DATE: YYYY/MM/DD

FROM: Enter Name

THRU: Enter Name

TO: Enter Name

SUBJECT: Internal QMS Assessment Summary Report / Site: Enter Site Name - Example FDA MDSAP QMS

An internal assessment of the MDSAP quality management system was conducted dates. This assessment determines whether or not the Name - Example FDA MDSAP QMS is operating in accordance with the policies and procedures set out in the quality manual and related documentation (SOPs, Policies and Requirements).

Report of assessed component at location, date of submittal, names of assessor(s).

Executive Summary:
This section should summarize audit results. Nonconformities and their implications; also statement of system effectiveness based on assessment conclusions. Summarize open items and state whether nonconformity reports and/or corrective actions are to be issued. In addition, and as applicable, summarize the results of actions of items classified as open or follow-ups from “previous assessments” if available.

Assessment Overview:
- Date(s) of assessment.
- Purpose (objective): Why the assessment was conducted.
- Assessment Criteria: Requirements against which observations were evaluated.
- Scope: Brief description of areas, processes, etc., covered in the assessment. Listed by criterion or activity. Additionally, list work products/SOPs covered during the assessment.
- Persons contacted during the assessment. Lists names or persons at the opening and closing of meetings and contacted during the assessment along with titles and/or job function.
- Assessment Team: If more than one assessor, list names/titles of team members and their function during the assessment.

The following areas were assessed:

1. Standard Operating Procedures:
2. Document Control Requests:
3. Complaint Reports:
4. Corrective Action/Feedback Reports:
5. Preventive Actions:
6. Training:
7. Program Performance Reviews: brief overall summary; for each review may consist of summary, discrepancies, corrective action and conclude with recommendations for improvement. Such as:
    - Nonconformities and severity (if applicable).
    - Specific deficiencies or trends noted.
    - Assessment evidence.
    - List on-the-spot or corrective actions taken during the assessment.
    - Recommendations for improvement.
    - Concerns.
8. Other:

Conclusion:

Provide a statement of compliance or noncompliance using the above stated assessment criteria.

NOTE: Assessment summaries should be maintained under record control of subsequent actions, follow-up and management reviews.

Assessor(s) Name and Title

MDSAP QMS Manager Name

Forwarded to RAC: Date