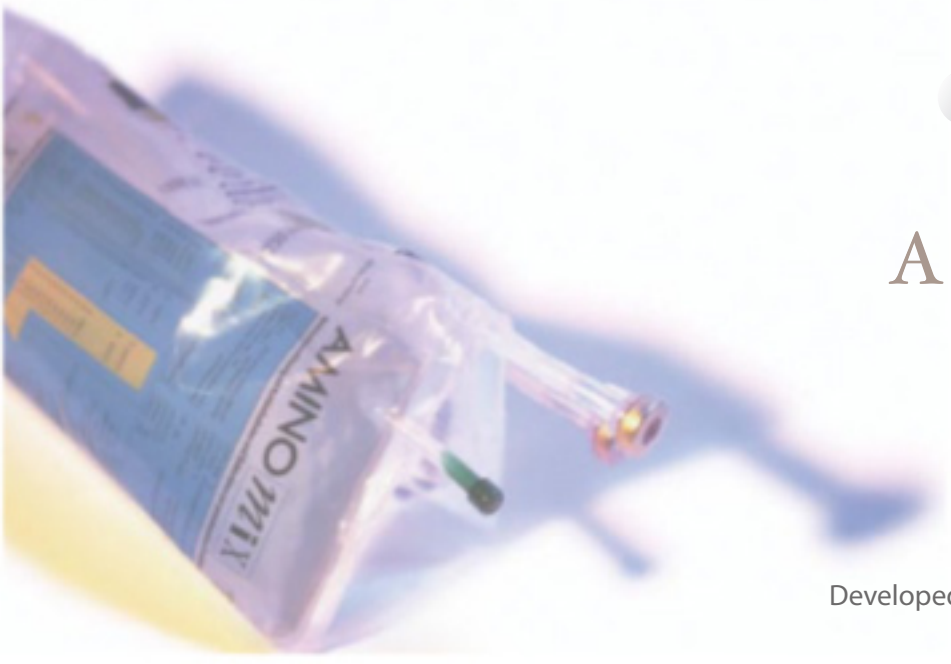
OUTSOURCING STERILE PRODUCTS PREPARATION

CONTRACTOR ASSESSMENT TOOL



ASHP Foundation™

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Principles for Use

- When outsourcing sterile products preparation services, every hospital/health system-based department of pharmacy should take a comprehensive and organized approach to vendor selection.
- Departments of pharmacy are strongly encouraged to engage other key hospital/health system stakeholders in the vendor selection process.
- While this tool is intended to be useful for all health-system/hospital-based departments of pharmacy, its use will vary based on the institution's size, geographic location, services provided and available resources.
- The ASHP Foundation has attempted to include the assessment questions under the most appropriate category. However, in some cases an assessment question might be applicable to multiple categories.
- While this document is intended to be helpful to hospital/health-system departments of pharmacy in their selection of a sterile products outsourcing organization, it does not purport to establish a standard of care.
- Hospitals/health systems that plan to use this tool as a component of their evaluation of a sterile products outsourcing organization can also use the tool to develop a Request for Proposals (RFP) for these services.
- The ASHP Foundation strongly encourages hospitals/health systems to use this tool along with site visits to ensure a comprehensive review of potential sterile products outsourcing organizations. Items that should be closely evaluated during the site visit are indicated throughout the tool.
- As part of the hospital's/health system's overall planning for selection of a sterile products outsourcing organization, see the ASHP Guidelines on Outsourcing Sterile Compounding Services.
- The term "disqualification" as used in this tool means that the outsourcing contractor should not be considered for the provision of sterile products preparation services.
- This tool is not intended for use in the evaluation of nuclear pharmacies.

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How to Use this Tool

Step 1. Minimum Requirements for a Vendor

When outsourcing the production of sterile products the first step in vendor evaluation is to see if they meet the minimum requirements. We have developed a group of questions that can be used to qualify a vendor. There is not a score for this section. A vendor simply meets the minimum requirements or they are disqualified. Once a vendor has been qualified we suggest further assessment of the vendor to determine which vendor is the best fit for your hospital or health-system.

