Questions for Registered 503Bs (Compounding Outsourcing Facilities)

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This study is being conducted on behalf of the U.S. Food and Drug Administration.

As part of its commitment to the compounding industry, FDA established the Compounding Quality Center of Excellence (CoE) to help the compounding outsourcing facility industry meet its intended function. To continue to inform the CoE's activities, FDA is inviting all compounding outsourcing facilities to provide insights, perspectives, and input on operational barriers and opportunities related to the outsourcing facility market, compliance with federal policies and good quality drug production, and interactions and engagement with FDA. For those who participated in this survey last year, a few of the questions may appear to be very similar to those included in last year's survey. This is done in order to understand changes in the outsourcing facility sector and outsourcing facilities views in certain areas over time so the CoE can evolve in concert with any changing needs.

The survey will take ~35 minutes to complete. All responses to the survey will be anonymous and non-attributable. The survey is being administered by a third party. While FDA will utilize the information obtained from your survey responses, FDA will not have any direct involvement with administering the survey or collecting and tabulating the results.

We look forward to hearing from you!

Section One – Background. The questions in this section are intended to help understand the characteristics and demographics of your compounding outsourcing facility(ies).

1. Are you responding to this survey on behalf of: *[multiple choice – select one]*
    a. A single compounding outsourcing facility
    b. Multiple compounding outsourcing facilities owned by the same company
    c. Other (please specify): _____

2. How many states is your outsourcing facility licensed in? *[multiple choice – select one*]
    a. Not yet licensed
    b. 1
    c. 2-5
    d. 6-20
    e. 20-49

f. 50
g. Other (please specify): _____

3. What types of practice settings receive your compounded products? Please check all that apply. *[multiple choice – select all that apply]*
    a. Hospital(s) / Medical Center(s)
    b. Physician Office(s)
    c. Clinic(s)
    d. Nursing home(s)
    e. Health System(s) / Integrated Delivery Network(s)
    f. Other. Please specify: _____

4. What is your compounding outsourcing facility(ies)' average gross **revenue**? *[multiple choice – select one]*
    a. < $100,000
    b. $100,000 to $499,999
    c. $500,000 to $999,999
    d. $1,000,000 to $4,999,999
    e. $5,000,000 to $14,999,999
    f. $15,000,000 to $24,999,999
    g. $25,000,000 to $49,999,999
    h. $50,000,000 to $99,999,999
    i. $100,000,000+

5. What percent (estimated) of your compounding outsourcing facility(ies)' total gross **revenue** is from: *[select and numerical entry for all that apply]*
    a. Compounding from approved FDA products *[numerical entry]*
    b. Compounding from bulk drug substances *[numerical entry]*
    c. Other *[numerical entry]*

If other, please explain *[open-ended]*

6. What percent (estimated) of your compounding outsourcing facility(ies)' total gross **revenue** is from: *[select and numerical entry for all that apply]*
    a. Repackaging FDA approved substances *[numerical entry]*
    b. Compounding drug substances *[numerical entry]*
    c. Other *[numerical entry]*
        i. If other, please explain *[open-ended]*

Section Two - Market Factors and Influencing Trends. The questions in this section are intended to help understand the opportunities, barriers, and dynamics of the outsourcing facility market.

7. As a 503B, what are the key business challenges that your compounding outsourcing facility(ies) faces? *[multiple choice – select top five]*
    a. Costs of acquiring equipment
    b. Costs of maintaining equipment

c. Costs of maintaining and operating facilities
d. Costs of API and drug inputs
e. Costs of testing drug products
f. Costs of shipping / delivery
g. Other costs. Please specify: _____
h. Maintaining compliance with CGMP. Please specify: _____
i. Availability of API and drug inputs
j. Recruiting skilled staff
k. Retaining skilled staff / high staff turnover
l. Other staff issues. Please specify: _____
m. High profile adverse events from compounded drugs
n. Contracts with GPOs or PBMs
o. Keeping up with high or growing demand
p. Stagnant demand
q. Inconsistent demand
r. Other. Please specify: _____

