

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)

Agency Name (select from list)

State or US Territory (auto-filled)

Contract Type

Date Completed (MM/DD/YYYY)

State Report Preparer's Name

State Report Preparer's Email

Select Agency

Select

Select Agency

MDV

Period of Performance Start Date

Period of Performance End Date

Reporting Period Start Date

Reporting Period End Date
Reporting Period Frequency
Current Reporting Period

Select
Select

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DivisionReport](#)

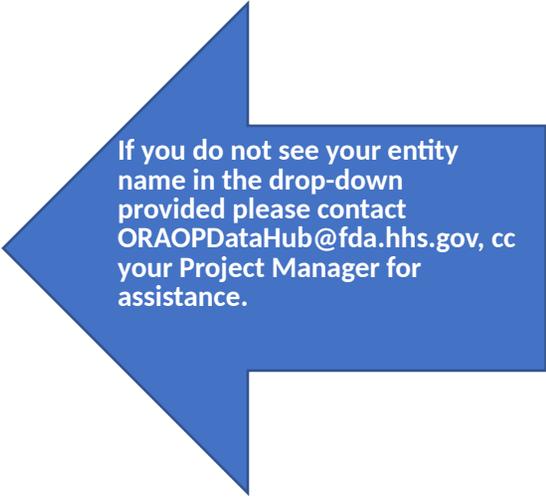
The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 36.67 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

**DO NOT SEND YOUR COMPLETED FORM TO
THIS PRA STAFF EMAIL ADDRESS.**



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.

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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**.

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	Contract Reporting Elements	Line Item <i>(for current option)</i>	Total Contract Requirement	Total Completed <i>(this reporting period)</i>	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 Contractor	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	
<p>12. Select the current status based on your assessment of contract performance for this reporting period.</p>	Select
<p>13. List any major challenges encountered this reporting period and corrective actions taken. Include how these actions directly address those challenges.</p> <p style="text-align: center;"><i>(Use Alt+Enter for new line if desired)</i></p>	
<p>14. Write a brief narrative detailing any positive, significant events identified during this reporting period.</p> <p style="text-align: center;"><i>(Use Alt+Enter for new line if desired)</i></p>	

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

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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**.

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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. <i>(Use Alt+Enter for new line if desired)</i>	
22. Enter the name of the Division Representative approving this report.	
23. Enter the date this Division Review was completed.	

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Contract Quarterly Summary Report Instructions

State agencies:

Save this form as an excel file using filename "**State_Agency Abbreviation_MDV_QSR**". An agency in Maryland would use: MD_FDA_MDV_QSR.xlsx.

Complete the Coversheet and StateReport tabs of this workbook. E-mail the completed workbook to the FDA Division representative. You must utilize this form's fillable feature to enter the information; this information in any other format is not permitted, e.g. photocopied, handwritten. If you need to change 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 menu. If you are a new agency, please notify ORAOPDataHub@fda.hhs.gov and Project Manager for assistance.

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/D/YYYY format for this contract.

Period of Performance End Date: Enter the Period of Performance End Date in M/D/YYYY format for this contract.

Reporting Period Start Date: Enter the reporting start date in M/D/YYYY format, e.g. 1/1/2010.

Reporting Period End Date: Enter the reporting end date in M/D/YYYY format, e.g. 12/31/2010.

Reporting Period Frequency: Select from the drop-down menu for either quarterly or annual reporting.

Current Reporting Period: Select the corresponding reporting period, e.g. 3rd Quarter.

StateReport Tab: Contract Report Data and Self-Evaluation

Enter the line item number, the total required by contract, the total completed with the total remaining in the table provided for items 1.-11. as applicable. Fields for those items that are not in the 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 value.
4. Enforcement Notices (e.g. warning letters)
5. Embargoes/Seizures - Enter total dollar value in field 15. if desired. When required, a detail breakdown of dollar amounts may be included in field 16. as additional information.

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

State Liaison: Complete the DivisionReport tab of this workbook and e-mail the completed report to the 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 reporting period. work has not started yet for this contract year (e.g. work is seasonal and work is seasonal for the year).
18. (Optional) If the contractor experienced challenges or issues during this reporting period, describe the corrective actions taken or agreed to by the contractor.
19. (Optional) Write a brief narrative detailing any positive, significant events identified during this reporting period.
20. Use the drop-down menu provided to indicate if this report is approved. If not approved, use the provided to include an explanation.
21. (Optional) Provide any additional comments as desired for the division report.
22. Enter the name of the Division Representative approving this report.
23. Enter the date the Division Review was completed.

20. Use the drop-down menu provided to indicate if this report is approved. If not approved, provide an explanation.
21. (Optional) Provide any additional comments as desired for the division representative.
22. Enter the name of the Division Representative approving this report.
23. Enter the date the Division Review was completed.

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abbreviation_MDV_QSR", for example the Food & Drug
6R.xlsx.

k. 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
re or State Liaison.

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

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ut form.
nce Start Date in M/D/YYYY format as listed on the
nce 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.
period, e.g. 3rd Quarter.

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

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and total dollar value for other columns.

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

and total dollar value for other columns.

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

(enter the item number) with the desired short description. Entered will be extracted at processing.

(enter the item number) with the desired short description. Entered will be extracted at processing.

(enter the item number) with the desired short description. Entered will be extracted at processing.

performance for this reporting period. N/A may be selected if work is seasonal and will be performed later in the year.

period and corrective actions taken. Include how these actions were taken to ensure your State Liaison receives the report. If you are unable to complete this report in its entirety by the reporting period, provide applicable information as to specific challenges and corrective actions taken. Submit a corrected complete report as soon as possible.

events identified during this reporting period
Arrests/Seizures from the table above. To also provide a
field 16. Additional State Reporting Comments to list values.
the report.

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

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

significant events identified during the contractor's

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

for the division report.

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

for the division report.

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[Report](#)

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