Survey Questions for Registered 503Bs (Compounding Outsourcing Facilities)

OMB Control No.: 0910-XXXX

Expiration Date : XX/XX/2020

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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, in FY2020 FDA is establishing the Compounding Quality Center of Excellence (CoE) to help the compounding outsourcing facility industry meet its intended function. The aim is to formally stand up the center in FY2021. To inform the development of the CoE, the 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.

The survey will take ~60 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. Is your compounding outsourcing facility(ies) publicly-traded or a privately held? *[multiple choice – select one]*
    a. Publicly-traded
    b. Privately held
3. How many **full-time** staff are employed by your compounding outsourcing facility(ies)? *[multiple choice – select one]*
    a. 0-10
    b. 11-30
    c. 31-70

    d. 71-100
    e. 100+
    f. I don't know
4. How many **part-time** staff are employed by your compounding outsourcing facility(ies)? *[multiple choice – select one]*
    a. 0-10
    b. 11-30
    c. 31-70
    d. 71-100
    e. 100+
    f. I don't know
5. What State(s) in the U.S. is your compounding outsourcing facility(ies) licensed in? Please check all that apply. *[multiple choice – select all that apply]*
    a. Alabama
    b. Alaska
    c. Arizona
    d. Arkansas
    e. California
    f. Colorado
    g. Connecticut
    h. Delaware
    i. Florida
    j. Georgia
    k. Hawaii
    l. Idaho
    m. Illinois
    n. Indiana
    o. Iowa
    p. Kansas
    q. Kentucky
    r. Louisiana
    s. Maine
    t. Maryland
    u. Massachusetts
    v. Michigan
    w. Minnesota
    x. Mississippi
    y. Missouri
    z. Montana
    aa. Nebraska
    bb. Nevada
    cc. New Hampshire
    dd. New Jersey
    ee. New Mexico

ff. New York
gg. North Carolina
hh. North Dakota
ii. Ohio
jj. Oklahoma
kk. Oregon
ll. Pennsylvania
mm. Rhode Island
nn. South Carolina
oo. South Dakota
pp. Tennessee
qq. Texas
rr. Utah
ss. Vermont
tt. Virginia
uu. Washington
vv. West Virginia
ww. Wisconsin
xx. Wyoming

6. 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:_____
7. 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+
8. What percent (estimated) of your compounding outsourcing facility(ies)' total gross **revenue** is from: *[select and numerical entry for all that apply]*
    a. Repackaging *[numerical entry]*
    b. Compounding from approved FDA products *[numerical entry]*
    c. Compounding from bulk drug substances *[numerical entry]*
    d. Other *[numerical entry]*
        i. If other, please explain *[open-ended]*

9. What percent (estimated) of your compounding outsourcing facility(ies)' total annual **resources** (time, staff, funds) are allocated to: *[select and numerical entry for all that apply]*
    a. Repackaging *[numerical entry]*
    b. Compounding from approved FDA products *[numerical entry]*
    c. Compounding from bulk drug substances *[numerical entry]*
    d. Other *[numerical entry]*
        i. If other, please explain *[open-ended]*
10. How many units of drug product does your compounding outsourcing facility(ies) produce each year? *[numerical entry]*
11. Of your compounding outsourcing facility(ies)' total annual products, what percent are: *[select and numerical entry for all that apply]*
    a. Sterile products *[numerical entry]*
    b. Non-Sterile products *[numerical entry]*
12. Of your compounding outsourcing facility(ies)' total annual products, what percent are: *[select and numerical entry for all that apply]*
    a. Produced per a patient-specific prescription *[numerical entry]*
    b. Non patient-specific *[numerical entry]*
13. Which therapeutic areas does your compounding outsourcing facility(ies) produce compounded drugs for? Please include the estimated annual percentage of total products for each therapeutic area. *[select and numerical entry for all that apply]*
    a. Analgesia/Pain/Addiction *[numerical entry]*
    b. Anesthesia *[numerical entry]*
    c. Anti-Infective *[numerical entry]*
    d. Antiviral *[numerical entry]*
    e. Cardiovascular *[numerical entry]*
    f. Dental *[numerical entry]*
    g. Dermatology *[numerical entry]*
    h. Endocrinology/Metabolism *[numerical entry]*
    i. Gastroenterology *[numerical entry]*
    j. Hematology *[numerical entry]*
    k. Inborn Errors *[numerical entry]*
    l. Medical Imaging *[numerical entry]*
    m. Musculoskeletal *[numerical entry]*
    n. Neurology *[numerical entry]*
    o. Oncology *[numerical entry]*
    p. Ophthalmology *[numerical entry]*
    q. Pediatric *[numerical entry]*
    r. Psychiatry *[numerical entry]*
    s. Pulmonary/Allergy *[numerical entry]*
    t. Renal *[numerical entry]*
    u. Reproductive *[numerical entry]*
    v. Rheumatology *[numerical entry]*
    w. Total Parenteral Nutrition *[numerical entry]*
    x. Transplant *[numerical entry]*