8. As a 503B, what are the key drivers of growth for your compounding outsourcing facility(ies)? *[multiple choice – select top five]*
    a. Responding to drug shortages
    b. Tracking and planning for emerging trends that impact demand
    c. Using automation or technology
    d. Targeted marketing
    e. Brand loyalty
    f. Applying data and analytics
    g. Building and maintaining relationships with buyers
    h. Building and maintaining relationships with suppliers
    i. Learning from best practices in the compounding Outsourcing Facilities industry
    j. Learning from best practices in the broader drug manufacturing industry
    k. Contracts with GPOs or PBMs
    l. Producing drugs for Office Stock
    m. Competitive pricing
    n. Targeting specific therapeutic areas
    o. Low direct competition
    p. Research and development
    q. Increasing demand (growing market)
    r. Capturing market share from competitors
    s. Mergers or Acquisitions
    t. Other. Please specify: _____

9. What is the average batch size that your outsourcing facility produces? [open ended- allow for numeric answer, no maximum value and text for unit of measure]

10. How many batches does your outsourcing facility produce in a six-month reporting period? [open ended- allow for numeric answer, no maximum value and text for unit of measure]

11. What percentage of your outsourcing facility's batches contain less than 60 units/batch? [open ended –- only allow for numeric answer, maximum value of 100, with a "%" after the text box]

12. What percentage of your outsourcing facility's batches are sterile products? [open ended– only allow for numeric answer, maximum value of 100, with a "%" after the text box]

13. What percentage of your outsourcing facility's batches of sterile products are terminally sterilized? [open ended– only allow for numeric answer, maximum value of 100, with a "%" after the text box]

14. What percentage of your outsourcing facility's product batches utilize FDA-approved product as starting material? [open ended– only allow for numeric answer, maximum value of 100, with a "%" after the text box]

15. Does your compounding outsourcing facility(ies) produce products that are on the FDA's drug shortage list? *[multiple choice – select one]*
    a. Yes
        i. If yes, which ones? Please select all that apply *[alphabetic drop down list from here.]*
    b. No
        i. If no, why not? Please specify: _____
    c. I don't know what drugs are on the FDA shortage list
    d. I'm not sure if the drugs we produce are on the FDA shortage list

16. How does your compounding outsourcing facility(ies) choose which shortage drugs to make? *[multiple choice – select top three]*
    a. High demand signal
    b. Low ramp up time to production (e.g., process validation, stability testing). If selected, please specify: _____
    c. High ramp up time to production (e.g., process validation, stability testing). If selected, please specify: _____
    d. High profit margin
    e. High frequency on the drug shortage list
    f. High expected time on the drug shortage list
    g. Low level of drug product complexity
    h. Availability of production line capacity
    i. Other. Please specify: _____

17. How quickly can your compounding outsourcing facility(ies) ramp up production of a shortage drug (i.e. time from decision to produce drug until the drug goes to market)? *[multiple choice – select one]*
    a. Under 2 months
    b. 2-4 months

c. 4-6 months
d. 6-8 months
e. 8-10 months
f. 10-12 months
g. Over 12 months
h. Other. Please specify: _____

18. In April 2020, FDA released the Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency. Did / is your compounding outsourcing facility(ies) produce(ing) a new drug product under this temporary policy? *[multiple choice – select one]* (***Note:*** *the term* ***"new drug products"*** *above refers to drugs made from active ingredients (e.g., not repackaged drug products) and drug products not previously made by a compounding outsourcing facility(ies) before release of the temporary guidance).*
    a. Yes
        i. If yes, did / is the temporary policy impact(ing) the time it took to ramp up production of the drug (i.e., time from decision to produce drug until the drug goes to market)? *[multiple choice – select one]*
            - Yes
                a. If yes, how? Please specify: _____
            - No
            - Unsure

    b. No
    c. Unsure

19. Which, if any, of the policies under the COVID Compounding guidances were helpful in expediting the ability to provide drugs to the marketplace [please specify]?

20. How could the ramp up of production of shortage drugs be expedited? *[open-ended]*

Section Three - Business Model: Financial and Operational Considerations and Decisions. The questions in this section are intended to help understand the factors that influence the decisions of compounding outsourcing facilities.

