Questions for Registered 503Bs (Outsourcing Facilities)

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 engage with outsourcing facilities and other stakeholders to improve the quality of compounded drugs. To continue to inform the CoE's activities, FDA is inviting all outsourcing facilities to participate in this survey 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 survey intentionally revisits questions asked last year 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 be open until the end of the day on [day of week], [month, day], 2022 and will take ~ one hour 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.

Please limit responses to one per outsourcing facility. If you represent multiple outsourcing facilities, please complete a response per outsourcing facility. Questions in this survey touch on facility production, culture, record of compliance, and stakeholder engagement. Please coordinate with colleagues to ensure that your facility's response answers the content queried as accurately as possible. Please answer all of the survey questions and note that if you would like to be able to save your survey responses and come back to them later, you need to enable cookies on your browser, ensure that you are not in incognito or private mode, and continue to use the same device and browser as you began filling the survey out in. For additional technical support and questions, please reach out to src@deloitte.com.

We look forward to hearing from you and thank you for your participation!

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

1. To the best of your knowledge, are you the sole respondent responding on behalf of your outsourcing facility? *[multiple choice – select one]*
    a. Yes

b. No

2. To the best of your knowledge, has your outsourcing facility previously submitted a response for this 2022 outsourcing facility survey? *[multiple choice – select one]*
    a. Yes
    b. No

3. At the time of taking this survey, please select the training sessions your outsourcing facility has taken to date. *[multiple choice – select all that apply]*

    Virtual Instructor Led Trainings
    a. Environmental Monitoring
    b. Sterile Drug Compounding
    c. Cleanroom
    d. Investigations and Corrective and Preventive Actions
    e. *Upcoming: Process Validation, and Quality Management Systems (both expected late Spring 2022)*

    Self-Paced Web-based Trainings
    f. Regulatory Framework for Human Drug Compounding
    g. Airflow
    h. Insanitary Conditions and Sterility Assurance
    i. Stability and Beyond Use Dates
    j. Outsourcing Facility Guide
    k. Investigations and Corrective and Preventive Actions
    l. Personnel Gowning in Sterile Drug Production
    m. Supplier/Contractor Qualification and Management

4. Does the company in which your 503B outsourcing facility operates also operate a separate 503A facility? *[multiple choice – select one]*
    a. Yes
    b. No.
        i. Was your outsourcing facility formerly a 503A facility? *[multiple choice – select one]*
            a. Yes
                a. If yes, what were factors that influenced your decision to become a 503B facility? *[Please select all that apply.]*
                    i. To produce drug products that leverage the benefits of a CGMP standard
                    ii. To produce drug products at scale for a health/hospital system
                    iii. Desire to produce larger batch products to improve profit margin
                    iv. Ability to meet CGMP standards through access to capital and/or trained staff
                    v. Other. Please specify: *[open ended]* _____

b. No. My company does not currently operate a separate 503A facility and did not formerly operate a 503A facility.

5. What percentage of your outsourcing facility's product portfolio are created to address patient-specific prescriptions?
    a. None. My facility only produces non-patient-specific prescription products (0%). Please specify *[open-ended]*:_____
    b. A smaller percentage (1% to 19%). Please specify *[open-ended]*:_____
    c. A substantial percentage (20% to 49%). Please specify *[open-ended]*:_____
    d. Most of the portfolio (50% to 79%). Please specify *[open-ended]*:_____
    e. Nearly all of the portfolio (80% to 100%). Please specify *[open-ended]*:_____

6. How many employees do you have at your outsourcing facility? *[multiple choice - select one]*
    a. 1-10
    b. 11-50
    c. 51-100
    d. 101-500
    e. 501-1,000
    f. 1,001+
    g. Other. Please specify: *[open ended]*_____

7. What is your role at your outsourcing facility? Please select all that apply to you, or select one that best describes your role. *[multiple choice - select one/select all that apply]*
    a. Pharmacist
    b. Pharmacy technician
    c. Laboratory staff
    d. Quality staff including quality control, quality assurance
    e. Manufacturing staff (e.g., operations, production, manufacturing)
    f. Microbiologist
    g. Management
    h. Other. Please specify: *[open ended]* _____

