Office of Partnerships Medical Devices Contract Quarterly Summary Report: Coversheet

This Quarterly Summary Report contains multiple sections and tabs to complete. See accompanying instructions tab for specific information to complete each section.

State Agencies:
Save this form using filename "**State_Agency Abbreviation_MDV_QSR**".
Complete Coversheet and State Report Tabs and email the completed report to your State Liaison or Division Representative.

State Liaison:
Complete the Division Reporting Tab and email the completed report to the **State, Project Manager, and** ORAOPDataHub@fda.hhs.gov.

Contract Number (auto-filled)	Select Agency
Agency Name (select from list)	Select
State or US Territory (auto-filled)	Select Agency
Contract Type	MDV
Date Completed (MM/DD/YYYY)	
State Report Preparer's Name	
State Report Preparer's Email	

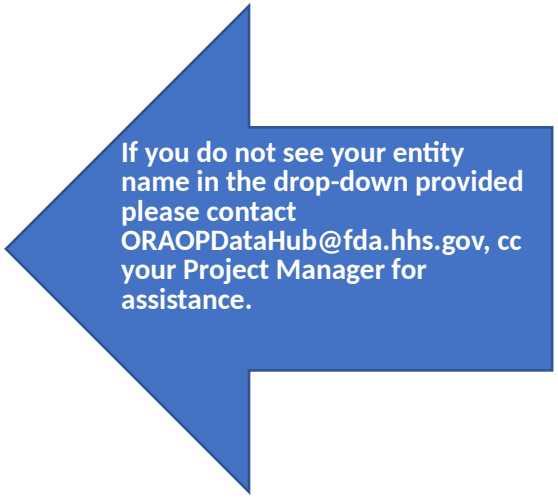
Period of Performance Start Date	
Period of Performance End Date	
Reporting Period Start Date	

Reporting Period End Date	
Reporting Period Frequency	Select
Current Reporting Period	Select

Review Instructions

Continue to StateReport

Continue to DivisionReport


If you do not see your entity name in the drop-down provided please contact ORAOPDataHub@fda.hhs.gov, cc your Project Manager for assistance.

Office of Partnerships Medical Devices Contract Quarterly Summary Report: State Reporting

This summary report contains multiple sections and tabs to complete. See accompanying instructions tab for specific information to complete each section.

State Agencies:
Complete all questions on this tab and the Coversheet and email the completed report to your State Liaison or Division Representative with a list of contract inspections completed showing the inspection classification, firm name, FEI, city, and date of inspection.

Note: it is your responsibility to ensure your State Liaison receives this report by the deadline specified in the current Statement of Work. Failure to submit by the deadline may negatively impact processing and issuing payment for completed. However, in the case that you are unable to complete this report in its entirety by the deadline it is still expected you will email this form with information as to specific challenges and corrective actions in field 13. State Challenges and Corrective Actions, by the deadline and submit a corrected complete report as soon as possible.

State Liaison:
Review the state report information below but complete the Division Reporting Tab before you email the completed report to the **State, Project Manager, and** ORAOPDataHub@fda.hhs.gov.

Review Instructions | Complete Coversheet | Continue to StateReport | Continue to DivisionReport

	Contract Reporting Elements	Line Item *(for current option)*	Total Contract Requirement	Total Completed *(this reporting period)*	Total Remaining
Contract Work Accomplished	**Contract Inspection Types**				
	1. QSIT Level I	0	0	0	0
	2. QSIT Level II	0	0	0	0
	3. Other - Training (dollar amount)	0	$0.00	$0.00	$0.00
Actions	4. Enforcement Notices (e.g. warning letters)			0	
	5. Embargoes/Seizures			0	
	6. Hearings Conducted			0	
	7. Prosecutions/Injunctions			0	
	Other Contract Actions List Below				

State Contract	8. [Replace bracketed text]		0	
	9. [Replace bracketed text]		0	
	10. [Replace bracketed text]		0	
	11. Re-Inspections (Follow-ups to violative Inspections)		0	