21. Outside of protecting patients from harm, what do you see as the incentives for investing in good quality compounded drug production at your compounding outsourcing facility(ies)? [open-ended]

22. Outside of the potential for patient harm, what do you see as the risks for not investing in good quality compounded drug production at your compounding outsourcing facility(ies)? [open-ended]

23. Do purchasers place greater value on outsourcing facility products they consider to have greater quality assurance?

24. How does your compounding outsourcing facility(ies) select API suppliers? *[open-ended]*

25. How does your compounding outsourcing facility(ies) qualify API suppliers? *[open-ended]*

26. Does your compounding outsourcing facility(ies) establish quality agreements with API suppliers as a part of your contracts? *[multiple choice – select one]*
    a. Yes
        i. If yes, what are the key elements of these quality agreements? *[open-ended]*
    b. No
        i. If no, why not? *[open-ended]*

27. Does your compounding outsourcing facility(ies) determine / identify the active ingredient source manufacturers for the drugs that your outsourcing facility(ies) produces?
    a. Yes
        i. If yes, how? Please specify: _____
    b. No
        i. If no, why not? Please specify: _____
    c. Unsure

28. How would you describe your compounding outsourcing facility(ies)'s relationship and interaction with API suppliers? *[open-ended]*

29. What challenges does your compounding outsourcing facility(ies) face with their API suppliers (if any)? *[multiple choice –select top three]*
    a. High costs
    b. Inconsistent quality
    c. Consistently low quality
    d. Inconsistent customer service
    e. Inconsistent supply
    f. Lack of transparency
    g. Slow delivery
    h. Other. Please specify: _____

30. Does your compounding outsourcing facility(ies) work on investigational drugs? *[multiple choice – select one]*
    a. Yes
        i. If yes, why does your compounding outsourcing facility(ies) seek out these projects? *[open-ended]*
    b. No
    c. Unsure

31. How has COVID-19 affected your compounding outsourcing facility(ies)'s operations? *[multiple choice – select all that apply]*
    a. Decreased production volume. Please specify: _____
    b. Increased production volume. Please specify: _____

c. Limited production capacity. Please specify: _____
d. Increased production capacity. Please specify: _____
e. Limited engagement with buyers. Please specify: _____
f. Increased engagement with buyers. Please specify: _____
g. Narrowed product portfolio. Please specify: _____
h. Expanded product portfolio. Please specify: _____
i. Narrowed shortage drugs product portfolio. Please specify: _____
j. Expanded shortage drugs product portfolio. Please specify: _____
k. Decreased production volume of shortage drugs. Please specify: _____
l. Increased production volume of shortage drugs. Please specify: _____
m. Limited geographic footprint. Please specify: _____
n. Expanded geographic footprint. Please specify: _____
o. Increased costs. Please specify: _____
p. Decreased costs. Please specify: _____
q. Other. Please specify: _____
r. N/A. COVID has not affected our operations.

Section Four - Compliance and Quality: Federal Legislative and Regulatory Policies. The questions in this section are intended to help understand the opportunities and barriers related to compliance and quality for the compounding outsourcing facility market.

32. What areas of CGMP requirements are most challenging to implement at your facility and why? *[multiple choice – select top three]*
    a. Quality assurance activities. Please specify why: _____
    b. Facility design. Please specify why: _____
    c. Control systems and procedures for maintaining suitable facilities. Please specify why: _____
    d. Environmental and personnel monitoring. Please specify why: _____
    e. Equipment. Please specify why: _____
    f. Containers and closures. Please specify why: _____
    g. Components. Please specify why: _____
    h. Production and process controls. Please specify why: _____
    i. Laboratory controls. Please specify why: _____
    j. Stability/expiration dating for compounded drug products. Please specify why: _____
    k. Packaging and labels. Please specify why: _____
    l. Reserve samples. Please specify why: _____
    m. Complaint handling. Please specify why: _____
    n. Other. Please specify what and why: _____

33. What training topics would be useful for staff at your compounding outsourcing facility(ies)? *[open-ended]*

34. Has your compounding outsourcing facility(ies) received 483 observations related to CGMP? *[multiple choice – select one]*
    a. Yes
        i. If yes, was your compounding outsourcing facility(ies) aware of the CGMP provisions identified in the 483?
            - Yes
                a. If yes, was your compounding facility(ies) able to address the CGMP issues?
                    i. Yes
                    ii. No
                        - If no, what is the reason your compounding outsourcing facility(ies) could not address the CGMP issues? *[multiple choice – select one]*
                            a. realized it was a requirement, but did not realize it was happening at my compounding outsourcing facility(ies);
                            b. realized it was a requirement and knew it was happening, but did not believe it was significant enough to correct;
                            c. knew it was happening and planned to correct, but did not have time before inspection;
                            d. knew it was happening, but did not have adequate available funding to correct immediately;
                            e. knew it was happening, but correcting it would render product or facility not economically viable;
                            f. knew it was happening, but did not know how to correct it;
                            g. Other. Please specify: _____
            - No
            - Unsure