8. What specialties do your outsourcing facility hire? Please select all that apply. *[multiple choice - select all that apply]*
    a. Pharmacists
    b. Pharmacy technicians
    c. Laboratory staff
    d. Quality staff, including quality control and quality assurance
    e. Manufacturing staff (e.g., operations, production, manufacturing)
    f. Microbiologists
    g. Management
    h. Other. Please specify: *[open ended]* _____

9. 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. 21-49
    f. 50+

10. What types of practice settings receive your 503B compounded products and what 503B product is commonly requested? Please select all practice settings that apply and enter the 503B product(s) in the open-ended response field. *[multiple choice – select all that apply]*
    a. Independent hospital(s)/Medical center(s). Please specify: *[open-ended]*_____
    b. Physician office(s). Please specify: *[open-ended]*_____
    c. Clinic(s). Please specify: *[open-ended]*_____
    d. Nursing Home(s). Please specify: *[open-ended]*_____
    e. Health system(s)/Integrated delivery network(s). Please specify: *[open-ended]*_____
    f. Surgery center(s). Please specify: *[open ended]* _____
    g. Ambulatory care center (Outpatient Care). Please specify: *[open ended]* _____
    h. Pharmacy services. Please specify: *[open ended]* _____
    i. Veterinary services. Please specify: *[open ended]* _____
    j. Wellness clinic(s). Please specify: *[open ended]* _____
    k. Refineries. Please specify: *[open ended]* _____
    l. Infusion therapy centers. Please specify: *[open ended]* _____
    m. Other. Please specify: *[open ended]* _____

11. *For the following question, please use numbers and do not include symbols like %. Answers for selected practice settings should sum to a total of 100.*
    What percent (estimated) of your outsourcing facility's product volume is being provided to the following providers? Please select all practice settings that apply and enter the corresponding estimated percentage of products provided. *[select and numerical entry for all that apply]*
    a. Independent hospital(s)/Medical center(s) *[numerical entry]*
    b. Physician office(s) *[numerical entry]*
    c. Clinic(s) *[numerical entry]*
    d. Nursing home(s) *[numerical entry]*
    e. Health system(s)/Integrated delivery network(s) *[numerical entry]*
    f. Surgery center(s) *[numerical entry]*
    g. Ambulatory care center (Outpatient Care) *[numerical entry]*
    h. Pharmacy services *[numerical entry]*
    i. Veterinary services *[numerical entry]*
    j. Wellness clinic(s) *[numerical entry]*
    k. Refineries *[numerical entry]*
    l. Infusion therapy centers *[numerical entry]*
    m. Other *[numerical entry]*
        a. If other, please specify: *[open-ended]*

12. Is your outsourcing facility a nonprofit? *[multiple choice – select one]*
    a. Yes
    b. No

13. What was your outsourcing facility's gross revenue last year? *[multiple choice – select one]*
    a. 0 < $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+
    j. Other. Please specify: *[open ended]* _____

14. *For the following question, please use numbers and do not include symbols like %. Numerical answers provided should sum to a total of 100.* What portion (estimated) of your outsourcing facility' portfolio is: *[select and numerical entry for all that apply]*
    a. Compounded from FDA approved drugs *[numerical entry]*
    b. Compounded from bulk API *[numerical entry]*
    c. Other *[numerical entry]*
        If other, please explain *[open-ended]*

15. *For the following question, please use numbers and do not include symbols like %. Numerical answers provided should sum to a total of 100.* What portion (estimated) of your outsourcing facility portfolio consists of:
    [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]*
        If other, please explain *[open-ended]*

16. 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*]

17. How many batches does your outsourcing facility produce in a 6-month reporting period? [*open-ended; allow for numeric answer, no maximum value and text for unit of measure*]

18. 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*]

19. What is the minimum number of units per batch needed for a specific formulation/product to make it economically feasible to produce? *[open-ended]*

a. How many units of this particular formulation/product are produced per year? *[open-ended]*

20. Are there any examples of specific products that your outsourcing facility has chosen not to make because it was not economically feasible? If so, please explain why. *[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.

