

Insert Company Logo here	SOP NAME	Change Management Procedure			
	SOP Category	SOP Number	Revision Number	Date of Previous Revision	Revision Effective Date
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Supersedes: Original Procedure	SME: G. Host			Date XX/XX/XX	
CONFIDENTIAL	Approved by: G. Host			Date XX/XX/XX	

1. PURPOSE

To describe the policy and guidelines established for a standardized format of Change Control.

2. SCOPE (Optional)

2.1 The scope of this SOP applies Change Control used in the quality system at **enter the name of your company**.

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.

3.2 **Requestor** - Responsible for initiating and documenting a Change Order, coordinating, implementing, and completing the change when authorized.

3.3 **4.2. Quality Assurance (QA)** - Responsible for ensuring that Change Orders are properly documented and assisting with change review, impact, analysis, implementation, and authorization where necessary and appropriate.

3.4 **4.3. Other Departments** - Responsible for assisting with change review, impact, analysis, implementation, and authorization where necessary and appropriate.

4. DEFINITIONS

4.1 **Change** - An intentional introduction, alteration, modification, revision, substitution, or discontinuation. Change can be as follows:

4.1.1 **Permanent** - A change with the intent to remain effective for the foreseeable future.

4.1.2 **Temporary** - A change that reverts to pre-change conditions upon completion of a pre-determined duration.

4.2 **Change Order (CO)** - A document used to propose and manage amendments made to GMP related item.

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.