

# OUTSOURCING STERILE PRODUCTS PREPARATION

## *Vendor Assessment Tool*

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### 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've developed a group of questions that can be used to qualify a vendor. There is not an absolute score for this section. A pie chart will be displayed upon the completion of all of step 1. Areas of green represent the percentage of questions answered that are in compliance with applicable standards based on your answers to the questions. Areas in yellow indicate the vendor is partially compliant based on the applicable standard. Areas in orange indicate areas to follow-up on because you indicated you do not know the answer to the items. Caution should be used in evaluating a vendor with more than 10% orange as this indicates there are likely too many unknowns about that vendor to make an informed decision. Consider reevaluating the vendor once you have further information. The red section of the chart indicates the percentage of questions answered in such a way that the vendor is considered noncompliant with the applicable standards. 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.

## THRESHOLD QUESTIONS

These questions are used to determine whether your assessment should address a 503B or 503A vendor. Both tracks of assessment questions are included in this PDF, but in the online tool you would only use on track.

### Question T.1

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) can be found on the FDA website. Facilities registered with the FDA are held to a different standard than 503A compounding pharmacies. Is the Vendor registered with the FDA as a 503B outsourcing facility?

- Yes
- No

### Question T.2

Does the vendor prepare non patient-specific preparations?

- Yes
- No
- Not Applicable

### Question T.3

Is the vendor compounding non-patient specific preparations in limited quantities before the receipt of a prescription based on compounding history of the vendor?

- Yes, limited quantities only
- No, quantities are not limited
- Vendor only prepares patient specific preparations

# PART 1: REGULATORY COMPLIANCE

503 A Track

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## Question A.1.1

Does the vendor prepare non patient-specific preparations?

- Yes
- No
- Not Applicable

## Question A.1.2

Is the vendor compounding non-patient specific preparations in limited quantities before receipt of a prescription based on compounding history of the vendor?

- Yes, limited quantities only
- No, quantities are not limited
- Vendor only prepares patient specific preparations

## Question A.1.3

Obtain a statement from the pharmacy with results of their last state board of pharmacy (BOP) inspection, including the date inspected, and any elements scored and comments written concerning compounding. If a state board of pharmacy inspection is not available consider asking for NABP or PCAB inspection reports.

- Pharmacy Provided
- Pharmacy will not provide
- Request report from pharmacy

## Question A.1.4

What was the outcome of the state board of pharmacy inspection as it applies to sterile compounding?

- Passed, no violations
- Warning issued, passed follow up inspection
- Warning issued, follow-up inspection pending
- Ordered to cease and desist compounding of sterile preparations
- I don't know

## Question A.1.5

Has the compounding pharmacy provided a detailed report to you about the issues cited on the state board of pharmacy report and how they were addressed?

- Yes
- No

**Question A.1.6**

Are you and your organization comfortable with the remediation plan provided by the compounding pharmacy that addresses all citations by the state board of pharmacy?

- Yes
- No
- Awaiting the report from the compounding pharmacy**

**Question A.1.7**

FDA compounding inspections, recalls and other actions can be found on the FDA website. Has the compounding pharmacy received a form 483 or a warning letter from the FDA In the last 12 months due to sterility or another critical observation?

- 483 or warning letter issued**
- No
- I don't know

**Question A.1.8**

FDA compounding inspections, recalls and other actions can be found on the FDA website. Has the compounding pharmacy had a product recall within the past year due to sterility assurance concerns or other issues that could present risks to patients?

- Yes
- No
- I don't know

**Question A.1.9**

Based on the findings from the state board of pharmacy, NABP, PCAB, and/or FDA inspections, is your organization comfortable with proceeding with this compounding center?

- Yes
- No

**Question A.1.10**

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

- Yes
- No
- I don't know

**Question A.1.11**

If required by the state board of pharmacy, has the compounding pharmacy provided written assurance that they have completed all steps necessary to ship to my state?

- Yes
- No
- Not Applicable**
- I don't know

**Question A.1.12**

If the compounding pharmacy prepares controlled substance preparations, is the compounding pharmacy registered with the DEA?

- Yes
- No
- Not Applicable
- I don't know

**Question A.1.13**

Are all pharmacists working for the compounding pharmacy licensed in the state in which they are practicing?

