ION LABS QUALITY FIRST	Standard Operating Procedure **Quality – General Responsibility and Authority**	**SOP Number** **A-109**	**Revision** **4**
		Effective Date 02/18/22	**Page** **Page 1 of 3**
Written by/ Date 08-11-21	**Reviewed by/ Date** 08/11/21	**Approved by/ Date** 08-11-21	
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1.0 Purpose

The purpose of this procedure is to define and clarify the lines of responsibility and of authority for quality matters within Ion Labs, Inc.

2.0 Scope

This procedure describes the responsibilities for quality that apply to all personnel at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of Quality Management to take an active role in assuring total quality, and reports all areas in which compliance is not satisfactory to senior management.

3.2 It is the responsibility of all personnel to comply with cGMP Quality and Regulatory requirements.

3.3 It is the responsibility of the Quality Unit to ensure that the Quality System complies with governmental regulatory requirements. The Quality Unit is a separate and distinct part of the company and is charged with ensuring the quality and efficacy of the company's products. The Quality Unit reports directly to the CEO.

3.4 It is the responsibility of the VP of Quality and Regulatory Affairs or designee to serve as the primary host for inspections from regulatory agencies and customer audits.

4.0 Definitions

4.1 **cGMP** – Current Good Manufacturing Practices

4.2 **SOP** – Standard Operating Procedure

5.0 References

5.1 21 CFR part 111, 114, 117, 210, 211 - as applicable to Dietary Supplements, Cosmetics and OTC (reference FDA CFR -Code of Federal Regulations Title 21 for specific part

reference)

6.0 Procedure

6.1 Duties of the Quality Unit

6.1.1 The Quality Unit will have the final responsibility of ensuring the quality of all products manufactured, packaged and distributed by the company. Including the authority to reject any component or product if any specification is not met.

6.1.2 The Quality Unit will lead any investigations related to customer complaints regarding the quality of any products manufactured, packaged, and distributed by the company. The Quality Unit will perform a full investigation and document any findings which have a negative effect on the quality of the product.

6.1.3 The Quality Unit will ensure that all internal and external laboratories and testing facilities are qualified to carry out the tests and assays required to ensure that raw materials, packaging materials, in-process product, and finished product meet the specifications established for them, as well as other appropriate quality standards.

6.1.4 Quality Unit personnel are responsible for the actions and procedures in the following areas:

6.1.4.1 Analytical and microbiological testing of raw materials, in-process product, and finished product.

6.1.4.2 Vendor qualification for raw materials and packaging materials.

6.1.4.3 Sampling of raw materials and packaging materials.

6.1.4.4 Inspection of labels, primary containers, components, and closures for acceptance or rejection.

6.1.4.5 In-process inspection of finished product to ensure that packaging specifications are being met.

6.1.4.6 Conducting line audits during changeovers.

6.1.4.7 Designing, maintaining, improving, and auditing the quality systems which ensure the safety, integrity, quality, and purity of all products manufactured by the company.

6.1.4.8 Approving SOPs that impact product integrity and cGMP.

6.1.4.9 Final release of finished product

6.1.4.10 Reviewing and approving reprocessing plans.

6.1.4.11 Approving capable and reliable contract manufacturers and packagers, suppliers of raw and packaging materials, and services that meet or exceed the standards set forth by the company. Such providers shall be subject to qualification and periodic re-evaluation to provide confidence in the provider's ability to meet acceptable standards.

6.1.4.12 Working with production to ensure compliance with cGMP in production areas and at contract manufacturing facilities.

6.1.4.13 Conducting internal audits and reviewing results to ensure that the company and all related systems and procedures meet cGMP requirements.

6.1.4.14 Verifying the compliance of materials with their product specifications prior to release of finished product.

6.1.4.15 Approving manufacturing equipment, facilities, and procedures for use in production that will lead to manufactured products successfully meeting established quality standards.

6.1.4.16 Staying current with local laws and regulations as well as domestic and International agency requirements, including Certifying Bodies (e.g. NSF), that may impact product manufactured at the company.

6.1.4.17 Testing to ensure that all product specifications are being met.

6.1.4.18 Assessing manufacturing conditions, new/revised formulations or packaging requirements, and new/revised procedures or processes before implementation to ensure acceptable quality standards and regulatory compliance, as well as requirements specified by the customer.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/04/10	New	-	-
1	02/18/13	Changed SOP format, SOP title, and SOP number. Updated SOP to be consistent with restructured quality system.	13-100	R. Howard
2	06/24/15	Biennial review: updated SOP format.	15-0569	S. Millar
3	01/03/19	Scheduled review: update responsibilities.	19-0016	K. Burris
4	08/04/21	Added 21 CFR parts. Added statement of authority to reject in section 6.1.1. Added further clarification to section 6.1.4.16	CC-21-0309	C. Mitchell