1.0 Purpose

To establish a list of required QA records/documents for identification, retention period, storage and disposition at the end of the retention period.

2.0 Scope

This procedure is applicable to the QA records/documents listed herein unless otherwise noted in specific policies, procedures or forms. Records/documents may be in paper and/or electronic form.

3.0 Responsibility

Quality Assurance is responsible for assuring that this procedure is followed. Area managers shall apply this procedure to their respective quality documents if applicable.

4.0 Safety Considerations

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

Paper shredder

6.0 Procedure

6.1 Identification - Quality Assurance will review the retention of QA records/documents on an on-going basis as a part of the routine maintenance of files in the cGMP library. QA will identify and clearly mark records/documents that have exceeded the retention period and need to be destroyed. Any obsolete documents retained for legal and/or knowledge preservation purposes shall be suitably identified as such.

6.2 Retention Period - The minimum required time to retain a specified document is listed in the table below. These retention periods are aligned with requirements described in cGMP.

6.3 Storage - If necessary, QA records/documents that are more than two years old may be archived and relocated to a secure off-site location. During storage, records must be securely stored in a suitable environment to prevent damage, deterioration and potential loss. Additionally, records must remain readily available for authorized inspection during the retention period.

6.4 Disposition – Paper QA records/documents identified as having exceeded the retention period shall be destroyed. Invalid or obsolete documents will be promptly removed from all points of issue or otherwise assured against unintended use. Destruction shall be accomplished by shredding.
Electronic records/documents identified as having exceeded the retention period shall be permanently removed from the electronic documentation system.

6.5 Record/Document Retention Period

Record	Retention Period
Quality Surveys	Current + 1 year
Maintenance Checklists, Pest Control Reports, Cleaning logs	2 years
Environmental Records	2 years
Equipment Calibration, Cleaning Logs	3 years
Lab PO copies, budgets	3 years
Management Review	3 years
Obsolete Procedures, Policies and Forms	3 years
Supplier Evaluations	3 years
Supplier CAPA Reports	3 years
Employee Training Records	3 years after termination
Lab Records (raw materials, packaging materials, in-process, COA, specs, logs, OOS)	4 years
Production Records	4 years
Supplier Corrective Actions	4 years
Internal and External Audits	4 years
Regulatory (permits, registrations, certifications)	4 years
Non-Conforming, Deviation, Change Control	4 years
Customer Complaints, CAPA Reports, Returns, Recalls	4 years
Internal & External Inspection Records	5 years
Validations	10 years
OSHA Logs	30 years

7.0 Reference Documents

N/A

8.0 Change Information

Minor changes throughout including converting to new format and document numbering system.