- Yes
- No
- I don't know

**Question A.1.14**

Some state laws require the pharmacist-in-charge or another designated pharmacist at the compounding pharmacy to be licensed in the state receiving the outsourced preparations. If required by state law, are the appropriate pharmacists at the compounding pharmacy licensed in the state where the CSPs are being received?

- Yes
- No
- Not Applicable
- I don't know

**Question A.1.15**

Do ALL of the compounding pharmacy's pharmacy technicians meet the requirements of the state board of pharmacy (i.e., registration, national certification)?

- Yes
- No
- Not Applicable
- I don't know

**Question A.1.16**

If required by the state board of pharmacy, does the compounding pharmacy meet or exceed state required pharmacist-to-pharmacy technician ratios for the state in which the compounding center is located?

- Yes
- No
- Not Applicable
- I don't know

**Question A.1.17**

If an FDA-approved product is commercially available (not on FDA drug shortage list), does the compounding pharmacy compound the same drug formulation?

- Yes
- No
- I don't know

**Question A.1.18**

Does the compounding pharmacy compound products on FDA's list of drugs because they have been withdrawn or removed from the market for reasons of safety or effectiveness?

- Yes
- No
- I don't know

**Question A.1.19**

Does the compounding pharmacy compound products on FDA's list of drugs that should not be compounded by a 503A facility because they are demonstrably difficult to compound?

- Yes
- No
- I don't know

**Question A.1.20**

If the compounding pharmacy prepares CSPs from bulk drug products, are all of the bulk drug products on the FDA list of substances that a 503A pharmacy can use?

- Yes
- No
- I don't know
- Not Applicable

**Question A.1.21**

When no commercial source exists to prepare admixtures, does the compounding pharmacy use only USP grade bulk drug products?

- Yes
- No
- Compounding pharmacy does not use bulk drug products
- I don't know

**Question A.1.22**

When admixtures are compounded from USP grade bulk ingredients can the compounding pharmacy provide a certificate of analysis and potency testing of all bulk ingredients used?

- Yes
- No
- I don't know

**Question A.1.23**

If the compounding pharmacy 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
- Not Applicable
- I don't know

**Question A.1.24**

Does the compounding pharmacy meet USP standards for handling of hazardous drugs?

- Yes
- No
- Not Applicable
- I don't know

## **PART 2: QUALITY AND PATIENT SAFETY MEASURES**

503 A Track

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**Question A.2.1**

Can the compounding pharmacy provide staff competency documentation that confirms (garbing and hand hygiene, aseptic technique and related practices, and cleaning and disinfection procedures) that ALL staff are evaluated PRIOR to compounding of actual drug preparations

- Yes
- No
- I don't know

**Question A.2.2**

Can the compounding pharmacy provide documentation that confirms that the compounding pharmacy tests aseptic techniques by preparing media fill units per USP Chapter <797> standards?

- Yes
- No
- I don't know

### Question A.2.3

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

- Yes
- No
- I don't know

### Question A.2.4

How often are compounding pharmacy staff required to undergo re-qualification for low- and medium-risk sterile compounding using media fill testing?

- More than once a year (exceeds USP Chapter <797> standards)
- Annually (meets USP Chapter <797> standards)
- Less than annually or never (Does not meet USP Chapter <797> standards)
- I don't know

### Question A.2.5

How often are compounding pharmacy staff required to undergo re-qualification for high-risk sterile compounding using media fill testing?

- More frequently than every 6 months (Exceeds USP Chapter <797> standards)
- Every six months (Meets USP Chapter <797> standards)
- Less than every 6 months or never (Does not meet USP Chapter <797> standards)
- Not Applicable
- I don't know

### Question A.2.6

If a positive media fill occurs, does the compounding pharmacy perform a comprehensive investigation to identify root cause?

- Yes
- No
- I don't know

### Question A.2.7

If a positive media fill occurs, does the compounding pharmacy institute corrective and preventive action?

- Yes
- No
- I don't know



**Question A.2.8**

Does the compounding pharmacy provide CSPs that exceed the BUDs in USP Chapter <797>

- Yes
- No
- I don't know

**Question A.2.9**

When BUD limits in USP Chapter <797> are exceeded, does the compounding pharmacy provide customers with scientifically valid evidence of compliance with applicable USP chapters (i.e., strength and stability testing, microbial effectiveness and endotoxin testing) that supports extended dating for compounded sterile preparations?

