

Questions for Registered Outsourcing Facilities

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

As part of its commitment to the compounding industry, FDA established the Compounding Quality Center of Excellence (CQCoE) to engage with outsourcing facilities and other stakeholders to improve the quality of compounded drugs. To continue to inform the CQCoE'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 CQCoE 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], 2023 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, quality practices, quality culture, compliance challenges, 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 2023 outsourcing facility survey? [multiple choice - select one]

a. Yes

b. No

3. 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] _____

4. What percent (estimated) of your outsourcing facility's product volume is being provided to the following entities? [Likert scale]

	None (0%)	A smaller percentage (1% to 19%)	A substantial percentage (20% to 49%)	Most of the portfolio (50% to 79%)	Nearly all of the portfolio (80% to 100%)
Independent hospital(s)/Medical center(s)	●	●	●	●	●
Physician office(s)	●	●	●	●	●
Medical Clinic(s)	●	●	●	●	●
Long Term Care Facilities	●	●	●	●	●
Health system(s)/Integrated delivery network(s)	●	●	●	●	●
Surgery center(s)	●	●	●	●	●
Ambulatory care center (Outpatient Care)	●	●	●	●	●
Pharmacy services	●	●	●	●	●
Veterinary services	●	●	●	●	●
Wellness clinic(s)	●	●	●	●	●
Refineries	●	●	●	●	●
Infusion therapy centers	●	●	●	●	●

a. If other, please specify: [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.

5. As an outsourcing facility, 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)
Providing competitive pricing for purchasers (e.g., providers)	●	●	●	●
Building and maintaining relationships with buyers	●	●	●	●
Increasing market demand for outsourcing facility's products	●	●	●	●
Responding to drug shortages	●	●	●	●
Using automation or technology	●	●	●	●
Capturing market share from competitors	●	●	●	●

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]

6. What are the key business challenges that your outsourcing facility faces? Please assess how challenging the following factors 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	●	●	●	●	-----

(e.g., stability testing, strength, sterility)					
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 active pharmaceutical ingredients/excipients	●	●	●	●	
Availability of inactive pharmaceutical ingredients/excipients	●	●	●	●	
Availability of 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]*

7. Has your outsourcing facility faced difficulty obtaining materials needed for production (e.g., API, vials, stoppers, glassware, IV bags, other, etc.) due to supply chain issues? *[Likert scale]*

	Never	Rarely: At least one to three times a year	Moderately: At least every other month	Frequently: At least once every month
Active Pharmaceutical Ingredients	●	●	●	●
Inactive pharmaceutical ingredients (e.g., sterile water for injection, buffers)	●	●	●	●
Vials	●	●	●	●
Stoppers	●	●	●	●
Glassware	●	●	●	●
IV Bags	●	●	●	●

a. Other: If your outsourcing facility has difficulties obtaining materials that are not listed above, please specify: _____ *[open-ended]*

8. Aside from challenges related to accessing materials, has your outsourcing facility been impacted by supply chain issues? *[multiple choice - select all that apply]*
- a. Price increases
 - b. Loss of customer base/relationships due to production delays
 - c. Difficulty fulfilling contractual obligations
 - d. Qualifying new suppliers
 - e. Decreased revenue
 - f. Staff management issues (e.g., shortage, strain)
 - g. Other. Please specify: *[open-ended]*
 - h. No, my outsourcing facility has not been impacted by supply chain issues aside from accessing materials.
9. Are there bulk drug substances that your firm has difficulties obtaining? *[multiple choice - select one]*
- a. Yes
 - i. If yes, please describe your difficulties *[open ended]*
 - b. No
10. Does your outsourcing facility compound products on the drug shortages list? *[multiple choice - select one]*
- a. Yes
 - a. If yes, have you encountered difficulties obtaining active pharmaceutical ingredients to produce products on the drug shortage list? *[multiple choice - select one]*
 - i. Yes
 - 1. If yes, please describe your difficulties *[open ended]*
 - ii. No
 - b. No
11. Has your outsourcing facility encountered difficulties shipping products to customers? *[multiple choice - select one]*
- a. Yes
 - i. If yes, please explain: _____ *[open-ended]*
 - b. No
12. Which of the following technologies does your outsourcing facility utilize? *[multiple choice - select all that apply]*
- a. 3D printing
 - b. 3D barcoding
 - c. Advanced film coating

- d. Aseptic isolator
- e. Other aseptic ISO-5 devices (e.g., open, laminar flow hood, RABS)
- f. Automation (e.g., robotics, equipment, systems, devices).
 - a. If selected, please specify the types of automation your outsourcing facility uses: _____ *[open-ended]*
- g. Hot melt
- h. Lyophilization
- i. Radio frequency identification (RFID)
- j. Other. Please specify: _____ *[open ended]*

13. What is your average cost of one stability study? For reference, please consider the following definition for a stability study: a study undertaken on batch(es) according to a prescribed stability protocol, that is product-specific and evaluates the specific formulation of a drug product, in the specific container in which it is to be stored, and under the conditions to which it may be exposed, to establish or confirm the beyond use date/expiration date of a drug product. *[open-ended]*

14. Has your outsourcing facility ever partnered with providers or other non-profits to share in drug production costs? *[multiple choice – select one]*

- a. Yes. Please describe: _____ *[open-ended]*
- b. No.
 - i. If no, are you aware of examples where outsourcing facilities have partnered with providers or other non-profits to share in drug production costs?
 - a. Yes
 - b. No
 - ii. Would you be interested in learning more about these types of opportunities?
[open-ended]

15. Does your outsourcing facility have a system/process to keep reserve samples (e.g., after a certain number of units are produced of a given product formulation/container closure)? If so, please explain: _____ *[open-ended]*

Section Three - 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.

