GMP Certification Program
for Health Supplements

2021 Edition

Good Manufacturing Practice (GMP)
for Health Supplements

Standards for Manufacturing Control and
Quality Control of Health Supplements

This English version is unofficial and provided for reference only.

Japan Health and Nu trition Food Association (JHNFA)

Introduction

Based on the Notification by Director General, Department of Food Safety, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare (Food Safety Notification No. 0201003), “Basic Concept for Proper Manufacturing of Foods in Tablet, Capsule and Other Forms” published on February 1, 2005, Japan Health and Nutrition Food Association (JHNFA) launched the “GMP certification program for health supplements” as a third-party certification program in April of the same year, and has certified over 150 manufacturing sites to date.

Amid significant changes in the environment surrounding the health food industry, JHNFA was designated in March 2014 as the first GMP certification body of the Council on Accreditation of Health Foods supported by the Ministry of Health, Labour and Welfare, and the need for such an accreditation system is becoming increasingly greater. Furthermore, the system for foods with functional claims started in April 2015, and GMP-based manufacturing process control has become indispensable for quality assurance to ensure functionality and safety. Furthermore, the Food Sanitation Act was revised in June 2018 to require the establishment of a new notification system for “so-called health food manufacturing business” and standards, etc. for manufacturing and processing of foods containing designated ingredients, etc., and thus the GMP-based manufacturing process control for health food has become increasingly important.

Therefore, this document has been revised with a view to more global GMP. Major revisions include the addition of provisions on disintegration tests as well as adjustments in accordance with the revision of the Food Sanitation Act, and the document has been made easier to understand by using unified expressions and phrases.

JHNFA will continue to strive for GMP certification and its dissemination in order to improve the quality of health supplements, and we ask for your continued understanding and support.
Finally, we would like to express our sincere appreciation to the GMP Factory Certification Committee members and GMP investigators who contributed to this revision, as well as to the companies that provided us with their opinions.

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Definitions of Terms

* Definitions of Terms

1	Health supplement	A food that is taken as a supplement to a normal meal or food with the intention of maintaining or improving health and contains one or more components useful for health in tablet, capsule, granule/powder, jelly, or liquid form. This term is synonymous with food that is called a nutritional supplement or dietary supplement.
2	Active components	1) Vitamins, minerals, lipids, proteins (amino acids), dietary fibers, lactic acid bacteria, etc. 2) Herbs and other plant components (including flavonoids and carotenoids) 3) Components derived from marine products, livestock products and ores 4) Other components proven to be useful for living organisms
3	Ingredients	All substances used in the manufacture of health supplements, including those not finally contained in products, excluding packaging materials and intermediate products.
4	Packaging materials	Containers and wrappers of products, and labels attached to containers and wrappers. “Wrapper” means packaging materials and does not include packing materials.
5	Intermediate products	Products made in intermediate processes of product manufacturing, which become final consumer products through further subsequent manufacturing processes. Also include bulk preparations.
6	Bulk products	Bulk preparations that are sold or transferred to other companies, and are handled in the same way as “final consumer products” at one’s own manufacturing site. Furthermore, if “bulk products” are purchased or transferred, they are handled in the same way as “ingredients.”
7	Final consumer product	A product that has gone through all manufacturing processes and can be sold or transferred as a commodity to consumers in that form.
8	Products, etc.	Include all intermediate products, bulk products and final consumer products.
9	Reprocessing	A process of returning products, etc. that do not conform to standards to a known process and repeating it.
10	Lot	A group of products manufactured to be homogenous through a series of manufacturing processes within the same manufacturing period.
11	Control unit	A group of packaging materials that are confirmed to be identical.

12	Contract given	A manufacturer that contract the manufacture of products, etc. to one's own manufacturing site.
13	Contract acceptor	A manufacturer to which one's own manufacturing site contract manufacturing.
14	Receipt of goods	Receiving ingredients, packaging materials, and products, etc. from other companies at one's own manufacturing site.
15	Shipment	Dispatching products, etc. from one's own manufacturing site.
16	Warehousing	Receiving ingredients, packaging materials, and products, etc. from a manufacturing department or other departments by a warehouse department.
17	Delivery	Dispatching ingredients, packaging materials, and products, etc. from a warehouse department to a manufacturing department or other departments.
18	Manufacturing site	An entire factory including buildings and premises for manufacturing products, etc. (including process inspection rooms, laboratory, office rooms, warehouses, etc.).
19	Workplace	An area with workrooms and equipment, etc. necessary for the workrooms.
20	Workroom	A room where manufacturing, testing, inspection, and related work are conducted.