Step 2. Vendor Assessment

The questions in this section are designed to help you objectively compare the services offered by potential outsourcing vendors. After answering each question, the Assesment Tool provides a score for the vendor and a table to interpret the score.

Step 3. Vendor Comparison

The vendor scores and score legend provided in the Assessment Summary can be used to compare potential outsourcing vendors.

Reset

Step 1: Minimum Requirement Questions

Part 1: Regulatory Compliance

1. Does the outsourcer have a state pharmacy license available where the compounding center resides?

   ◯ Yes ◯ No

2. Is the outsourcer licensed to ship to my state?

   ◯ Yes ◯ No ◯ N/A

3. If the outsourcer prepares a significant number of non patient-specific preparations (e.g., >5% of the outsourcer's volume), is the outsourcer registered as a drug manufacturer with the FDA, if required?

   ◯ Yes ◯ No ◯ N/A

4. If the outsourcer prepares non patient-specific controlled substance preparations, is the outsourcer registered as a drug manufacturer with the DEA?

   ◯ Yes ◯ No ◯ N/A

5. Are all pharmacists working for the outsourcer licensed in the state in which they are practicing?

   ◯ Yes ◯ No

6. If required, are all of the outsourcer's pharmacy technicians licensed or registered in the state where they are practicing?

   ◯ Yes ◯ No ◯ N/A

7. Does the outsourcer meet or exceed state required pharmacist-to-pharmacy technician ratios for the state in which the compounding center is located?

   ◯ Yes ◯ No ◯ N/A

8. If an FDA-approved product is commercially available (not on backorder), does the outsourcer compound the same drug formulation using non-sterile powders or other components?

   ◯ Yes ◯ No

9. When no commercial source exists to prepare admixtures, does the outsourcer use USP grade bulk ingredients obtained from a cGMP compliant supplier? If yes, can the outsourcer provide a certificate of analysis and potency testing of all bulk ingredients used?

Yes No N/A

10. Does the outsourcer have the required minimum amount of product liability insurance as outlined by my institution?

Yes No

11. Will my institution be covered by this insurance in the event that there is no written contract with the outsourcer?

Yes No

Part 2: Quality and Patient Safety Measures

12. Can the outsourcer provide documentation that confirms staff competency (garbing and hand hygiene, aseptic technique and related practices, and cleaning and disinfection procedures) is evaluated prior to compounding of actual drug preparations?

Yes No

13. Can the outsourcer provide documentation that confirms that the outsourcer tests aseptic techniques by preparing media fill units per USP chapter <797> standards?

Yes No

14. Can the outsourcer provide documentation that confirms that pharmacists and pharmacy technicians are pre-qualified using media fills before compounding of actual drug preparations?

Yes No

15. How often are outsourcing staff required to undergo re-qualification using media fills?

More than once per year Annually Less than annually or never

16. If a positive media fill occurs, does the outsourcer perform a comprehensive investigation to identify root cause?

Yes No

17. If a positive media fill occurs, does the outsourcer institute corrective and preventive action?

- ◯ Yes
- ◯ No

18. Does the outsourcer provide customers with substantial evidence that supports extended expiration dating for compounded sterile preparations when BUD limits in USP <797> are exceeded?

- ◯ Yes
- ◯ No

19. Does the outsourcer perform studies to determine extended expiration dates, using evidence-based and validated stability testing procedures, for compounded sterile preparations for which no extended expiration evidence exists?

- ◯ Yes
- ◯ No

20. Does the outsourcer verify that staff members are complying with gowning, gloving, and glove-tip processes that are consistent with USP chapter <797> standards?

- ◯ Yes
- ◯ No

21. Does the outsourcer perform routine surface microbiological and fungal environmental monitoring to minimize contamination?

- ◯ Performs More than Weekly
- ◯ Performs Weekly
- ◯ Does Not Perform Weekly

22. Does the outsourcer perform comprehensive investigations of out-of-limit findings, as recommended by USP chapter <797>, to determine root cause, followed by corrective and preventative actions?