- Yes
- No
- I don't know

**Question A.2.10**

If the evidence that supports extended expiration dating for compounded sterile preparations when BUD limits in USP Chapter <797> are exceeded is a study by a third party, is the compounded product and its packaging the same as the product examined in the study?

- Yes
- No
- Not Applicable
- I don't know

**Question A.2.11**

For compounded sterile preparations for which no extended expiration evidence exists, does the compounding pharmacy perform scientifically-valid studies to determine extended expiration dates, using evidence-based and validated stability indicating methods?

- Yes
- No
- Not Applicable
- I don't know

**Question A.2.12**

Does the compounding pharmacy verify that staff members are complying with hand hygiene, gowning, and gloving processes that are consistent with USP chapter <797> standards?

- Yes
- No
- I don't know

**Question A.2.13**

Does the compounding pharmacy perform routine surface bacterial environmental monitoring to detect microbiologic contamination?

- Performs more than monthly**
- Performs monthly**
- Does not perform monthly**
- I don't know**

**Question A.2.14**

Does the compounding pharmacy perform routine surface fungal/sporicidal environmental monitoring to detect microbiologic contamination?

- Performs more than monthly**
- Performs monthly**
- Does not perform monthly**
- I don't know**

**Question A.2.15**

Can the compounding pharmacy provide documentation that confirms that the compounding pharmacy tests aseptic techniques by performing gloved fingertip testing per USP Chapter <797> standards?

- Yes**
- No**
- I don't know**

**Question A.2.16**

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

- Yes**
- No**
- Not Applicable**
- I don't know**

**Question A.2.17**

How frequently does the compounding pharmacy 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 Chapter <797> Guidelines (Performs more than semiannually)**
- Meets USP Chapter <797> Guidelines (Performs semiannually)**
- Does not meet USP Chapter <797> Guidelines**
- I don't know**

**Question A.2.18**

Does the compounding pharmacy have a policy that requires validation of new or changed facilities, equipment formulations, processes and/or container types, for sterility, and repeatability?

- Yes
- No
- I don't know

**Question A.2.19**

Does the compounding pharmacy perform and document cleaning methods and agents that have been shown to be effective in maintaining a suitable sterile compounding environment for production of sterile preparations, including properly diluted germicidal detergents, sterile alcohol, etc.

- Yes
- No
- I don't know

**Question A.2.20**

Does the compounding pharmacy have documented processes and procedures to ensure that preparations maintain their integrity and stability until delivery to the customer?

- Yes
- No
- I don't know

# PART 1: REGULATORY COMPLIANCE

503 B Track

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## Question B.1.1

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) can be found on the FDA website. Facilities registered with the FDA are held to a different standard than 503A compounding pharmacies. Is the Vendor registered with the FDA as a 503B outsourcing facility?

- Yes
- No

## Question B.1.2

FDA registered outsourcing facility inspections are listed on the FDA 503B website. Has the FDA Registered outsourcing facility been inspected by the FDA?

- Yes
- Inspection not yet completed
- I don't know

## Question B.1.3

FDA registered outsourcing facility inspections and findings are listed on the FDA 503B website. Has the FDA Registered outsourcing facility received a Form FDA-483?

- Yes
- No
- I don't know

## Question B.1.4

FDA registered outsourcing facility inspections are listed on the FDA 503B website. Was a warning letter issued by the FDA?

- Yes
- No
- I don't know

## Question B.1.5

FDA registered outsourcing facilities are listed on the FDA website. This site indicates whether or not an FDA inspection has occurred, and if so, the outcome and/or vendor responses. Website may not contain all vendor responses – response may need to be requested directly from vendor. Has the outsourcing facility responded to the FDA's 483 and/or warning letters?

- Yes
- No
- I don't know

**Question B.1.6**

Did the FDA accept the outsourcing facilities' action plan and has the outsourcing facility implemented the plan to the satisfaction of the FDA?

- Yes
- No
- I don't know

**Question B.1.7**

FDA registered outsourcing facility recalls are listed on the FDA 503B website. Has the outsourcing facility had a product recall within the past year due to sterility assurance concerns or other issues that could present risks to patients?

- Yes
- No
- I don't know

**Question B.1.8**

In some instances entities other than the FDA may have inspected the outsourcing facility. Has the outsourcing facility disclosed any disciplinary or punitive action by any regulatory agency.(e.g., state board of pharmacy) within the past 36 months?