State Contractor Challenges, Issues, and Highlights	
12. Select the current status based on your assessment of contract performance for this reporting period.	Select
13. List any major challenges encountered this reporting period and corrective actions taken. Include how these actions directly address those challenges. *(Use Alt+Enter for new line if desired)*	
14. Write a brief narrative detailing any positive, significant events identified during this reporting period. *(Use Alt+Enter for new line if desired)*	

15. If applicable, report a dollar value for Item 5. Embargos/Seizures from the table above.	
16. Additional State Reporting Comments *(Use Alt+Enter for new line if desired)*	

Review Instructions | Complete Coversheet | Continue to StateReport | Continue to DivisionReport

Office of Partnerships Medical Devices Contract Quarterly Summary Report: Division Reporting

This summary report contains multiple sections and tabs to complete. See accompanying instructions tab for specific information to complete each section.

State Agencies:
Complete all questions on the StateReport tab and email the completed report to your State Liaison or Division Representative.

State Liaison:
Review the state report information from the StateReport tab, complete the Division Report below and email the completed report to the **State, Project Manager, and** ORAOPDataHub@fda.hhs.gov.

Review Instructions | Complete Coversheet | Continue to StateReport | Continue to DivisionReport

Contract Performance Feedback	
17. Indicate the overall status of the State contractor's performance this reporting period.	Select
18. (Optional) If the contractor experienced challenges or issues during this reporting period, please list them and detail any corrective actions taken or agreed to by the contractor. *(Use Alt+Enter for new line if desired)*	
19. (Optional) Write a brief narrative detailing any positive, significant events identified during the contractor's performance this reporting period. *(Use Alt+Enter for new line if desired)*	
20. Indicate Division Approval or Disapproval by selecting from the drop-down menu. **If this report is disapproved, provide your explanation below.**	***Select***

21. (Optional) Additional Division Reporting Comments. *(Use Alt+Enter for new line if desired)*	
22. Enter the name of the Division Representative approving this report.	
23. Enter the date this Division Review was completed.	

Review Instructions | Complete Coversheet | Continue to StateReport | Continue to DivisionReport

Contract Quarterly Summary Report Instructions

State agencies:

Save this form as an excel file using filename **"State_Agency Abbreviation_MDV_Q** Administration office in Maryland would use: MD_FDA_MDV_QSR.xlsx.

Complete the Coversheet and StateReport tabs of this workbook. E-mail the compl FDA Division representative. You must utilize this form's fillable feature to enter th this information in any other format is not permitted, e.g. photocopied, handwritte the pre-filled information notify your FDA Division Representative or State Liaison.

Coversheet Tab: Administrative Information

Contract Number: Pre-filled for you after selecting your Agency Name.
Agency Name: Select the name of the agency for this contract from the dropdown agency, please notify ORAOPDataHub@fda.hhs.gov and Project Manager for assist
State: Pre-filled for you after selecting your Agency Name.
Contract Type: Contract type is pre-filled for you.
Date Completed: Date form is completed by the state agency.
State Report Preparer's name: Name of person filling out form.
State Report Preparer's E-mail: E-mail address of person filling out form.
Period of Performance Start Date: Enter the Period of Performance Start Date in M contract.
Period of Performance End Date: Enter the Period of Performance End Date in M/D contract.
Reporting Period Start Date: Enter the reporting start date in M/D/YYYY format, e.
Reporting Period End Date: Enter the reporting end date in M/D/YYYY format, e.g.
Reporting Period Frequency: Select from the drop-down menu for either quarterly
Current Reporting Period: Select the corresponding reporting period, e.g. 3rd Quart

StateReport Tab: Contract Report Data and Self-Evaluation

Enter the line item number, the total required by contract, the total completed wit remaining in the table provided for items 1.-11. as applicable. Fields for those items current contract year are greyed out.