- ◯ Exceeds USP <797> Guidelines (Performs more than weekly)
- ◯ Meets USP <797> Guidelines (Performs weekly)
- ◯ Does not meet USP 797 Guidelines

23. How frequently does the outsourcer perform nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter <797> standards?

- ◯ Exceeds USP <797> Guidelines (Performs more than weekly)
- ◯ Meets USP <797> Guidelines (Performs weekly)
- ◯ Does not meet USP 797 Guidelines

24. Does the outsourcer have a policy that requires validation of new or changed facilities, equipment, processes, container types, for sterility, and repeatability?

Yes No

Part 3: Medication Administration Safety Features

25. Does the outsourcer provide readily accessible information regarding status of latex, DEHP and preservatives in the preparations they prepare?

Yes No

Part 4: Service Excellence

26. Does the outsourcer compound products in the containers types (e.g., syringes, minibags, pump-specific cassettes) to meet the needs of my institution?

Yes No

27. Does the outsourcer have business continuity plans in place in the event of a natural or man-made disaster or public health emergency?

Yes No

Minimum Requirement Assessment Results

You must answer all 27 minimum requirement questions before the results of the Minimum Requirement Assessment are displayed.

Step 2. Vendor Assessment

The following questions are designed to help you objectively compare the services offered by potential outsourcing vendors. After answering each question, the Assessment tool provides a score for the vendor and a table to interpret the score.

PART I: REGULATORY COMPLIANCE
(20% of Total Score)

Section One: Current Registration and Licensure

1. What percentage of the outsourcer's pharmacy technician staff are certified by an authoritative board (e.g., Pharmacy Technician Certification Board)?

   ◯ < 50 % ◯ 50-94% ◯ ≥95%

2. Does the outsourcer provide pedigree information that documents that they do not purchase products outside of traditional drug distribution networks or through secondary wholesalers?

   ◯ Yes, all available ◯ Some or no Pedigree Information available

3. If a commercial product component of a preparation is on backorder, can the outsourcer provide a certificate of analysis, potency testing, and proof that all other requirements are met (e.g., higher level clean room) for High Risk Level Compounding per USP <797>?

   ◯ Yes ◯ No ◯ N/A

4. Does the outsourcer meet ASHP guidelines for handling of hazardous agents?

   ◯ Yes ◯ No ◯ N/A

5. Does the outsourcer meet NIOSH guidelines for handling of hazardous agents?

   ◯ Yes ◯ No ◯ N/A

6. Does the outsourcer meet USP chapter <797> guidelines for handling of hazardous agents?

   ◯ Yes ◯ No ◯ N/A

Section Two: Availability of Reports and Technical Summaries

7. Has the outsourcer disclosed any disciplinary or punitive action by any regulatory agency.(e.g., FDA warning letter, state board of pharmacy) within the past 36 months?

- ◯ Yes, still unresolved
- ◯ Yes, resolved
- ◯ No

8. Does the outsourcer provide quality control history and quality assurance trend reports on a regular basis and upon request?

- ◯ All available
- ◯ Some or none available

PART 1 SCORE	Answer all questions to see score.	ASSESSMENT PROGRESS	Part 1	Part 2	Part 3	Part 4

PART 2: QUALITY AND PATIENT SAFETY MEASURES
(50% of Total Score)

Section One: Personnel Competency Through Media Fills

9. Can the outsourcer provide documentation that confirms that sterile media used are certified by the manufacturer to be sterile and guaranteed to promote growth?

- ◯ Yes
- ◯ No

10. Can the outsourcer provide detailed reports on the incidence of positive media test results and the follow-up retests after corrective action is completed? During ongoing media monitoring, how many times in the last year were positive media fills reported on requalifications?

- ◯ Never
- ◯ Once
- ◯ More than once

Section Two: Availability of Reports and Technical Summaries

11. In assigning expiration and beyond-use dating, does the outsourcer follow evidence-based and validated stability testing procedures to evaluate each preparation's (drug, diluent and device/container) potency at room temperature or refrigerated temperature as applicable?

○ Follows procedures ○ Does not follow procedures

12. In assigning expiration and beyond-use dating, does the outsourcer follow evidence-based and validated stability testing procedures to evaluate each preparation (drug, diluent and device/container), based on a range of extreme temperatures per USP chapter <797> guidelines, to ensure stability and determine the impact on the preparation (e.g. evaporation, precipitation, degradation, concentration)?

