SSCI’s DSSC Initiative
Requirements for Manufacturing Facilities
Table of Contents

1. Introduction .......................................................................................................................... 3
2. Purpose ................................................................................................................................. 3
3. References ........................................................................................................................... 3
4. Definitions ............................................................................................................................ 4
5. Scope of Recognition: ......................................................................................................... 4
7. Use of SSCI Logo: ................................................................................................................ 4
8. Product Labelling: ............................................................................................................... 4
9. Product Recalls: ................................................................................................................... 4
10. Other Notifications: .......................................................................................................... 5
1. Introduction

1.1. The Supplement Safety & Compliance Initiative (SSCI) is a non-profit foundation comprising major global retailers, distributors, raw material suppliers (including cultivators), raw material manufacturers, finished product manufacturers, certifying bodies, and experts in quality control, quality assurance, and safety of dietary supplement.

1.2. SSCI’s vision is to elevate the quality and credibility of dietary supplements globally by continuously driving improvements in quality processes. The initiative is focused on engaging and collaborating with stakeholders in the supply chain with the goal of raising standards of the entire industry.

2. Purpose

2.1. This document specifies requirements for applicant and certified organization seeking recognition under the SSCI’s Dietary Supplement Safety and Compliance (DSSC) program. Through routine audits, certification bodies (CBs) recognized under the DSSC program, verify the conformance of organizations to the requirements of this document.

2.2. SSCI monitors evaluations that organizations meet the requirements of this document. Through its relationship with accreditation bodies (ABs) and CBs, SSCI will be informed about organizations’ conformance with these requirements.

2.3. To be eligible for recognition under the DSSC program, the scope of certification must match the scope of CB’s recognition.

2.4. Contact information for all recognized ABs is listed on the SSCI website.

2.5. English is the official language of SSCI. All correspondence, reports, and certificates shall be submitted in English.

2.6. The following verbal forms are used (consistent with their use in ISO/IEC 17065):

- “Shall” indicates a requirement.
- “Should” indicates a recommendation.
- “May” indicates a permission.
- “Can” indicates a possibility or a capability.

2.7. Unless otherwise specified the latest version of the referenced documents apply.

3. References

3.1. 21 CFR Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, labeling and holding operations for dietary supplements
3.2. 21 CFR Part 117, Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventative Control for Human Food

4. Definitions

4.1. Refer to DSSC initiative definitions document.

5. Certification:

5.1. Depending on the scope of operations, an organization is eligible to obtain certification and SSCI recognition for the SSCI recognized schemes/programs.

6. Quality System Requirements:

6.2. In addition to the conforming to the requirements for certification under a specific scope, the organization shall implement the following quality system requirements:

a) Requirements of ISO 9001 for internal audits.

b) Requirements of ISO 9001 for management review.

c) Requirements of ISO 9001 for corrective action process.

7. Use of SSCI Logo:

7.1. The SSCI logo may be used on the certified organization’s website, printed material, and other promotional material.

7.2. The SSCI logo shall not be used on products, labelling on packaging, or in any other manner that could imply that SSCI approved or certified the product.

7.3. The organization shall not use the logo in any way that could bring SSCI into disrepute and shall not make any statement regarding their recognition that SSCI may consider inaccurate, misleading, or unauthorized.

8. Product Labelling:

8.1. The organization shall ensure that the finished product is labelled according to the applicable intended sale regulations.

9. Product Recalls:

9.1. Recognized organizations is required to inform SSCI and the CB within two business days of any product recall. Information shall be emailed to info@ssciglobal.org with the subject line “Product Recalls-NAME OF THE ORGANIZATION.”
9.2. This information will be shared with members of the SSCI for the purposes of recognition only.

10. Other Notifications:

10.1. The recognized facility is required to inform SSCI and the certifying CB of any site visits by the FDA.

10.2. The recognized facility is required to inform SSCI and the certifying CB within two business days of any infractions issued by the FDA, such as 483, as well as inspection qualifications NAI, VAI, and OAI.

10.3. This information will be shared with members of the SSCI for the purposes of recognition only.