- Yes, still unresolved
- Yes, resolved
- No
- Not Applicable

**Question B.1.9**

If required, is the outsourcing facility properly licensed in my state?

- Yes
- No
- Not Applicable
- I don't know

**Question B.1.10**

If the outsourcing facility is registered as a pharmacy, does the outsourcing facility comply with federal traceability requirements for non-compounded drugs, including maintaining traceability information for drug shipments, and investigating suspect products in their possession?

- Yes, all available
- Some pedigree information available
- No pedigree information available
- Not Applicable
- I don't know

**Question B.1.11**

If the outsourcing facility prepares non patient-specific controlled substance preparations, is the outsourcing facility registered with the DEA as a manufacturer?

- Yes
- No
- Not Applicable
- I don't know

**Question B.1.12**

Does the outsourcing facility employ a licensed pharmacist to directly supervise compounding?

- Yes
- No
- I don't know

**Question B.1.13**

If required by state law, are all of the outsourcing facility's pharmacy technicians licensed or registered in the state where they are practicing?

- Yes
- No
- Not Applicable
- I don't know

**Question B.1.14**

If an FDA-approved product is commercially available (not on the FDA shortage list), does the outsourcing facility compound the same drug formulation?

- Yes
- No
- I don't know

**Question B.1.15**

If compounding medicines from bulk ingredients, does the outsourcing facility use bulk ingredients obtained from an FDA registered supplier?

- Yes
- No
- I don't know
- Not Applicable

**Question B.1.16**

If compounding medicines from bulk ingredients, does the outsourcing facility use bulk ingredients that are NOT included on a list of bulk drug products the FDA has designated may be used in compounding by 503B facilities?

- Yes
- No
- I don't know
- Not Applicable

**Question B.1.17**

If compounding medicines from bulk ingredients, does the outsourcing facility identity test all bulk ingredients?

- Yes
- No
- I don't know
- Not Applicable

**Question B.1.18**

Does the outsourcing facility compound products on FDA's list of drugs that should not be compounded because they have been withdrawn or removed from the market for reasons of safety or effectiveness?

- Yes
- No
- I don't know

**Question B.1.19**

Does the outsourcing facility compound products on FDA's list of drugs that should not be compounded by a 503B facility because they are demonstrably difficult to compound?

- Yes
- No
- I don't know

**Question B.1.20**

Based on the information found on the FDA website or responses received from the outsourcing facility, is your organization comfortable with the level of regulatory compliance of the outsourcing facility?

- Yes
- No

# PART 2: FACILITY DESIGN AND MAINTAINING SUITABLE FACILITIES

503 B Track

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## Question B.2.1

Is the air cleanliness of the compounding area ISO Class 5 or better and zone adjacent to the aseptic processing line at minimum ISO 7?

- Yes
- No
- I don't know

## Question B.2.2

If a compounding aseptic isolator is used, is the surrounding area at least ISO 8?

- Yes
- No
- I don't know
- Not Applicable

## Question B.2.3a

The ISO 5 area is qualified using at least the following studies and tests which should be conducted, including the particular conditions under which the studies and tests were conducted:

Airflow studies are conducted under dynamic conditions (i.e., in-situ smoke study) to qualify the HVAC/HEPA units initially and when any changes are made that might affect airflow.

- Yes
- No
- I don't know

## Question B.2.3b

The ISO 5 area is qualified using at least the following studies and tests which should be conducted, including the particular conditions under which the studies and tests were conducted:

HEPA periodic testing/recertification is performed at least twice annually and includes HEPA filter integrity testing, particle counts, and velocity checks

- Yes
- No
- I don't know



**Question B.2.4**

Pressure differential, humidity, and temperature ranges/limits are established and built-in alarms or scheduled checks recorded in logs are available to detect and document excursions

- Yes
- No
- I don't know

**Question B.2.5**

If powdered formulations of drugs are handled, procedures are established and followed to manage cross-contamination risk

- Yes
- No
- I don't know
- Not Applicable

**Question B.2.6**

If powdered forms of penicillin/beta-lactam products are compounded, a physically separate space is utilized.

- Yes
- No
- I don't know
- Not Applicable

**Question B.2.7**

Are sterile disinfectants and lint-free sterile wipes used for disinfecting all critical areas?