21. As a 503B, what are the key business challenges that your outsourcing facility faces? Please assess how challenging the following business challenges are for your facility between challenging (1) and not a challenge (4). *[Likert scale]*

	Challenging (1)	Moderately challenging (2)	Mildly challenging (3)	Not a challenge (4)	If "challenging" was selected, please specify: *[open ended]* _____
Cost of testing drug products	●	●	●	●	
Cost of maintaining and operating facilities	●	●	●	●	
Maintaining compliance with CGMP	●	●	●	●	
Recruiting skilled staff	●	●	●	●	
Cost of acquiring equipment	●	●	●	●	
Keeping up with high or growing demand	●	●	●	●	
Inconsistent demand	●	●	●	●	
Availability of bulk API or FDA approved drug products	●	●	●	●	

a. Other: If your outsourcing facility has a key business challenge that is not listed above, please specify what that challenge is and how it impacts your business. *[open-ended]*

22. As a 503B, what are the key drivers of growth for your outsourcing facility? Please assess the following drivers of growth between strong drivers of growth (1) and not a driver of growth (4). : *[Likert scale]*

	Strong driver of growth (1)	Moderately driver of growth (2)	Mild driver of growth (3)	Not a driver of growth (4)	If "strong driver of growth" was selected, please specify: *[open ended]* _____
Competitive Pricing	●	●	●	●	
Increasing demand (growing market)	●	●	●	●	
Building and maintaining relationships with buyers	●	●	●	●	
Increasing market demand for 503B products	●	●	●	●	
Responding to drug shortages	●	●	●	●	
Using automation or technology	●	●	●	●	
Capturing market share from competitors	●	●	●	●	
Tracking and planning for emerging trends that impact demand	●	●	●	●	

a. Other: If your outsourcing facility has a key driver of growth that is not listed above, please specify what that key driver is and how it impacts your business. *[open-ended]*

23. If your outsourcing facility has produced at least one product infrequently and in small batches, what are the key factors affecting your business decision to produce this product? *[multiple choice – select all that apply]*
    a. Addressing drug shortage concerns
    b. Increasing variety of drugs available in product portfolio
    c. Meeting customer need through company's business model
    d. Strengthening business relationship with purchasers
    e. My outsourcing facility does not produce products infrequently and in small batches.-
    f. Other. Please specify: *[open ended]* _____

24. Does your outsourcing facility produce products that are on FDA's drug shortage list? *[multiple choice – select one]*
    a. Yes
        i. If yes, which ones does your outsourcing facility produce from the FDA shortage list? Please specify: *[open-ended]*_____

    b. No
        i. If no, why not? Please specify: *[open-ended]* _____

25. What are the continuing effects of the COVID-19 pandemic on your outsourcing facility between June 2021 and the present? *[Please select all that apply.]*
    a. Use of COVID-19: Guidance: *Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency* to *produce a new drug product. (**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 an outsourcing facility before release of the temporary guidance).*
    b. Changes in product portfolio
    c. Supply shortages in office materials (e.g., PPE)
    d. Difficulty accessing bulk API
    e. Decreased production volume
    f. Increased production volume
    g. Limited engagement with buyers
    h. Other. Please specify: *[open ended]* _____

26. Is your outsourcing facility currently using any of the COVID-19 guidances developed by FDA in response to the pandemic? *[multiple choice – select one]*
    a. Yes
        i. If yes, which COVID-19 guidance(s) are currently being used by your outsourcing facility?
    b. No

27. What is your perspective on the future of the outsourcing facility sector? Please provide any insights on business model operations, best practices, or any barriers to the future prosperity of the sector. *[multiple choice – select all that apply]*
    a. Consolidation of the market through mergers and acquisitions
    b. Bifurcation in the market between large players and facilities focused on niche, therapeutic areas
    c. Entry of Big Pharma
    d. Enhanced community cohesiveness and collaboration across the outsourcing facility sector
    e. Rise in new players entering the market
    f. Other. Please specify: *[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 outsourcing facilities.