y. Urology *[numerical entry]*
z. Other (please specify):_____

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.

14. What factors influenced the decision to register as a 503B? [open-ended]
15. As a 503B, what are the key business challenges that your compounding outsourcing facility(ies) faces? *[multiple choice – select all that apply]*
    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: _____
16. As a 503B, what are the key drivers of growth for your compounding outsourcing facility(ies) *[multiple choice – select all that apply]*
    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: _____

17. 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
    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
18. Does your compounding outsourcing facility(ies) produce products for purchasers that have indicated a supply interruption, but the product is **not** on the FDA's drug shortage list? *[multiple choice – select one]*
    a. Yes
        i. If yes, please specify for which products: _____
    b. No
    c. Unsure
19. From your perspective, is demand for **sterile** compounded drugs: *[multiple choice – select one]*
    a. Increasing. Please explain: _____
    b. Stagnant. Please explain:_____
    c. Decreasing. Please explain:_____
    d. Varies by product and sector. Please explain:_____
    e. Other. Please explain:_____
20. From your perspective, is demand for **non-sterile** compounded drugs: *[multiple choice – select one]*
    a. Increasing. Please explain: _____
    b. Stagnant. Please explain:_____
    c. Decreasing. Please explain:_____
    d. Varies by product and sector. Please explain:_____
    e. Other. Please explain:_____
21. What areas does your compounding outsourcing facility(ies) see as potential for new market growth?(e.g. disease states, populations, etc.) *[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.

22. Are there products that your compounding outsourcing facility(ies) have been asked to make but chose not to? *[multiple choice – select one]*
    a. Yes
        i. If yes, why? *[open-ended]*
    b. No
    c. Unsure
23. What are the most difficult compounded products for your compounding outsourcing facility(ies) to make? Why? *[open-ended]*

24. Does cost to develop a formulation influence which drug products your OF makes?
    a. Yes
        i. If yes, how? [open-ended]
    b. No
25. Do regulatory parameters restrict which compounded products your compounding outsourcing facility(ies) can make? *[multiple choice – select one]*
    a. Yes
        i. If yes, what are they? *[open-ended]*
    b. No
    c. Unsure
26. What technological advancements does your compounding outsourcing facility(ies) views as a differentiator or driver of potential business growth? *[open-ended]*
27. How does your compounding outsourcing facility(ies) select API suppliers? *[open-ended]*
28. How does your compounding outsourcing facility(ies) qualify API suppliers? *[open-ended]*
29. How does you compounding outsourcing facility(ies) monitor the suitability and quality of API suppliers? *[open-ended]*
30. What challenges does your compounding outsourcing facility(ies) face with their API suppliers (if any)? *[multiple choice – select all that apply]*
    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:_____
31. Does your compounding outsourcing facility(ies) utilize a Group Purchasing Organization? *[multiple choice – select one]*
    a. Yes
        i. If yes, what are the benefits and challenges of contracting with Group Purchasing Organizations? *[open-ended]*
    b. No
        i. If no, why? *[open-ended]*
    c. Unsure
32. Does your compounding outsourcing facility(ies) interface with Pharmacy Benefit Managers? *[multiple choice – select one]*
    a. Yes
        i. If yes, what are the benefits of interfacing with Pharmacy Benefit Managers? *[open-ended]*
        ii. If yes, what are the challenges of interfacing with Pharmacy Benefit Managers? *[open-ended]*
    b. No
    c. Unsure

33. Does your compounding outsourcing facility(ies) rely on any outside entities to market or promote your products? *[multiple choice – select one]*
    a. Yes
        i. If yes, what are the names of these entities?
    b. No
    c. Unsure

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.