35. What challenges does your compounding outsourcing facility(ies) face in responding to Form 483s? *[multiple choice – select all that apply]*
    a. Not aware of CGMP observation. Please specify: _____
    b. Do not know how to address the CGMP provision / observation. Please specify: _____
    c. Do not know what is expected in a Form 483 response. Please specify: _____
    d. Do not know the process for responding to Form 483s. Please specify: _____

e. Do not have a point of contact at FDA with whom to communicate with about a Form 483 response. Please specify: _____
f. Lengthy response time from FDA. Please specify: _____
g. Other. Please specify: _____

36. What challenges does your compounding outsourcing facility(ies) face in addressing Warning Letters? *[multiple choice – select all that apply]*
    a. Not aware of FDCA violation. Please specify: _____
    b. Do not know how to address the FDCA violation Please specify: _____
    c. Do not know what is expected in a Warning Letter response. Please specify: _____
    d. Do not know the process for responding to a Warning Letter. Please specify: _____
    e. Do not have a point of contact at FDA with whom to communicate with about a Warning Letter response. Please specify: _____
    f. Lengthy response time from FDA. Please specify: _____
    g. Other. Please specify: _____

37. FDA is considering engaging in targeted scientific / lab-based research to help inform policy and regulatory decisions. What research topics do you think it would be useful for the CoE examine through this capability? *[multiple choice – select all that apply]*

38. Does your compounding outsourcing facility(ies) conduct the following types of tests on products? *[multiple choice – select multiple]* If yes, approximately how many of each test is run over a 6-month period? T*he frequency should* be your best estimate without spending time reviewing documentation. If you use both in-house testing and contract laboratories for the type same test, please answer yes and approximate the number for both.

a. In-house testing

Test	Conducted **In-house** (Check all that apply)	Please indicate the approximate number of tests completed **in-house** during the last 6 months.
Sterility testing	☐	
Impurity testing	☐	
endotoxin	☐	
PH	☐	
Visible particulates	☐	
Subvisible particulates	☐	
Anti-microbial effectiveness testing	☐	
Preservative content	☐	

Microbial Enumeration	☐	
Tests for specified microorganisms	☐	
Stability testing	☐	
Container closure integrity testing	☐	
Strength/assay testing	☐	
Other. Please specify: _____	☐	

If you said yes to Strength/assay testing, do you use HPLC or another highly specific method?

☐HPLC

☐Other highly specify method

b. Contract laboratories

Test	Conducted **Contract laboratories** (Check all that apply)	Please indicate the approximate number of tests completed **Contract laboratories** during the last 6 months.
Sterility testing	☐	
Impurity testing	☐	
endotoxin	☐	
PH	☐	
Visible particulates	☐	
Subvisible particulates	☐	
Anti-microbial effectiveness testing	☐	
Preservative content	☐	
Microbial Enumeration	☐	
Tests for specified microorganisms	☐	
Stability testing	☐	
Container closure integrity testing	☐	
Strength/assay testing	☐	
Other. Please specify: _____	☐	

If you said yes to Strength/assay testing, do you use HPLC or another highly specific method?

☐HPLC

☐Other highly specify method

a. If you use "contract laboratories:"
    i. How does your compounding outsourcing facility(ies) confirm whether the contract laboratory complies with CGMP? *[open-ended]*How does your compounding outsourcing facility(ies) qualify testing laboratories? *[open-ended]*
    ii. Does your compounding outsourcing facility(ies) establish quality agreements with testing laboratories as part of your contracts? *[multiple choice – select one]*
        - Yes

    a. If yes, what are the key elements of these quality agreements? *[open-ended]*
- No
    a. If no, why not? *[open-ended]*
- Unsure

39. How would you describe your compounding outsourcing facility(ies)'s relationship and interactions with testing laboratories? *[open-ended]*

40. What difficulties are encountered in reporting adverse events? *[multiple choice – select all that apply]*

a. Understanding how to report adverse events. Please explain: _____
b. Level of effort required. Please explain: _____
c. Tracking / identifying adverse events. Please explain: _____
d. Other. Please specify: _____
e. N/A. We do not face difficulties in reporting adverse events.

Section Five – Engagement with FDA. This section is intended to help understand the opportunities and barriers related to the outsourcing facility market's interactions and engagement with FDA.

