

Insert Company Logo here	SOP NAME	Document and Data Control Procedure			
	SOP Category	SOP Number	Revision Number	Date of Previous Revision	Revision Effective Date
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Supersedes: Original	SME: David Haynie			Date XX/XX/XX	
CONFIDENTIAL	Approved by:			Date XX/XX/XX	

1. PURPOSE

To describe the policy and guidelines established for a standardized format of controlled documents.

2. SCOPE

2.1 The scope of this SOP applies controlled documents used in the quality system at insert your company name.

3. PERSONNEL RESPONSIBILITIES

3.1 It is the responsibility of the Quality Manager or a member chosen and trained by the Quality Department to ensure these procedures are being enforced and followed.

4. DEFINITIONS

4.1 Controlled Document - is an authorized written or electronic document that is uniquely identified, approved, issued, and maintained as part of the quality system. These documents include the following:

- 4.1.1 Form - is a uniquely designed worksheet used to record data, display facts, or convey information.
- 4.1.2 Specifications - are a document containing detailed information regarding component or product quality attributes, expectations, design, technical details, testing methods, and release requirements.
- 4.1.3 Protocol/Report - is a document that fulfills special regulatory requirements or internal needs such as a validation or stability.
- 4.1.4 Record - is a document containing legal entries, statement of facts, or results from related actions.

4.2 Revision - is any change to a controlled document.

4.3 Supportive Document - is a document, record, chart, log, report, correspondence, or memorandum that provides substantiating information or history concerning the quality system, products, or procedures.

5. REFERENCES

- 5.1 21 CFR 111
- 5.2 21 CFR part 11
- 5.3 NSF Guidelines
- 5.4 GMP requirements are listed in NSF/ANSI 455-2 which is the only American National Standard in the dietary supplement industry developed in accordance with the FDA's 21 CFR part 111.