○ Follows procedures ○ Does not follow procedures

13. In assigning expiration and beyond use dating, does the outsourcer follow evidence-based and validated stability testing procedures to evaluate each preparation (drug, diluent and device/container) for chemical characteristics such as pH, particulate matter, color, sterility (container closure integrity testing)?

○ Follows procedures ○ Does not follow procedures

14. Does the outsourcer provide minimum guaranteed shelf life upon delivery?

○ Yes ○ No

Section Three: Maintenance of Sterility and Environmental Monitoring

Site Visit Question

15. Does the outsourcer document that cleaning methods and agents are effective in preventing contamination of the sterile preparations area?

○ Yes ○ No

Site Visit Question

16. Are sporicidal agents used to sanitize vials and ports to prevent spore growth?

○ Yes ○ No

17. Does the outsourcer have action and alert limits for environmental monitoring?

○ Yes ○ No

18. For systems that require validation, does the outsourcer initiate corrective and preventive actions based on a formal review process?

Yes No

19. Does the outsourcer have a change control process for times when preventive maintenance is completed or equipment or software upgrades are installed?

Yes No

20. Does the outsourcer have documented processes and procedures (including shipping validation studies) to ensure that preparations leaving the site retain their integrity and stability through the shipping cycle?

Yes No

PART 2 SCORE | Answer all questions to see score. | ASSESSMENT PROGRESS | Part 1 | Part 2 | Part 3 | Part 4

PART 3: MEDICATION ADMINISTRATION SAFETY FEATURES
(20% of Total Score)

Section One: Quality Label

21. Does the outsourcer use drug name differentiation in the form of TALL MAN lettering as defined by an authoritative body for sound-alike and look-alike drugs?

Yes No

22. Does the outsourcer use visual cues on the label to differentiate drug names and drug concentrations within a therapeutic class?

Yes No

23. Does the outsourcer's labeling provide total drug amount and concentration (e.g., mg/mL) to ensure administration of the correct dose?

Yes No

24. Does the outsourcer provide auxiliary cautionary labeling to indicate contraindicated routes of administration?

Yes No

25. Does the outsourcer use ASTM (American Society for Testing and Materials) color coding for anesthesia syringe preparations?

Yes No N/A

26. Does the outsourcer have the capability to provide additional risk cues on anesthesia syringes to differentiate drugs within a therapeutic class and/or concentration?

Yes No N/A

27. Does the outsourcer provide access to information on latex, DEHP and preservative free products 24 hours per day, 7 days per week?

Yes No

28. Does the outsourcer provides machine-readable bar codes on all of its labels?

Yes No

29. Does the outsourcer provide comprehensive bar coding that includes the national drug code (when available) number, lot number, and expiration date?

Yes No

30. Does the outsourcer provide label formats and bar code placement that allow visualization of drug name and concentration when used in the institution's automated infusion pumps or syringe pumps?

Yes No N/A

Section Two: Tamper Evidence

31. Does the outsourcer offer tamper-evident options which may include overwrap, shrink wrap, tamper-evident foil, and/or tamper-evident caps?

Yes No

PART 4: SERVICE EXCELLENCE
(10% of Total Score)

Section One: Product Availability and Breadth of Line

32. Can the outsourcer provide concrete examples of their ability to provide new services to meet the evolving patient care needs of my institution?