41. Please rate your level of agreement with the following statements:

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree
The current engagement my compounding outsourcing facility(ies) has with the FDA is useful	●	●	●	●	●
FDA public communications are useful for my compounding outsourcing facility(ies)	●	●	●	●	●

42. What means does your compounding outsourcing facility(ies) use to interpret / understand FDA policy information? *[multiple choice – select all that apply]*

a. Consultants.
b. Staff with relevant experience.
c. The FDA website. Please specify: _____
d. Trainings. Please specify: _____
e. Other outsourcing facilities.

f. Trade associations / industry groups.
g. Other. Please specify: _____

43. Please rate your agreement with the following statement in terms of how clear you believe FDA policy communications are. *[multiple choice – select one]*

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree
FDA policy communications are clear	●	●	●	●	●

a. If you selected "Disagree," what elements specifically make FDA policy communications unclear and why? *[open-ended]*
b. If you selected "Strongly Disagree," what elements specifically make FDA policy communications unclear and why? *[open-ended]*

44. Please rate your agreement with the following statements in terms of how useful the following methods of communication are when trying to obtain information related to FDA policies and activities.

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree
Answers to inquiries submitted to FDA are useful for obtaining information related to FDA policies and activities	●	●	●	●	●
Presentations made by FDA staff at conferences are useful for obtaining information related to FDA policies and activities	●	●	●	●	●
Listening sessions are useful for obtaining information related to FDA policies and activities	●	●	●	●	●
Compounding Risk Alerts are useful for obtaining information related to FDA policies and activities	●	●	●	●	●
FDA Twitter is useful for obtaining information related to FDA policies and activities	●	●	●	●	●
FDA Website is useful for obtaining information related to FDA policies and activities	●	●	●	●	●

45. Does your compounding outsourcing facility(ies) engage in the CoE (e.g. through participating in trainings, , conversations, the annual conference)? *[multiple choice – select one]*

a. Yes
    i. If yes, why does your compounding outsourcing facility(ies) choose to engage in the CoE? *[multiple choice – select all that apply]*
        - To better understand regulatory processes
        - To better understand guidances and policies
        - To train our staff
        - To get connected with other stakeholders in the compounding outsourcing facility(ies) market
        - To engage directly with FDA
        - To share our perspective and provide feedback (e.g. on challenges, opportunities, etc.)
        - To stay up to date on the latest information, decisions, and guidance
        - Other. Please specify: _____
b. No
    i. If no, what barriers to participation in the CoE does your compounding outsourcing facility(ies) face to the below opportunities? *[open-ended]*

	Do not have enough time	Do not know how to participate	Do not see benefit of participation	N/A (do not face barriers)	Other	If other, please specify:
Training	●	●	●	●	●	
Annual Conference	●	●	●	●	●	
Conversations	●	●	●	●	●	

46. Which of the following factors impact your motivation to participate in FDA CoE training courses? *[multiple choice – select all that apply]*

a. Length of the course. Please specify: _____
b. Opportunity to claim Continuing Education (CE) credits. Please specify: _____
c. Relevancy of training topic(s) to my job. Please specify: _____
d. Encouragement from outsourcing facility leadership/colleagues to attend. Please specify: _____
e. Course format (e.g. self-paced vs. instructor-led). Please specify: _____

f. Other. Please specify: _____

47. Which of the following FDA CoE training course formats do you generally prefer? *[multiple choice – select all that apply]*

a. Self-paced web-based training
b. Virtual instructor-led training
c. In-person instructor-led training
d. Cohort-style training
e. Other. Please specify: _____

48. What is the ideal approximate length for FDA CoE training courses taught in the following formats? *[numerical entry in hours]*

a. Self-paced web-based training: *[numerical entry in hours]*
b. Virtual instructor-led training: *[numerical entry in hours]*
c. In-person instructor-led training: *[numerical entry in hours]*
d. Cohort-style training: *[numerical entry in hours]*

49. What channels are the most useful for receiving communications about CoE events and engagement opportunities? *[multiple choice – select all that apply]*

a. CoE e-mail communications
b. CoE webpage
c. CoE phone outreach
d. FDA social media (e.g. Twitter)
e. Other. Please specify: _____

50. How would you enhance productive collaboration and engagement between compounding outsourcing facility(ies) and the FDA moving forward? *[open-ended]*