Reference (Definitions of Terms Related to Ingredient GMP)

1	Starting materials	Substances used as base materials in the manufacture of ingredients. In the case of plant/animal individuals, microorganisms, minerals or chemically synthesized products, substances that are incorporated in ingredients as an important constituent part of the structure of the ingredients. In the case of ingredients derived from fermentation/culture, substances necessary for fermentation/culture. Packaging materials and materials are not included in raw materials.
2	Starting materials, etc.	Starting materials and other materials necessary for manufacturing of ingredients.
3	Ingredients	Substances or mixtures of substances used in health supplements that become useful ingredients when used in the manufacture of health supplements. (This term is synonymous with ingredients

		that are associated with functionality of foods with functional claims)
4	Ingredients, etc.	Include all intermediates, bulk ingredients, ingredients and ingredients (products).
5	Materials	Water, solvents, excipients, etc. blended to manufacture ingredients.
6	Intermediates	Matters obtained in intermediate processes of ingredient manufacturing, which become ingredients in subsequent manufacturing processes. Include bulk ingredients.
7	Packaging materials	Containers and wrappers of ingredients and products, and labeling materials attached to containers and wrappers. “Wrapper” means packaging materials and does not include packing materials.
8	Reworking	Reworking ingredients, etc. that do not conform to standards by a process that is different from the specified process.

I. Voluntary Standards for GMP for Health Supplements

(1) Control Standards for GMP for Health Supplements

Chapter 1 General Provisions

Article 1 (Purpose)

The purpose of the Control Standards for GMP for Health Supplements is to ensure the quality of health supplements by providing guidelines for manufacturing control and quality control related to the manufacture of health supplements and for accurate and smooth implementation of these controls.

Article 2 (Responsibility of Business Operators)

1. Business operators who are health supplements manufacturers (hereinafter referred to as "Business Operators") shall endeavor to implement these standards.
2. The Business Operators shall appoint a general manager for each manufacturing site and give the general manager overall authority for GMP control.
3. The Business Operators shall support the general managers so that they can take all possible measures to execute their duties.
4. The Business Operators shall take necessary measures for manufacturing control and quality control when their improvements are required.
5. The Business Operator shall establish "Control Rules for GMP for Health Supplements" and standards, etc. that are suitable for its own manufacturing site in order to comply with the "Control Standards for GMP for Health Supplements" and "Structure and Equipment Standards for GMP for Health Supplements."

Article 3 (Duties of the General Manager)

The general manager shall perform the duties listed in each of the following items.

(i) Supervise GMP operations upon appointment by the Business Operator.
(ii) Appoint and supervise a manufacturing control manager and a quality control manager. In addition, appoint other necessary managers.
(iii) Establish standards, etc. necessary for smooth implementation of GMP.
(iv) Properly evaluate the results of manufacturing control, manufacturing hygiene control and quality control to determine whether or not to ship products.
(v) Operations related to confirmation of validity
(vi) Operations related to response to abnormalities in quality, etc.
(vii) Operations related to GMP education and training for employees
(viii) Operations when manufacturing processes are entrusted to other companies
(ix) Self-inspection operations

Article 4 (Product Standards)

The general manager shall establish “Product Standards” for each product that describe the matters listed in each of the following items.

(i) Outline of product

(ii) Standards and test methods for ingredients, packaging materials, and products, etc.

(iii) Standards for labeling

(iv) Manufacturing methods and procedures

(v) Other necessary matters

Chapter 2 Manufacturing Control

Article 5 (Manufacturing Control Standards)

The general manager shall establish “Manufacturing Control Standards” that describe the matters listed in each of the following items concerning the manufacturing control of health supplements.

(i) Precautions when receiving, storing and delivering ingredients and packaging materials

(ii) Precautions when delivering, storing and shipping products, etc.

(iii) Matters related to management of manufacturing processes

(iv) Matters related to management of manufacturing equipment and apparatus

(v) Matters related to changes in ingredients, packaging materials, manufacturing methods, manufacturing equipment, etc.

