers. Chart recorders track the temperature of the incubator, and the information is immediately available. Data loggers collect information that can be downloaded to a computer. Some models are capable of wireless transmission. The benefits of continuous recording by the data loggers and chart recorders must be weighed against the increase in expense and the effort involved in their maintenance.

The same specifications of size, temperature, manufacturer requirements, and appropriate materials need to be considered when purchasing a temperature device for the incubator. If it is an immersion instrument, the temperature device should fit into the incubator, or it should have a probe if it is intended for use outside the incubator. Make sure the incubator has a port for the probe to fit through if the device is to be kept outside of the incubator. Placing the probe or thermometer in glycerol will minimize the effects of brief temperature changes – such as those that occur when you open the incubator door – and will mimic the temperature of the materials in the incubator. Some incubators come with a thermometer or a

recorder already built in. Make sure that the built-in temperature devices are able to read in increments small enough to verify the acceptable temperature range in the incubator, as defined by the pharmacy's written procedures. If the device records continuously, the power source should be compatible with the facility's electrical requirements or could be from a battery. Many recorders will have a battery backup in case the electrical power fails. As with the incubator, the temperature device should be non-shedding, non-permeable, and non-corrosive so that it is easy to clean and maintain. The same requirements for incubators themselves apply to their supporting pieces of equipment: they must be calibrated and maintained, and work within specifications. They also require written procedures on use, calibration, and preventative maintenance.

Conclusion

Selecting an incubator to complement your pharmacy's <797>-compliant compounding operations does not need to be a daunting task. By following the guidelines established in this article and by taking into account your pharmacy's needs for an incubator, you will be able to choose a piece of equipment that operates properly on a consistent basis. ■

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WHERE TO FIND Incubators:

Vendor	Reader Service Number
Best Lab Deals	51
Fisher Scientific	52
Forma Scientific, Inc./Thermo Electron Corporation	53
NuAire	54
VWR International	55