16. Has your outsourcing facility participated in [any CQCoE training courses](#) that have led to either operational changes within your firm or personal changes within your job function? *[multiple choice – select one]*

- a. Yes.
 - i. If yes, please specify which courses you participated in and what changes you have implemented because of the course: _____ *[open-ended]*
- b. No, the training courses I participated in did not lead to operational changes.

- i. If no, please specify which courses you participated in and why the training courses did not lead to operational changes:_____ [open-ended]
- c. No, employees in my outsourcing facility have not attended CQCoE training courses.

17. 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
 - iii. If no, what prevents your outsourcing facility from implementing a quality management system? [open-ended]

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

19. “Quality culture is an environment in which those who have responsibility for oversight and control over manufacturing taking ownership for quality” - *Whitepaper Quality Management Maturity: Essential for Stable U.S. Supply Chains of Quality Pharmaceuticals*

What challenges does your outsourcing facility face when implementing a quality culture? Please rank these challenges from most challenging (1) to least challenging (8) [ranking]

- a. Making a focus on quality culture germane to all roles
- b. Perception among staff that responsibility for quality resides in the quality department
- c. Quality division is not empowered to promote a culture of quality within the organization
- d. Lack of CGMP experience among all employees
- e. Lack of effective leadership communication around quality
- f. Lack of incentives to prioritize quality
- g. Lack of information to create and continuously improve upon your organization’s quality culture
- h. Among staff, a reactive mindset toward quality issues rather than a preventive mindset

If there is a challenge that your outsourcing facility faces when implementing quality culture that is not listed above, please specify:_____ [open-ended]

20. What roles are integral to your organization’s quality culture and how? [open-ended]

21. What is your organization’s level of confidence with the following quality risk management tools? [Likert Scale]

	Not Confident (1)	Mildly Confident (2)	Moderately Confident (3)	Extremely Confident (4)	If you selected “Mildly Confident,” or “Not Confident,” please specify:_____
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Risk Based Impact Assessment (RBIA):	•	•	•	•	
REM (Risk Estimation Matrix)	•	•	•	•	
LOPA (Layers of Protection Analysis)	•	•	•	•	
HACCP (Hazard Analysis and Critical Control Points)	•	•	•	•	
FMEA (Failure Modes and Effects Analysis)	•	•	•	•	

a. Other: If your outsourcing facility utilizes a quality risk management tool that is not listed above, please specify the tool(s). *[open-ended]*

22. What difficulties do you face responding to the following?

- a. Form 483s, please explain: _____ *[open-ended]*
- b. Warning Letters, please explain: _____ *[open-ended]*

23. Please list the various ways or channels in which your organization receives reports of adverse events? *[multiple-choice - select all that apply]*

- a. Providers (e.g., physicians, nurses, health systems)
- b. Consumers (e.g., patients, family members, lawyers)
- c. Group Purchasing Organizations
- d. MedWatch
- e. Third-party vendor monitoring adverse events
- f. Other. Please specify: _____ *[open-ended]*

24. Please describe your organization's approach toward investigating reports of adverse events? *[open-ended]*

25. Your organization may determine that some customer concerns may not rise to the level of an adverse event report. What does your organization do in these instances? *[open-ended]*

Section Four – 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.

26. 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	Disagree (2)	Neither Disagree	Agree (4)	Strongly Agree	If you selected
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	(1)		nor Agree (3)		(5)	“strongly disagree” or “disagree,” please specify: [open ended]
Current engagement between CQCoE and my outsourcing facility improves our understanding of CGMP guidance.	•	•	•	•	•	
Current engagement between CQCoE 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]*: _____

27. 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: <i>[open ended]</i>
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 CQCoE.	●	●	●	●	●	

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

28. Why does your outsourcing facility choose to engage in the CQCoE? *[multiple choice – select and rank all that apply with 1 being most important and 7 being least important.]*

- a. To better understand regulatory processes
- b. To better understand guidances and other policies
- c. To train our staff
- d. To connect with other stakeholders in the outsourcing facility market
- e. To engage directly with FDA
- f. To share our perspective and provide feedback to the CQCoE (e.g., on challenges, opportunities)
- g. To stay up to date on the latest information, decisions, and guidance

29. In the past, what barriers to participation in the CQCoE does your outsourcing facility face to the below opportunities? *[multiple choice – select all that apply]*

	Do not have enough time	Do not see benefit of participation	Was not aware of these opportunities	N/A (do not face barriers)	Other	If other, please specify:
Training	●	●	●	●	●	
Annual Conference	●	●	●	●	●	
CQCoE research conversations to support the annual landscape study	●	●	●	●	●	

30. What training topics (e.g., “more advanced,” net new) would be useful for staff at your outsourcing facility? Please list the training topic(s) and explain your answer. *[open-ended]*

31. 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: <i>[open ended]</i>
The CQCoE understands my business model.	●	●	●	●	●	
The CQCoE creates opportunities to have two-way engagement.	●	●	●	●	●	
The CQCoE is transparent and establishes a collaborative culture.	●	●	●	●	●	
The CQCoE provides my business with the information it needs to better understand provider needs.	●	●	●	●	●	
My outsourcing facility is aware of the CQCoE's purpose and their role in the outsourcing facility sector.	●	●	●	●	●	

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