(vi) Matters related to work control of persons in charge of work

(vii) Other matters necessary for manufacturing control

Article 6 (Manufacturing Hygiene Control Standards)

The general manager shall establish “Manufacturing Hygiene Control Standards” that describe the matters listed in each of the following items concerning the manufacturing hygiene control of health supplements.

(i) Matters related to hygiene control of manufacturing equipment (including those related to process inspections; the same shall apply hereinafter)

(ii) Matters related to hygiene control of employees

(iii) Other matters necessary for manufacturing hygiene control

Article 7 (Duties of the Manufacturing Control Manager)

The manufacturing control manager shall properly perform the operations related to manufacturing control of health supplements listed in each of the following items in accordance with the “Product

Standards," "Manufacturing Control Standards," "Manufacturing Hygiene Control Standards," "Validity Confirmation Procedures," and "Procedures for Response to Abnormalities."

(i) Prepare a "manufacturing direction" that describes instructions, precautions, and other necessary matters in manufacturing processes.

(ii) Perform the following operations by himself/herself, or have a person designated in advance according to the contents of the operations perform them.

(a) Manufacture health supplements in accordance with the "manufacturing direction."

(b) Prepare records concerning manufacturing for each lot.

(c) Conduct proper storage and receipts and disbursements of ingredients, and products, etc. for each lot, and of packaging materials for each control unit, and prepare records of them.

(d) Confirm that manufacturing equipment is clean, and prepare a record of it.

(e) Conduct hygiene control of persons in charge of work, and prepare a record of it.

(f) Periodically inspect and maintain manufacturing of equipment, and prepare a record of it.

(g) When changes are made to ingredients, packaging materials, manufacturing methods, manufacturing equipment, etc., or when there is a risk of affecting quality, confirm the validity in accordance with the "Validity Confirmation Procedures," and revise the "Product Standards."

(h) Other operations necessary for manufacturing control and manufacturing hygiene control.

(iii) Confirm that manufacturing control and manufacturing hygiene control are properly implemented according to the preceding items, and report the results in writing to the general manager.

Chapter 3 Quality Control

Article 8 (Quality Control Standards)

The general manager shall establish "Quality Control Standards" that describe the matters listed in each of the following items concerning the quality control of health supplements.

(i) Matters related to methods for specimen collection

(ii) Matters related to quality control of ingredients, and packaging materials

(iii) Matters related to implementation of testing and inspection and judgment of results

(iv) Matters related to reporting and communication of judgment results to the general manager and the manufacturing control manager

(v) Matters related to collection and management of stored samples of products, etc.

(vi) Matters related to handling of long-term stock items

(vii) Matters related to inspection and maintenance of equipment and apparatus for testing and inspection

(viii) Matters related to implementation of testing and inspection

(ix) Other matters necessary for quality control

Article 9 (Duties of the Quality Control Manager)

The quality control manager shall properly perform the operations related to quality control of health supplements listed in each of the following items in accordance with the "Product Standards," "Quality Control Standards," "Validity Confirmation Procedures," and "Procedures for Response to Abnormalities."

(i) Perform the following operations by himself/herself, or have a person designated in advance according to the contents of the operations perform them.

(a) Collect specimens necessary to conduct testing and inspection for each lot or control unit of ingredients, packaging materials, and products, etc., and prepare records of them.

(b) Test and inspect the collected specimens for each lot or control unit, and prepare records of them. When testing and inspection results provided by suppliers of ingredients and packaging materials are used, one's own manufacturing site may omit its testing and inspection. However, for ingredients that act as or contain active components, at least one confirmation test to identify them must be conducted.

(c) For products, etc., store the amount necessary for a prescribed test for each lot under appropriate storage conditions for the required period as stored samples of products, etc., and prepare records of them.

(d) Periodically inspect and maintain equipment and apparatus for testing and inspection, and prepare a record of it.

(e) Specify expiration dates for use of reagents, reference standards, etc. used in testing, and properly manage them.

(f) If one's company's test method is not officially approved, establish a reliable analytical method.

(g) Evaluate the impact on quality when changes are made to manufacturing conditions, etc. of products.

(h) For products, etc. in tablet, capsule or other forms, a separately specified disintegration test must be conducted for each lot.

(i) Other operations necessary for quality control.

(ii) Judge the results of testing and inspection, and report the results in writing to the general manager and the manufacturing control manager.