34. What areas of CGMP requirements are most challenging to implement at your facility and why? *[multiple choice – select all that apply]*
    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: _____
35. What areas of CGMP requirements would training be useful for? *[open-ended]*
    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: _____

36. 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
                        o 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

37. What are the consequences for the following failures and actions: *[matrix table – select all that apply]*

	Financial	Brand reputation	Public health	State Licensing	Other	If other, please specify:
A product failure	●	●	●	●	●	

Enforcement action brought against a compounding outsourcing facility	●	●	●	●	●	
Violative inspection	●	●	●	●	●	
Written response(s) to 483	●	●	●	●	●	
Written response(s) to Warning Letter	●	●	●	●	●	
Enforcement actions	●	●	●	●	●	
Adverse events	●	●	●	●	●	
Recalls	●	●	●	●	●	

38. How does your compounding outsourcing facility(ies) conduct testing of products? *[multiple choice – select one]*
    a. In-house testing
        i. If selected, please indicate for which types of testing: *[multiple choice – select all that apply]*
            - Sterility testing
            - Strength/assay testing
            - Impurity testing
            - Other. Please specify:_____
    b. Contract laboratories

        i. If selected, please indicate for which types of testing: *[multiple choice – select all that apply]*
            - Sterility testing
            - Strength/assay testing
            - Impurity testing
            - Other. Please specify:_____
    c. Both
        i. If selected, please indicate for which types of testing:
            - Sterility testing
            - Strength/assay testing
            - Impurity testing
            - Other. Please specify:_____

39. What factors are relevant to deciding whether to do in-house testing or outsource to contractors? *[multiple choice – select all that apply]*
    a. Cost. Please explain:_____
    b. Time. Please explain:_____
    c. Quality. Please explain:_____
    d. Access. Please explain:_____
    e. Knowledge. Please explain:_____
    f. Staff. Please explain:_____
    g. Physical space. Please explain:_____
    h. Other. Please specify and explain:_____
40. How does your compounding outsourcing facility(ies) confirm whether contract labs are in compliance with CGMP? *[multiple choice – select all that apply]*
    a. Reviewing publicly available information
    b. Requesting information from the contract lab(s)
    c. Requesting information from inspectors of the contract lab(s)
    d. Other. Please specify_____
    e. My compounding outsourcing facility(ies) does not use contract labs
    f. My compounding outsourcing facility(ies) is not able to confirm this. Please explain why: _____
41. Does your compounding outsourcing facility(ies) have a process in place for tracking and reporting adverse events? *[multiple choice – select one]*
    a. Yes
        i. If yes, is the process formalized in an SOP or other standardized documentation? Please explain. *[open-ended]*
    b. No
        i. If no, please explain *[open-ended]*
    c. Unsure
        i. If unsure, please explain *[open-ended]*
42. What are the difficulties 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 and explain: _____

43. Does your compounding outsourcing facility(ies) incorporate automated technologies such as robotics, etc. into production processes? *[multiple choice – select one]*

    a. Yes
        i. If yes, what technologies does your OF(s) use? *[open-ended]*
        ii. If yes, how does your compounding outsourcing facility(ies) qualify the new automated equipment and acquire in-house expertise to oversee the automation *[multiple choice – select all that apply]*
            - Hiring for specific skill sets and knowledge
            - Training current staff
            - Hiring consulting entities
            - Other. Please specify: _____
    b. No
        i. If no, why not? *[open-ended]*
    c. Unsure

44. What other technologies does your compounding outsourcing facility(ies) most frequently use in its production processes? *[open-ended]*
45. What are the internal processes in place to identify and address quality failures? *[open-ended]*

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

46. 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)	●	●	●	●	●

47. The FDA uses several mechanisms to communicate deficiencies to OFs. Please rate your agreement with the following statements in terms of how useful the mechanism is for preventing or correcting violations at your OF prior to patient harm or enforcement action.