1. QSIT Level I
2. QSIT Level II
3. Other - Training – Enter a training count under line item and total dollar valu
4. Enforcement Notices (e.g. warning letters)
5. Embargoes/Seizures - Enter total dollar value in field 15. if desired. When re detail breakdown of dollar amounts may be included in field 16. as addition
6. Hearings Conducted
7. Prosecutions/Injunctions

2. QSIT Level II
3. Other - Training – Enter a training count under line item and total dollar valu
4. Enforcement Notices (e.g. warning letters)
5. Embargoes/Seizures - Enter total dollar value in field 15. if desired. When re
   detail breakdown of dollar amounts may be included in field 16. as addition
6. Hearings Conducted
7. Prosecutions/Injunctions
8. Other Actions (8) – Replace only the bracketed text (leave the item number)
   The text entered may exceed the visible field, all text entered will be extract
9. Other Actions (9) – Replace only the bracketed text (leave the item number)
   The text entered may exceed the visible field, all text entered will be extract
10. Other Actions (10) – Replace only the bracketed text (leave the item numbe
    The text entered may exceed the visible field, all text entered will be extract
11. Re-inspections (Follow-ups to violative inspections)
12. Select the status based on your assessment of contract performance for th
    selected if work has not started yet for this contract year (e.g. work is seas
    the year).
13. List any major challenges encountered this reporting period and corrective
    actions directly address those challenges. - Note: it is your responsibility to
    this report the deadline. However, in the case that you are unable to comp
    deadline it is still expected you will email this form with applicable informa
    corrective actions in this field by the deadline and submit a corrected com
14. Write a brief narrative detailing any positive, significant events identified d
15. If desired, report a total dollar value for Item 5. Embargos/Seizures from t
    dollar value for each embargo or seizure event, use field 16. Additional Sta
16. Provide any additional comments as desired for the state report.

State Liaison: Complete the DivisionReport tab of this workbook and e-mail the co
Project Manager, and ORAOPDataHub@fda.hhs.gov.

DivisionReport: Division Review and Performance Evaluation

17. Indicate the overall status of the State Contractor's performance this repo
    work has not started yet for this contract year (e.g. work is seasonal and w
18. (Optional) If the contractor experienced challenges or issues during this re
    corrective actions taken or agreed to by the contractor.
19. (Optional) Write a brief narrative detailing any positive, significant events
    performance this reporting period.
20. Use the drop-down menu provided to indicate if this report is approved. If
    provided to include an explanation.
21. (Optional) Provide any additional comments as desired for the division rep
22. Enter the name of the Division Representative approving this report.
23. Enter the date the Division Review was completed.

Review Instructions | Complete Coversheet | Continue to State

Review Instructions | Complete Coversheet | Continue to State

previation_MDV_QSR", for example the Food & Drug
SR.xlsx.

x. E-mail the completed report to your State Liaison or
feature to enter the required information. Submitting
copied, handwritten, etc. If you find any discrepancies in
ve or State Liaison.

Skip to Division Instructions

Name.
rom the dropdown provided. If you do not see your
Manager for assistance.

Complete Coversheet

ut form.
nce Start Date in M/D/YYYY format as listed on the

ce End Date in M/D/YYYY format as listed on the

/D/YYYY format, e.g. 3/1/2020.
)/YYYY format, e.g. 6/30/2020.
for either quarterly or monthly.
eriod, e.g. 3rd Quarter.

otal completed within this reporting period and the total
elds for those items that were not included for the

Continue to StateReport

and total dollar value for other columns.

if desired. When reporting more than one event, the
ield 16. as additional comments.

and total dollar value for other columns.

if desired. When reporting more than one event, the
ield 16. as additional comments.

e the item number) with the desired short description.
ered will be extracted at processing.
e the item number) with the desired short description.
ered will be extracted at processing.
ve the item number) with the desired short description.
ered will be extracted at processing.

performance for this reporting period. N/A may be
r (e.g. work is seasonal and will be performed later in

iod and corrective actions taken. Include how these
ur responsibility to ensure your State Liaison receives
are unable to complete this report in its entirety by the
applicable information as to specific challenges and
it a corrected complete report as soon as possible.
events identified during this reporting period
os/Seizures from the table above. To also provide a
d 16. Additional State Reporting Comments to list values.
e report.

k and e-mail the completed report to the State, OP

formance this reporting period. N/A may be selected if
k is seasonal and will be performed later in the year).
ssues during this reporting period list them and detail any

significant events identified during the contractor's

port is approved. If it is not approved, use the space

for the division report.
g this report.

Report | Continue to DivisionReport

Report

Continue to DivisionReport