- Yes
- No
- I don't know

**Question B.2.8**

Are sporicidal disinfectants used in the ISO 5 and classified rooms on a regular basis?

- Yes
- No
- I don't know

## PART 3: ENVIRONMENTAL AND PERSONNEL MONITORING

503 B Track

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### Question B.3.1

Does the EM program cover all production shifts and include monitoring during normal production conditions?

- Yes
- No
- I don't know

### Question B.3.2

Does the outsourcing facility perform daily surface microbiological environmental monitoring (EM) according to cGMP?

- Performs daily EM according to cGMP
- Does not perform EM according to cGMP
- I don't know

### Question B.3.3

Does the outsourcing facility have a CAPA program that includes performing comprehensive investigations of out-of-limit findings, as required by cGMPs, to determine root cause, followed by corrective and preventative actions?

- Meets cGMP Guidelines
- Does not meet cGMP Guidelines
- I don't know

### Question B.3.4

How frequently does the outsourcing facility perform nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to cGMP?

- Meets cGMP, at least daily
- Does not meet cGMP
- I don't know

### Question B.3.5

Does the outsourcing facility have a policy that requires validation of new or changed facilities, equipment, processes and/or container types, for sterility, and repeatability?

- Yes
- No
- I don't know

### Question B.3.6

Are the sampling, alert and action limits, and testing methods designed to detect environmental contaminants, including changes in microflora type and amount?

- Yes
- No
- I don't know

## PART 4: EQUIPMENT, CONTAINERS, CLOSURES, AND COMPONENTS

503 B Track

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### Question B.4.1

Are equipment, containers and closures that come into contact with drug product evaluated to ensure adequacy for intended use and to ensure sterility and cleanliness at time of use?

- Yes
- No
- I don't know

### Question B.4.2

If pre-sterilized and depyrogenated single-use equipment, containers, and closures are used are the items sterilized and depyrogenated before first use using a validated process?

- Yes
- No
- I don't know
- Not Applicable

### Question B.4.3

Is any equipment used qualified as capable of performing its intended function before first use and are procedures for routine calibration and maintenance established and followed?

- Yes
- No
- I don't know

### Question B.4.4

Are scientifically sound and appropriate criteria for containers and closures established and available?

- Yes
- No
- I don't know

**Question B.4.5**

Are containers and closures stored under the supplier's labeled storage conditions and protected from contamination when portions of the lot are removed?

- Yes
- No
- I don't know

**Question B.4.6**

If required by cGMP, is each lot of drug components (bulk active ingredients and excipients) tested to verify identity and evaluated for conformity prior to being used for compounding?

- Yes
- No
- I don't know
- Not Applicable

**Question B.4.7**

If required by cGMP, are bulk components tested to verify endotoxin level before use in compounding?

- Yes
- No
- I don't know
- Not Applicable

**Question B.4.8**

Are components stored under supplier's labeled storage conditions and used within the supplier's labeled re-test or expiration date?

- Yes
- No
- I don't know

## **PART 5: PRODUCTION AND PROCESS CONTROLS**

503 B Track

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**Question B.5.1**

Does the outsourcing facility have, and can they be made available upon request, batch records that provide complete documentation of production of each batch of drug product?

- Yes
- No
- I don't know

**Question B.5.2**

Are hold times (i.e., prior to sterilization, post-sterilization prior to container fill) assessed and limits supported by data?

- Yes
- No
- I don't know

**Question B.5.3**

Can the outsourcing facility provide documentation that confirms staff competency (garbing and hand hygiene, aseptic technique, procedures covering aseptic manufacturing area operations, cleanroom behavior and cleaning and disinfection procedures, etc.) is evaluated prior to compounding of actual drug preparations?

- Yes
- No
- I don't know

**Question B.5.4**

Media fills should be performed in the same area where production occurs, and should closely simulate aseptic manufacturing operations and, as appropriate, worst-case activities and conditions. Can the outsourcing facility provide documentation that confirms that the outsourcing facility tests aseptic techniques by preparing media fills in accordance with FDA's current Good Manufacturing Practices (cGMP) expectations for 503B facilities?

