QUALITY ASSURANCE SURVEILLANCE PLAN

Transaction # 501-12-3-237-0170

Task	Standard	Acceptable Quality Level	Surveillance Method
Manufacture the active pharmaceutical ingredient (API) – N-Acetylcysteine, USP Grade, to be delivered to the VA CSPCRPCC	Certificate of Analysis	1. Manufacturer's testing meets or exceeds USP standards/specifications for the manufacture of the API, N-Acetylcysteine, USP Grade 2. Analytical testing of the API product to be performed by the CSPCRPCC Lab meets or exceeds the appropriate USP specifications	Analytical test results
API, N-Acetylcysteine, USP Grade has at least 57 months of expiration dating remaining when received by the CSPCRPCC	Date on Certificate of Analysis	Meets the specification	Receipt and review of the Certificate of Analysis
Distributor/Manufacturer must provide a *Letter of Authorization*, allowing the US Food and Drug Administration (FDA) to access their Drug Master File (DMF)	Signed Letter of Authorization	Non-applicable	Receipt of an original, signed *Letter of Authorization*
Manufacturer must hold a DMF with the US FDA	Manufacturer's name listed on the FDA list of manufacturers holding a DMF for the API (N-Acetylcysteine, USP Grade)	Named on list	Review list
Manufacturer must have a good inspection history with *European Union Authorities (EUA) *EUA – the European equivalent of the US FDA	List of inspections conducted by FDA and EUA and results for the facility that manufactures the API, N-Acetylcysteine, USP Grade	Inspection history satisfactory to reviewers	Read inspection history

1. METHODS OF QUALITY ASSURANCE SURVEILLANCE: Various methods exist to monitor performance. The Contracting Officer's Representative (COR) shall use the surveillance methods listed below in the administration of this QASP.

Regardless of the surveillance method, the COR shall always contact the contractor's task manager or on-site representative when a defect is identified and inform the manager of the specifics of the problem. The COR shall be responsible for monitoring the contractor's performance in meeting a specific performance standard/AQL.

- **DIRECT OBSERVATION** – Can be performed periodically or through 100% surveillance.

- **MANAGEMENT INFORMATION SYSTEMS (MIS)** – Evaluates outputs through the use of management information reports. Best used for general surveillance and may need to be supplemented by periodic inspections.

- **PERIODIC INSPECTION** – Uses a comprehensive evaluation of selected outputs. Inspections may be scheduled as required.

    - Analysis of contractor's progress reports (cost, schedule, etc.)
    - Performance Reporting

Surveillance results may be used as the basis for actions (to include payment deductions) against the contractor. In such cases, the Inspection of Services clause in the Contract becomes the basis for the Contracting Officer's (CO) actions.

2. RATINGS: Metrics and methods are designed to determine if performance exceeds, meets, or does not meet a given standard and acceptable quality level. A rating scale shall be used to determine a positive, neutral, or negative outcome. The following ratings shall be used:

Example 1:

EXCEPTIONAL	Performance significantly exceeds contract requirements to the Government's benefit.
SATISFACTORY	Performance meets contractual requirements.
UNSATISFACTORY	Performance does not meet contractual requirements.

3. DOCUMENTING PERFORMANCE:

a. **Acceptable Performance:** The Government shall document positive performance. A report template is attached. Any report may become a part of the supporting documentation for fixed fee payments, award fee payments, or other actions.

b. **Unacceptable Performance:** When unacceptable performance occurs, the COR shall inform the contractor. This will normally be in writing unless circumstances necessitate verbal communication. In any case the COR shall document the discussion and place it in the COR file.

When the COR determines formal written communication is required, the COR shall prepare a Contract Discrepancy Report (CDR), and present it to the contractor's task manager or on-site representative. A CDR template is attached to this QASP.

The contractor shall acknowledge receipt of the CDR in writing. The CDR will specify if the contractor is required to prepare a corrective action plan to document how the contractor shall correct the unacceptable performance and avoid a recurrence. The CDR will also state how long after receipt the contractor has to present this corrective action plan to the COR. The Government shall review the contractor's corrective action plan to determine acceptability.

Any CDR's may become a part of the supporting documentation for contract payment deductions, fixed fee deductions, award fee nonpayment, or other actions deemed necessary by the CO.

4. FREQUENCY OF MEASUREMENT:

a. **Frequency of Measurement:** During contract/order performance, the COR shall take periodic performance measurements.

b. **Frequency of Performance Assessment Meetings:** The COR shall meet with the contractor quarterly or as needed to assess performance and shall provide a written assessment.

Prepared by: _____ March 26, 2012

Jan M. Hickey, M.S.
Chief, Clinical Manufacturing Section

Date

PERFORMANCE REPORT

[To be filled in after contract award when evaluating contractor performance]

1. CONTRACT NUMBER:	<Insert number>
2. Prepared by: (Name of COR)	<Insert name>
3. Date of observation:	
4. Time of observation:	
5. Observation:	

Examples of items to include in report are:

- Method of surveillance
- How frequently you conducted surveillance
- Surveillance results
- Number of observations

_____ _____

Signature – Contracting Officer's Representative Date

CONTRACT DISCREPANCY REPORT (CDR)

[To be filled in after contract award when evaluating contractor performance]

1. CONTRACT NUMBER	<Insert number>
2. **TO:** (Contractor Task Manager or on-site representative)	<Insert name>
3. **FROM:** (Name of COR)	<Insert name>
4. Date discrepancy observed	
5. Time discrepancy observed	
6. **DISCREPANCY OR PROBLEM** (describe in detail & identify any attachments)	
7. Corrective Action Plan: A written corrective action plan [ ] is required [ ] is ***not*** required If a written Correction Action Plan is required, include the following: The written Corrective Action Plan will be provided to the undersigned not later than <# days after receipt of this CDR>	
Prepared by:	<Insert name>

_____ _____

Signature – Contracting Officer's Representative Date

Received by:

_____ _____

Signature – Contracting Officer's Representative Date