28. Is your outsourcing facility pursuing 505(b)(1), 505(b)(2), and/or 505(j) applications now or in the future? Please select all that apply and please specify why you choose a particular approval path over another. *[multiple choice – select all that apply]*
    a. 505(b)(1) applications (NDAs). Please specify: *[open ended]* _____
    b. 505(b)(2) applications (NDAs). Please specify: *[open ended]* _____
    c. 505(j) applications (ANDAs). Please specify: *[open ended]*

29. What percentage of your outsourcing facility product portfolio uses packaged and labeled water sources that are not manufactured in-house? *[multiple choice – select one]*
    a. None (0%)
    b. A smaller percentage (1% to 19%)
    c. A substantial percentage (20% to 49%)
    d. Most of the portfolio (50% to 79%)
    e. Nearly all of the portfolio (80% to 100%)

30. What is the source of purified water/water for injection at your outsourcing facility? *[open-ended]*

31. Does your outsourcing facility perform water testing? *[multiple choice – select one]*
    a. Yes.
        i. Yes, my outsourcing facility tests water in-house.
            a. If selected, please specify, what challenges, if any, have you encountered with respect to water testing? *[open-ended]*
        ii. Yes, my outsourcing facility sends water samples to a contract testing laboratory for analysis.
            a. If selected, how are water samples prepared and stored for transport? *[open-ended]*
    b. No, my outsourcing facility does not perform water testing because my facility receives water from a qualified vendor/supplier that is certified and accompanied by a certificate of analysis.
    c. No, my outsourcing facility does not perform water testing.
        i. Please specify: *[open-ended]*

32. What type of testing does your outsourcing facility perform on water? *[display if answer choice a. (Yes, my outsourcing facility tests water in-house) is selected for Question 29; multiple-choice]*
    a. Chemical testing
        i. If selected, what type of chemical tests are performed? *[open-ended]:*
        ii. Where are chemical tests performed?
            a. At my outsourcing facility
            b. At a contact laboratory
            c. Other. Please specify *[open-ended]:*

b. Microbiological testing
    i. If selected, what type of microbiological tests are performed? *[open-ended]:*
    ii. Where are microbiological tests performed?
        a. At my outsourcing facility
        b. At a contact laboratory
        c. Other. Please specify *[open-ended]:*
c. Other. Please specify *[open-ended]:*

33. Please rank the top five resources used by your outsourcing facility's in-house staff to partner or source information for CGMP training? *[multiple choice – select multiple and rank top 5 in order of preference]*
    a. FDA guidances (posted on FDA website)
    b. Consulting organizations
    c. Trade associations
    d. Subject-matter experts
    e. Professional health organizations. Please specify: *[open ended]* _____
    f. Other. Please specify: *[open ended]* _____

34. What percentage of personnel are you looking to hire right now and why? [multiple choice – select one]
    a. None (0%)
    b. A small percentage (1 – 9%). Please specify: [open ended] _____
    c. A moderate percentage (10 – 20%). Please specify: [open ended] _____
    d. A substantial percentage (21 – 30%). Please specify: [open ended] _____

35. Please rank the top six sources for employment for your outsourcing facility from most preferred (1) to least preferred (7). *[multiple choice – select multiple and rank top 7 in order of preference]*
    a. Students from pharmacy schools
    b. Students from business schools
    c. Former nonprofit employees
    d. Former 503A employees
    e. Former hospital pharmacy employees
    f. Former Big Pharma employees
    g. Other. Please specify: *[open ended]* _____

36. What is your outsourcing facility's top staffing concern? *[multiple choice – select one]*
    a. Employee turnover
    b. Competing opportunities in the market
    c. Limited pool of qualified employees
    d. Other. Please specify: *[open ended]* _____

37. If employees have left your outsourcing facility recently, where have they found new employment? *[multiple choice – select all that apply]*
    a. Different 503B outsourcing facility
    b. 503A facility
    c. Big Pharma
    d. Independent hospital(s)/Medical center(s)
    e. Physician office(s)
    f. Clinic(s)
    g. Nursing home(s)
    h. Health system(s)/Integrated delivery network(s)
    i. Surgery center(s)
    j. Ambulatory care center (Outpatient Care)
    k. Pharmacy services
    l. Veterinary services
    m. Wellness clinic(s)
    n. Refineries
    o. Infusion therapy centers
    p. Other. Please specify: *[open-ended]*_____

38. If your outsourcing facility recruits from pharma, what challenges do you face during recruitment? *[open-ended]*

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 outsourcing facility market.