- Yes
- No
- I don't know

**Question B.5.5**

Can the outsourcing facility provide documentation that confirms compounding personnel that conduct aseptic operations are pre-qualified before compounding actual drug preparations by conducting at least three successful, successive media fill simulations designed to verify the adequacy of their technique and behavior, and conducted in the same area where production occurs?

- Yes
- No
- I don't know

**Question B.5.6**

If a positive media fill occurs, does the outsourcing facility perform a comprehensive investigation to identify root cause and institute corrective and preventive action?

- Yes
- No
- I don't know

**Question B.5.7**

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

- Yes
- No
- I don't know

## **PART 6: RELEASE TESTING, LABORATORY CONTROLS AND STABILITY/EXPIRATION DATING**

503 B Track

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**Question B.6.1**

Does the outsourcing facility perform a sterility test on every batch of compounded sterile preparations (unless the product is terminally sterilized using a validated sterilization cycle that uses biological indicators, or the product is prepared in batch of less than 10, is made pursuant to specific patient prescriptions, and is labeled with default BUDs set by the FDA for such products)?

- Yes
- No
- I don't know

**Question B.6.2**

Does the outsourcing facility adhere to cGMPs for laboratory controls for all in-house laboratory procedures?

- Yes
- No
- I don't know
- Not Applicable

**Question B.6.3**

Does the outsourcing facility have documentation of adherence to cGMPs for laboratory controls for all external laboratory procedures?

- Yes
- No
- I don't know
- Not Applicable

**Question B.6.4**

Does the outsourcing facility adhere to default BUDs established by the FDA, or have they utilized stability-indicating methods to establish longer dating?

- Adhere to default BUDs
- Conduct studies for longer dating
- Both default BUDs AND conduct studies
- Neither
- I don't know

**Question B.6.5**

Does the outsourcing facility perform studies to determine extended expiration dates, using evidence-based and validated stability testing procedures that demonstrate the compounded sterile preparation retains its quality and remains sterile through the labeled beyond use date?

- Yes
- No
- I don't know

**Question B.6.6**

In assigning beyond-use dating, does the outsourcing facility have and can the outsourcing facility provide evidence-based and stability indicating study data showing that each preparation's (drug, diluent and device/container) stability at room temperature or refrigerated temperature as applicable?

- Yes
- No
- I don't know

**Question B.6.7**

In assigning beyond-use dating, does the outsourcing facility have and can the outsourcing facility provide evidence-based and stability indicating study data evaluating each preparation (drug, diluent and device/container), based on a range of extreme temperatures, to ensure stability and determine the impact on the preparation (e.g. evaporation, precipitation, degradation, concentration)?

- Yes
- No
- I don't know

**Question B.6.8**

In assigning beyond use dating, does the outsourcing facility 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 procedure
- Does not follow procedure
- I don't know

## PART 7: PACKAGING AND LABELING

503 B Track

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### Question B.7.1

Does the outsourcing facility comply with federal labeling requirements for 503B facilities (i.e., including the statement "this is a compounded drug", drug name, lot number, ingredients, dosage, statements that the drug is not for resale)?

- Yes
- No
- I don't know

### Question B.7.2

Does the outsourcing facility have documented processes and procedures (including validated shipping studies) to ensure that preparations and packaging maintain their integrity and stability until delivery to the customer?

- Yes
- No
- I don't know

## PART 8: QUALITY ASSURANCE ACTIVITIES

503 B Track

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### Question B.1.8.1

Does the outsourcing facility have an independent quality control unit responsible for discrepancy and failure investigations and the development and oversight of appropriate corrective actions and preventive actions that does not take on the responsibilities of other units within the organization, (i.e., production unit)?

- Yes
- No
- I don't know

### Question B.1.8.2

Does the outsourcing facility have an independent quality control unit responsible for discrepancy and failure investigations and the development and oversight of appropriate corrective actions and preventive actions that does not take on the responsibilities of other units within the organization, (i.e., production unit)?

- Yes
- No
- I don't know



# VENDOR ASSESSMENT

The following questions are designed to help you objectively compare the services offered by potential outsourcing vendors. After answering all questions in this section, the assessment tool provides a score for the vendor and a table to interpret the score.

## PART 1: MEDICATION SAFETY FEATURES

### Section One: Label Features and Packaging

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#### Question 2.1.1

Does the vendor 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
- Not Applicable

#### Question 2.1.2

Does the vendor's labeling provide total drug amount and concentration (e.g., mg/mL)?

