Instructions: Add your company information as directed to the sections in **BLUE** text. Add/Remove information as it applies to your company/ needs. As you make changes, change the **BLUE** text to **BLACK**. Add the appropriate watermarks to the document to identify the status: DRAFT, ISSUED, for example. Add section and page breaks as you draft your document. **Remove this Instructions section once your document has been drafted.**

1. POLICY

1.1. This procedure provides the requirements for all cGMP documents at COMPANY NAME. All documents are uniquely identified and controlled throughout its lifecycle (initiation, maintenance, revision, and retirement/ archival) such that only the current version is available for use and approved documents cannot be altered while in use.

2. SCOPE

2.1. The procedure applies to all controlled documents managed within COMPANY NAME. This includes documents approved for use at COMPANY NAME or on behalf of COMPANY NAME by a contract service provider (CSP) or other outsourced personnel. The following are examples of controlled documents.

- Policies
- Standard Operating Procedures (SOPs)
- Release Specifications
- Protocols and Addenda
- Sample Plans
- Analytical Test Procedures
- Deviations
- Quality Manuals
- Batch Records
- Design History Files

2.2. Changes to qualified GMP systems, facilities, utilities, equipment, control systems, processes, Quality Control in-process and release or stability testing methods that support GMP manufacturing processes or emergency changes that have risk to, or impact safety of personnel, facility, or equipment are managed through SOP XXX – Change Management.

3. RESPONSIBILITY

3.1. COMPANY NAME Management is responsible for ensuring that the document control system is effective.

3.2. COMPANY NAME Quality Management is responsible for maintenance of the document system.