39. For the CGMP requirements provided below, please rank the top three in order of your (or the appropriate personnel at your facility's) level of knowledge from most knowledgeable to least knowledgeable. *[multiple choice – select multiple and rank top 3; 1-most knowledgeable; 3- least knowledgeable]*

	Extremely Knowledgeable (1)	Moderately Knowledgeable (2)	Mildly Knowledgeable (3)	Not Knowledgeable (4)	If "Not Knowledgeable " was selected, please specify: *[open ended]* _____
Quality assurance activities	●	●	●	●	
Facility design	●	●	●	●	
Control systems and procedures for maintaining suitable facilities	●	●	●	●	

Environmental and personnel monitoring	●	●	●	●	
Equipment	●	●	●	●	
Containers and closures	●	●	●	●	
Production and process controls	●	●	●	●	
Laboratory controls	●	●	●	●	
Stability/expiration dating for compounded drug products	●	●	●	●	
Packaging and labels	●	●	●	●	
Reserve samples	●	●	●	●	
Complaint handling	●	●	●	●	

40. Which of the following has your organization implemented when pursuing improvements to your Quality Culture? Please assess your level of agreement with the following statements on a scale of strongly disagree (1) to strongly agree (5). *[Likert scale]*

	Strongly Disagree (1)	Disagree (2)	Neither Disagree nor Agree (3)	Agree (4)	Strongly Agree (5)	If "strongly disagree" or "disagree" was selected, please specify: [open ended]_____
Promote quality in the organization	●	●	●	●	●	
Prioritize quality over cost	●	●	●	●	●	
Define/establish quality and employee role	●	●	●	●	●	
Include quality in performance reviews	●	●	●	●	●	
Employ objective quality in performance reviews	●	●	●	●	●	
Engage to understand behaviors that drive quality	●	●	●	●	●	

Effectively communicate quality strategy	●	●	●	●	●	
Focus on prevention over reaction	●	●	●	●	●	
Formally measure cost of quality	●	●	●	●	●	
Benchmark and share best practices	●	●	●	●	●	

a. If your outsourcing facility fosters a Quality Culture in a way that is not listed above, please specify how you foster a Quality Culture. *[open-ended]*
b. What are challenges your outsourcing facility faces when integrating Quality Culture? *[open-ended]*

41. Does your outsourcing facility have a formal process validation program established? *[multiple choice – select one]*
    a. Yes
        i. If so, please explain the methodology or tools used? *[open-ended]*
    b. No
        ii. If no, please describe what prevents your outsourcing facility from developing a process validation program? *[open-ended]*

42. Has your outsourcing facility implemented a quality management system? *[multiple choice – select one]*

    a. Yes
        i. If yes, please describe what features you have implemented into your quality management system? *[open-ended]*
        ii. If yes, what challenges or struggles does your outsourcing facility face when implementing a quality management system? *[open-ended]*
    b. No
        i. If no, what prevents your outsourcing facility from implementing a quality management system?

43. What quality management topics would your outsourcing facility like to learn more about? *[open-ended]*

44. Does your outsourcing facility currently employ computerized technology to perform real-time monitoring of your production processes? [multiple choice – select one]
    a. Yes
    b. No

45. Would your outsourcing facility pay for in-person training? *[multiple choice – select one]*
        a. Yes
            i. If you selected “yes”, what would you be willing to pay? Please specify *[open-ended]:*

b. No

i. Please specify *[open-ended]:*

46. Would your outsourcing facility pay for web-based trainings? *[multiple choice – select one]*
    a. Yes
        a. If you selected "yes", what would you be willing to pay? Please specify [open-ended]:
    b. No
        1. Please specify *[open-ended]*

47. What training topics would be useful for staff at your outsourcing facility? *[open-ended]*

48. How confident does your outsourcing facility feel in responding to Form 483s and Warning Letters? Please assess your level of confidence on a scale of extremely confident (1) to not confident (4). *[Likert scale]*

	Extremely Confident (1)	Moderately Confident (2)	Mildly Confident (3)	Not Confident (4)	If you selected "Mildly Confident," or "Not Confident," please specify:____
Form 483s	●	●	●	●	
Warning Letters	●	●	●	●	

49. FDA is considering engaging in targeted scientific/lab-based research to help inform policy and regulatory decisions. For the topics provided below, please rank your level of interest in accessing lab-based research through the CoE from very interested (1) to not interested (4). *[Likert scale].*

	Very Interested (1)	Moderately Interested (2)	Mildly Interested (3)	Not Interested (4)
Monographs for API on the bulks drug substance list	●	●	●	●
Stability testing	●	●	●	●
Beyond use dates	●	●	●	●
Sterile-to-sterile testing	●	●	●	●

information				

a. If there are other topics of interest that are not listed here, please specify: *[open ended]*_____