- Yes
- No
- Not Applicable

#### Question 2.1.3

Does the vendor provide auxiliary cautionary labeling to indicate contraindicated routes of administration, if applicable?

- Yes
- No
- Not Applicable

#### Question 2.1.4

Does the vendor use ASTM (American Society for Testing and Materials) color coding standard when labeling anesthesia syringe preparations?

- Yes
- No
- Not Applicable

**Question 2.1.5**

Does the vendor use AAO (American Academy of Ophthalmology) recommended color coding for ophthalmic preparations?

- Yes
- No
- Not Applicable

**Question 2.1.6**

Does the vendor provide access to information on latex, DEHP and preservative free products?

- Yes
- No
- Not Applicable

**Question 2.1.7**

Does the vendor provide bar codes readable in our hospital/health system on all of its labels?

- Yes
- No
- Not Applicable

**Question 2.1.8**

Does the vendor bar code labeling include the lot number and expiration date?

- Yes
- No
- Not Applicable

**Question 2.1.9**

Does the vendor 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
- Not Applicable

**Question 2.1.10**

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

- Yes
- No
- Not Applicable

**Question 2.1.11**

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

- Yes
- No
- I don't know

## **PART 2: SERVICE EXCELLENCE**

Section One: Product Availability and Breadth of Line

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**Question 2.2.1.1**

Does the vendor compound products in the container type (e.g., syringes, minibags, pump-specific cassettes) to meet the needs of my institution?

- Yes
- No

**Question 2.2.1.2**

Does the vendor compound products in the dosages and/or concentrations needed by my institution?

- Yes
- No

**Question 2.2.1.3**

Does the vendor compound medications and/or products from the therapeutic categories (i.e., cardioplegia, TPN, pediatric dosages) our organization needs?

- Yes
- No

## **PART 2: SERVICE EXCELLENCE**

Section Two: of Ordering and Turnaround Time

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**Question 2.2.2.1**

Does the vendor provide easy, convenient and reliable web-based ordering?

- Yes
- No
- Not Applicable

**Question 2.2.2.2**

Does the vendor offer E-222 "CSOS" ordering for controlled substance purchases?

- Yes
- No
- Not Applicable

**Question 2.2.2.3**

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

- Yes
- No
- Not Applicable

**Question 2.2.2.4**

Does the vendor provide guaranteed delivery timeframes for compounded sterile preparations?

- Yes
- No
- Not Applicable

**Question 2.2.2.5**

Does the vendor provide same-day delivery?

- Yes
- No
- Not Applicable

**Question 2.2.2.6**

Does the vendor provide next-day delivery?

- Yes
- No
- Not Applicable

## **PART 2: SERVICE EXCELLENCE**

Section Three: Storage and Space and Service Considerations

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**Question 2.2.3.1**

Can the vendor's current production capacity serve the new business that will be generated by servicing the organization?

- Yes
- No
- I don't know

**Question 2.2.3.2**

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

- Yes
- No
- Not Applicable
- I don't know

**Question 2.2.3.3**

Does the vendor negotiate prices with group purchasing organizations?

- Yes
- No
- Not Applicable
- I don't know

**Question 2.2.3.4**

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

- Yes
- No
- Not Applicable
- I don't know

**Question 2.2.3.5**

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

- Yes
- No
- I don't know

**Question 2.2.3.6**

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

- Yes
- No
- Not Applicable
- I don't know

**Question 2.2.3.7**

Will my institution be covered by this insurance in the event that there is no written contract with the outsourcing facility?

- Yes
- No
- Not Applicable
- I don't know

**LEGEND SCORING**

After completing the Vendor Assessment online you will receive a score for each section and overall. The scoring is explained below.

**90-100% (Excellent)**

Based on the information that was provided, this vendor appears to be able to meet most of the organization's outsourcing needs. Questions are not weighted for your specific situation.

**80-89% (Good)**

Based on the information that was provided, this vendor appears to be able to meet many of the organization's outsourcing needs, but not all. Questions are not weighted for your specific situation.

**70-79%**

Based on the information that was provided, this vendor appears to be able to meet some of the organization's outsourcing needs. Questions are not weighted for your specific situation.

**Less than 69%**

Based on the information that was provided, this vendor does not appear to be able to meet the organization's outsourcing needs. Questions are not weighted for your specific situation.