

Self-Assessment Test

Current Considerations for Outsourcing Pharmacy Sterile Preparations Compounding Services: Quality, Safety, and Selection

This program is located at <http://ashpmedia.org/symposia/outsource>



This self-assessment test has been provided as a study aid only. At the conclusion of the internet-based program, click on "Take CE Test" to proceed to the ASHP Learning Center and take the on-line program post-test. You may print your CE statement immediately after successful completion of the post-test.

There are a total of 23 questions associated with this self-assessment test.

1. In the most recent (2005) ASHP national survey of pharmacy practice in hospital settings that addressed dispensing and administration, the percentage of respondents who outsourced intravenous (i.v.) admixture preparation was:
 - a. Less than 10%.
 - b. Greater than 40%.
 - c. Approximately 60%.
 - d. More than 90%.

2. In a consensus conference on i.v. delivery system safety conducted in August 2008 in which five i.v. delivery systems were ranked for applicability, ease of use, regulatory compliance, cost, safety, and implementation using a Likert scale from 1 for "very weak" to 7 for 'very strong', outsourced ready-to-use (RTU) systems were ranked:
 - a. Highest followed by manufacturer RTU, point-of-care activated, pharmacy compounded, and non-pharmacy compounded at point of care systems.
 - b. Second highest after manufacturer RTU systems.
 - c. Second highest after pharmacy compounded systems.
 - d. Fourth highest after manufacturer RTU, point-of-care activated, and pharmacy compounded systems.

3. In the consensus conference on i.v. delivery system safety conducted in August 2008, which of the following was rated highest for outsourced RTU systems?
 - a. Cost.
 - b. Ease of use.
 - c. Regulatory compliance.
 - d. Safety.

4. Between 2002 and 2005, there was a decrease in the percentage of hospitals outsourcing which of the following types of sterile preparations?
 - a. Analgesic preparations.
 - b. Flush solutions.
 - c. Intravenous admixtures.
 - d. Parenteral nutrition.



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5. Which of the following is a potential disadvantage of outsourcing sterile product preparation?
 - a. The inability to outsource complex preparations.
 - b. The increase in personnel requirements.
 - c. The unwillingness of providers to prepare low-volume items.
 - d. The variable quality of providers.

6. Which of the following statements about the implications of outsourcing sterile product preparation for compliance with USP chapter <797> requirements is correct?
 - a. Outsourcing obviates the need for compliance.
 - b. Outsourcing does not obviate the need for compliance or affect the changes needed to achieve compliance.
 - c. Outsourcing does not obviate the need for compliance, although it could minimize the changes needed to achieve compliance.
 - d. Outsourcing does not obviate the need for compliance, and it could increase the changes needed to achieve compliance.

7. Which of the following statements about the implications of outsourcing sterile product preparation for personnel is correct?
 - a. Outsourcing of high-volume and complex items has the greatest impact on personnel.
 - b. Outsourcing of low-volume items has the greatest impact on personnel.
 - c. Reductions in workload from outsourcing typically lead to elimination of personnel.
 - d. Reductions in workload from outsourcing typically lead to reallocation of personnel.

8. Which of the following is the most important consideration in selecting a provider when outsourcing the preparation of sterile products?
 - a. Ability to meet institutional sterile product needs.
 - b. Commitment to social and environmental causes.
 - c. Ownership and not-for-profit status.
 - d. Participation in patient assistance programs.

9. Off-site pharmacies selected for outsourcing of sterile product preparation should comply with or exceed:
 - a. USP chapter <797> requirements, but not CMS rules and regulations or Joint Commission standards because they do not apply.
 - b. USP chapter <797> requirements and CMS rules and regulations, but not Joint Commission standards because they do not apply.