50. What challenges do you encounter regarding state regulation of your outsourcing facility? *[open-ended]*

51. What are the difficulties in reporting adverse events? *[multiple choice – select all that apply]*
    a. Understanding how to report adverse events. Please explain: *[open-ended]* _____
    b. Understanding advance events related guidance documents. Please explain: *[open-ended]*
    c. Level of effort required. Please explain: *[open-ended]* _____
    d. Tracking / identifying adverse events. Please explain: *[open-ended]* _____
    e. Following up with primary reporter to gain additional information. Please explain: *[open-ended]* _____
    f. Following up with FDA after initial report. Please explain: *[open-ended]* _____
    g. Other. Please specify: *[open-ended]* _____
    h. N/A. We do not face difficulties in reporting adverse events.

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

52. Please assess your level of agreement with the following statements on a scale of strongly disagree (1) to strongly agree (5). *[Likert scale]*

	Strongly Disagree (1)	Disagree (2)	Neither Disagree nor Agree (3)	Agree (4)	Strongly Agree (5)	If you selected "strongly disagree" or "disagree," please specify: *[open ended*
Current engagement between CoE and my outsourcing facility has provided my outsourcing facility improves our	●	●	●	●	●	

understanding of CGMP guidance.						
Current engagement between CoE and my outsourcing facility provides a means of connection and community to other stakeholders in the industry (e.g., other outsourcing facilities, providers, trade associations).	●	●	●	●	●	

a. Other. Please specify any additional thoughts, if any: *[open-ended]:* _____

53. This year, FDA is hoping to understand the degree of connection outsourcing facilities feel that they have within their community and with the broader outsourcing facility ecosystem (e.g., purchasers). Please assess your level of agreement with the following statements on a scale of strongly disagree (1) to strongly agree (5). *[Likert scale]*

	Strongly Disagree (1)	Disagree (2)	Neither Disagree nor Agree (3)	Agree (4)	Strongly Agree (5)	If you selected "strongly disagree" or "disagree," please specify: *[open ended*
I am looking for more opportunities to connect with colleagues in the outsourcing facility industry.	●	●	●	●	●	
I am looking for more opportunities to connect with other stakeholders in the broader ecosystem (e.g., hospital systems, trade associations, consultants, non-hospitals).	●	●	●	●	●	
I feel comfortable initiating collaboration with	●	●	●	●	●	

the CoE.						

a. Other. Please specify any additional thoughts, if any: *[open-ended]:* _____

54. Does your outsourcing facility 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 outsourcing facility choose to engage in the CoE? *[multiple choice – select and rank all that apply with 1 being most important and 7 being least important.]*
            - To better understand regulatory processes
            - To better understand guidances and policies
            - To train our staff
            - To get connected with other stakeholders in the outsourcing facility 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 outsourcing facility face to the below opportunities? *[multiple choice – select all that apply]*

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

55. 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: *[open-ended]* _____
    b. Opportunity to claim Continuing Education (CE) credits. Please specify: *[open-ended]* _____
    c. Relevancy of training topic(s) to my job. Please specify: *[open-ended]* _____
    d. Encouragement from outsourcing facility leadership/colleagues to attend. Please specify: *[open-ended]* _____

e. Course format (e.g., self-paced vs. instructor-led). Please specify: *[open-ended]* _____

f. Other. Please specify: *[open-ended]* _____

56. Please assess your level of agreement with the following statements on a scale of strongly disagree (1) to strongly agree (5). *[Likert scale]*

	Strongly Disagree (1)	Disagree (2)	Neither Disagree nor Agree (3)	Agree (4)	Strongly Agree (5)	If you selected "strongly disagree" or "disagree," please specify: *[open ended*
The CoE understands my business model.	●	●	●	●	●	
The CoE creates opportunities to have two-way engagement.	●	●	●	●	●	
The CoE is transparent and establishes a collaborative culture.	●	●	●	●	●	
The CoE provides my business with the information it needs to better understand provider needs.	●	●	●	●	●	
My outsourcing facility is aware of the CoE's purpose and their role in the outsourcing facility sector.	●	●	●	●	●	

a. Other. Please specify any additional thoughts, if any: *[open-ended]:* _____