	Strongly Disagree	Disagree	Neither Disagree nor Agree	Agree	Strongly Agree
483 (to firm) are useful for preventing or correcting	●	●	●	●	●

violations at your compounding outsourcing facility(ies) prior to patient harm or enforcement action					
483s (to competitor, partially redacted and posted online) are useful for preventing or correcting violations at your compounding outsourcing facility(ies) prior to patient harm or enforcement action	●	●	●	●	●
Untitled Letters are useful for preventing or correcting violations at your compounding outsourcing facility(ies) prior to patient harm or enforcement action	●	●	●	●	●
Warning Letters (to firm) are useful for preventing or correcting violations at your compounding outsourcing facility(ies) prior to patient harm or enforcement action	●	●	●	●	●
Warning Letters (to competitor, partially redacted and posted online) are useful for preventing or correcting violations at your compounding outsourcing facility(ies) prior to patient harm or enforcement action	●	●	●	●	●
Phone calls with FDA are useful for preventing or correcting violations at your compounding outsourcing facility(ies) prior to patient harm or enforcement action	●	●	●	●	●
In-person regulatory meetings are useful for preventing or correcting violations at your compounding outsourcing facility(ies) prior to patient harm or enforcement action	●	●	●	●	●
Conversations with FDA investigators during inspections are useful for preventing or correcting violations at your compounding outsourcing	●	●	●	●	●

facility(ies) prior to patient harm or enforcement action					
Pre-operational meetings or site visits are useful for preventing or correcting violations at your compounding outsourcing facility(ies) prior to patient harm or enforcement action	●	●	●	●	●

48. How regularly do you consult the FDA Website for information? *[multiple choice – select one]*
    a. Daily
    b. Weekly
    c. Monthly
    d. Every few months
    e. Annually
    f. Every few years
    g. Never

49. 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					

50. What are the most helpful methods for your compounding outsourcing facility(ies) to receive FDA communications? *[multiple choice – select all that apply]*
    a. FDA Website
    b. Infographics and Factsheets
    c. FDA Social Media
    d. Direct emails from FDA
    e. Newsletters from the FDA
    f. Newsletters from other organizations (e.g. Pharmacy Times)
    g. Industry conferences. Please specify on what topics:_____
    h. Webinars
    i. Other. Please specify:_____
51. Does your compounding outsourcing facility(ies) know how to effectively respond to deficiencies found after an FDA inspection? *[multiple choice – select one]*
    a. Yes
        i. If yes, how do you respond? *[open-ended]*
    b. No
        i. If no, why not? *[open-ended]*
    c. Unsure
52. Is there anything surprising about what is covered during an FDA inspection? *[multiple choice – select one]*
    a. Yes
        i. If yes, please explain *[open-ended]*
    b. No
53. How frequently does your compounding outsourcing facility(ies) train employees? [multiple choice – select one]
    a. Daily
    b. Weekly
    c. Monthly
    d. Quarterly
    e. Yearly
    f. Other. Please specify:_____
54. What forms of training does your outsourcing facility(ies) conduct? [multiple choice – select all that apply]
    a. On-the-job
    b. Mentoring
    c. Technical guides/manuals
    d. In-person classes
    e. Web-based classes
    f. Conferences/events
    g. Other. Please specify:_____

55. Did you attend, or do you plan to attend, the in-person trainings offered this year through the Center of Excellence on Compounding for Outsourcing Facilities in the areas of Sterile Processing, Cleanroom Design and Airflow, Investigations and CAPA, and Environmental Monitoring?
    a. Yes, I have attended.
        i. If yes, please provide any feedback you have on the training *[open-ended]*
    b. Yes, plan to attend
    c. No
        i. If no, please explain *[open-ended]*
56. What additional trainings would be useful? *[open-ended]*
57. How would you enhance productive collaboration and engagement between 503Bs and the FDA moving forward? *[open-ended]*