U.S. Food and Drug Administration

Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities
OMB Control No. 0910-0883

No Material or Non-Substantive Change to a Currently Approved Collection (83-C)

Proposed Changes

We propose changes to the survey to improve clarity and simplify the experience for participants by reducing the number of questions from 55 to 31. We anticipate a slight reduction in burden hours to 45 minutes (.75 hour) per survey response from 1 hour per response in the 2022 survey.

1. Deletions. We have deleted questions 3-6, 8-10, 12-20, 23-41, 44-46, 49-51, and 55 from the 2022 survey because, based on the survey responses received, we do not need to collect the information from these questions again during the current year.

2. Format: We have revised Q11 (now Q4 due to deleted questions) open-ended to closed-ended question. We have revised Q 22 (now Q5 due to deleted questions) to remove three previous drivers of growth. These changes are expected to save the participants' time and effort. We have revised Q21 (now Q6 due to deleted questions) to add two additional business challenges. This small addition was needed based on what we learned from last year's research. We revised Q48 (now Q22) from closed ended to open-ended because last year's survey indicated we need increased depth of understanding in this area. We revised Q 54 (now Q 28 and 29) by dividing the question into two separate questions to make it easier to understand for the participant. These questions are shown below in the "Reformatted Questions" section.

3. New questions: We have added new questions 7-16, 19-21, and 23-25. These questions were added because last year's research indicated that we need to obtain additional knowledge in these areas. The material covered in these questions is not substantively different because all of the new survey questions are related to at least one of the overarching research questions outlined in the 60-day notice for this information collection, 86 FR 54450. These questions will also not increase the overall burden to participants, as any burden added by the new questions will be offset by the deletion of previous survey questions outlined in 1.

Reformatted Questions

Q4: 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	●	●	●	●	●

Q5: 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	●	●	●	●

Q6: 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					

Q22: What difficulties do you face responding to the following?

a. FDA Form 483s (Inspectional Observation form), please explain: _____ *[open-ended]*

Warning Letters, please explain:_____ *[open-ended*

Q 28: Why does your outsourcing facility choose to engage in the Compounding Quality Center of Excellence (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

Q 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	●	●	●	●	●	