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- c. USP chapter <797> requirements and Joint Commission standards, but not CMS rules and regulations because they do not apply.
 - d. USP chapter <797> requirements, CMS rules and regulations, and Joint Commission standards.
10. Accreditation from which of the following organizations might be desired when selecting a provider for outsourcing of sterile product preparation?
 - a. ASHP.
 - b. National Committee for Quality Assurance.
 - c. Pharmacy Compounding Accreditation Board.
 - d. USP.
11. Which of the following hospital staff should be involved with drafting an agreement with an off-site pharmacy for the preparation of sterile products?
 - a. Pharmacy, medical, and infection control staff, but not finance, legal, or risk management staff because they slow down the process.
 - b. Pharmacy, finance, legal, and risk management staff, but not medical or infection control staff because they slow down the process.
 - c. Pharmacy staff alone because including medical, infection control, finance, legal, and risk management staff slow down the process.
 - d. Pharmacy, medical, infection control, finance, legal, risk management, and other staff as appropriate.
12. In the most recent (2005) ASHP national survey of pharmacy practice in hospital settings that addressed dispensing and administration, the percentage of respondents who did not have a formal quality improvement program for ensuring the sterility and accuracy of i.v. admixtures was:
 - a. Less than 10%.
 - b. Nearly 50%.
 - c. Approximately 60%.
 - d. More than 90%.
13. In 1997, what percentage of errors reported to the USP medication error database were attributed to drug labeling or packaging?
 - a. 10%.
 - b. 33%.
 - c. 50%.
 - d. 66%.
14. Which of the following describes a model approach to assessing the quality of sterile product compounding facilities?
 - a. Ask the vendor to complete a request for information (RFI) survey



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- providing basic information about the company, but site visits are unnecessary.
- b. Ask the vendor to complete an RFI survey providing basic information about the company and arrange for regular site visits by a member of the state board of pharmacy.
 - c. Ask the vendor to complete an RFI survey providing basic information about the company and arrange for regular site visits by the director of pharmacy or a member of the senior pharmacy leadership and an individual well versed in current good manufacturing practices and USP chapter <797> requirements.
 - d. Ask the state board of pharmacy to complete an RFI survey providing basic information about the company, but site visits are unnecessary.
15. Which of the following is an element of a model audit visit at a sterile product compounding facility?
- a. Interviews with former technicians who have been fired by management.
 - b. Meetings with key management and staff.
 - c. Sterility and pyrogenicity testing by an independent laboratory not chosen by the vendor.
 - d. Unannounced inspection of the facility for cleanliness.
16. Which of the following is the approximate duration of a model audit visit at a sterile product compounding facility?
- a. 1-2 hours.
 - b. 5-8 hours.
 - c. 2-3 days.
 - d. 5-8 days.
17. Which of the following should be addressed first in the document review process when evaluating a sterile product compounding facility?
- a. Environmental monitoring records.
 - b. Personnel training records.
 - c. Quality control records.
 - d. Standard operating procedures.
18. Which of the following should be addressed by direct observation of personnel preparing sterile products during a tour of a sterile product compounding facility?
- a. Appropriate supervision of staff based on experience.
 - b. Management commitment to diverse hiring practices.
 - c. Management receptiveness to quality improvement suggestions from staff.
 - d. Staff compliance with standard operating procedures.



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19. Which of the following should be addressed during a tour of a sterile product compounding facility?
 - a. Clean room location.
 - b. Drug storage area temperature and security.
 - c. Order processing efficiency.
 - d. Ratio of pharmacists to technicians.

20. Which of the following should be the most prominent feature of labels on sterile products compounded at an off-site pharmacy?
 - a. The expiration date and time.
 - b. The manufacturer.
 - c. The name of the drug.
 - d. The name of the patient.

21. Which of the following types of information might best be incorporated into two-dimensional “smart” bar codes on the labels of sterile products compounded in off-site pharmacies?
 - a. The lot number.
 - b. The identity of the technician who compounded it.
 - c. The results of sterility testing.
 - d. The vendor name and address.

22. Which of the following is a key element that should be included in periodic reports from a vendor providing sterile product compounding services?
 - a. Environmental monitoring results.
 - b. Financial statements demonstrating solvency.
 - c. Proof of current liability insurance.
 - d. State pharmacy licensure renewal information.

23. Which of the following should be included in a request for proposal submitted to a vendor of sterile product compounding services when outsourcing sterile product preparation?
 - a. Specifications for wholesale drug suppliers.
 - b. Restrictions on business operations and conflicts of interest.
 - c. Requirements for staffing and work shift length.
 - d. Product quality monitoring criteria as required by USP chapter <797>.



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