○ Yes ○ No ○ N/A

33. Does the outsourcer compound medications for epidural administration?

○ Yes ○ No ○ N/A

34. Does the outsourcer compound medications for intrathecal administration?

○ Yes ○ No ○ N/A

35. Does the outsourcer compound controlled substances?

○ Yes ○ No ○ N/A

36. Does the outsourcer compound patient controlled analgesia solutions?

○ Yes ○ No ○ N/A

37. Does the outsourcer compound anesthesia syringes?

○ Yes ○ No ○ N/A

38. Does the outsourcer compound solutions for continuous nerve blocks?

○ Yes ○ No ○ N/A

39. Does the outsourcer compound antibiotics?

○ Yes ○ No ○ N/A

40. Does the outsourcer compound electrolyte solutions?

○ Yes ○ No ○ N/A

41. Does the outsourcer compound total parenteral nutrition?

Yes No N/A

42. Does the outsourcer compound cardioplegia solutions?

Yes No N/A

43. Does the outsourcer compound solutions for use in the critical care setting?

Yes No N/A

44. Does the outsourcer compound CRRT (Continuous Renal Replacement Therapy) preparations?

Yes No N/A

45. Does the outsourcer compound oxytocin solutions?

Yes No N/A

46. Does the outsourcer compound chemotherapy?

Yes No N/A

47. Does the outsourcer fill elastomeric containers/pumps?

Yes No N/A

48. Does the outsourcer compound medications for use in pediatric patients?

Yes No N/A

Section Two: Ease of Ordering

49. Does the outsourcer provide easy, convenient and reliable web-based ordering?

Yes No

50. Does the outsourcer offer E-222 “CSOS” ordering for controlled substance purchases?

Yes No N/A

51. Does the outsourcer offer a real-time, online reporting tool (e.g., shipment tracking, order history, invoices)?

Yes No

Section Three: Order Turnaround Time

52. Does the outsourcer provide guaranteed timeframes that meet your organization’s needs for compounded sterile preparations?

Yes No

53. Does the outsourcer provide same-day delivery?

Yes No

54. Does the outsourcer provide next-day delivery?

Yes No

Section Four: Storage and Space

Site Visit Question

55. Does the outsourcer’s current production capacity meet the requirements of the organization?

Yes No

56. Is the outsourcer willing to work with the organization on suggestions for improvement in storage solutions (e.g., customized packaging)?

Yes No

57. Has the outsourcer incorporated green programs (e.g., waste reduction initiatives) into their services?

Yes No

Site Visit Question

58. If the outsourcer prepares compounded sterile products using controlled substances, is the storage area for these secure and is staff identification required prior to entry into the area?

Yes No

Section Six: Service Considerations

59. Does the outsourcer negotiate prices with group purchasing organizations?

Yes No N/A

60. Does the outsourcer have a mechanism to respond to customer service issues or questions 24 hours a day, 7 days a week?

Yes No

61. Does the outsourcer have the clinical expertise in the area of products provided (e.g., TPN)?

Yes No

62. Does the outsourcer have staff members who are knowledgeable in the necessary clinical pharmacy areas to the support the efforts of its customers in driving change within the hospital?

Yes No

63. Does the outsourcer have staff members who are knowledgeable in the necessary clinical pharmacy areas who can ensure that an order received from a hospital is clinically and therapeutically appropriate?

Yes No

64. Can the outsourcer provide consultation services regarding potential compounding efficiencies and practice changes that can result from analysis of compounding patterns?

Yes No

65. Does the outsourcer have a track record for innovation and process evolution as evidenced by customer testimonials?

Yes No

PART 4 SCORE | Answer all questions to see score. | ASSESSMENT PROGRESS | Part 1 | Part 2 | Part 3 | Part 4

Step 3: Assessment Summary

Sterile Products Outsourcing Tool (SPOT)					
Vendor Qualification*	Number of Questions	Total Raw Score			Total Points
Part 1-4	27				
Vendor Assessment	Number of Questions	Total Raw Points	Available Points	Section Weight	Section Score
Part 1: Regulatory	8	0	30	20%	0
Part 2: Quality and Patient Safety	12	0	23	50%	0
Part 3: Medication Administration Safety Features	11	0	32	20%	0
Part 4: Service Excellence	34	0	61	10%	0
Total	**65**	**0**	**146**	**100%**	**0%**

* A zero in the Total Points section under Vendor Qualification indicates that the vendor is disqualified due to an unacceptable response to one or more minimum requirement questions.

Contractor Assessment Tool Score:

0%

Interpret Your Score:

90-100%
Excellent

80-89%
Good

70-79%
Consider other options

≤ 69%
Vendor is disqualified due to an unacceptable response to one or more minimum requirement questions.