Chapter 4 Confirmation of Validity

Article 10 (Validity Confirmation Procedures)

The general manager shall establish “Validity Confirmation Procedures” that describe the procedures for confirming validity in processes of manufacturing health supplements, and have the validity confirmation manager perform the operations listed in each of the following items in accordance with the Procedures.

(i) Confirm the validity of the manufacturing processes listed below.

(a) When manufacturing of a new product is started

(b) When the quality of products is significantly affected by changes in manufacturing equipment, manufacturing conditions, etc.

(c) When the constancy of the manufacturing process of existing products is evaluated

(d) Other cases where it is deemed necessary to properly conduct manufacturing control and quality control of products

(ii) Prepare and confirm a “validity confirmation implementation plan” that describes instructions, precautions, and other necessary matters in manufacturing processes, and report them in writing to the general manager.

(iii) Prepare “validity confirmation report,” judge the results, and report them in writing to the general manager.

Chapter 5 Response to Abnormalities in Quality, Etc.

Article 11 (Procedures for Response to Abnormalities)

The general manager shall establish “Procedures for Response to Abnormalities” that describe how to respond in the event of any of the following abnormalities.

(i) Abnormalities at the time of receipt of ingredients and packaging materials and during acceptance testing and inspection

(ii) Abnormalities in processes

(iii) Products cannot be shipped

(iv) Complaints

(v) Recall

Article 12 (Duties of Responsible Persons in Relation to Response to Abnormalities)

1. If any abnormality (including abnormalities in testing and inspection results) is found at the time of receiving ingredients or packaging materials, the manufacturing control manager shall determine whether or not the ingredients or packaging materials in question can be used, and if they cannot be used, he/she shall take appropriate measures to prevent the ingredients or packaging materials in question from being used. If necessary, decisions shall be made after consultation with the quality control manager and the general manager.
2. The manufacturing control manager shall contact the supplier of ingredients or packaging materials to provide them with information on abnormalities, and request them to investigate the cause and prevent recurrence.
3. When any abnormality is found in the manufacturing process or when products cannot be shipped, the manufacturing control manager shall instruct the supplier to take measures for the products in question, investigate the cause of the abnormality, and strive to prevent its recurrence. Furthermore, measures to be taken for the ingredients or packaging materials in question shall be decided after consultation with the quality control manager and the general manager as necessary.
4. The quality control manager shall take the following measures in response to complaints from customers, contract given, etc.
   (i) Instruct the department that caused a complaint to investigate the cause of the complaint
   (ii) Responses to complainants
5. The general manager shall take prompt and appropriate actions in the event of a recall.
   (i) Report information on whether or not a recall is necessary to the Business Operator, and if necessary, to administrative organs and the Japan Health and Nutrition Food Association, and make a final decision.
   (ii) Give appropriate instructions to the department that deals with the recall.
   (iii) Report the progress and results of the recall to the Business Operator in a timely manner, and if necessary, to administrative organs and the Japan Health and Nutrition Food Association.
   (iv) Report the recall plan, and the progress and results of the recall to the Japan Health and Nutrition Food Association.

Chapter 6 Education and Training

Article 13 (Education and Training Procedures)

The general manager shall establish “Education and Training Procedures” that describe procedures for providing education and training for employees, and shall have the education and training manager perform the operations listed in each of the following items in accordance with the procedures.

(i) Plan and implement education and training for employees on manufacturing control, quality control and related matters.

(ii) Report in writing to the general manager on the plan and implementation status of education and training.

Chapter 7 Commissioning Manufacture

Article 14 (Contract Manufacturing)

The general manager who has a manufacturing site of another manufacturer (hereinafter referred to as “Contract acceptor”) perform part of the manufacturing process of health supplements shall establish “Control Procedures for Contract Manufacturing” that describe the arrangements on the matters listed below in order to ensure appropriate implementation of manufacturing control, quality control, etc. at the Contract acceptor, and shall perform the operations in accordance with the procedures. Contract Manufacturing to another manufacturing site of one’s company shall be treated the same.

(i) Scope of contract Manufacturing

(ii) Matters related to manufacturing control and manufacturing hygiene control pertaining to contract Manufacturing

(iii) Matters related to quality control pertaining to contract Manufacturing

(iv) Methods of quality control during transportation and delivery

(v) Timely or urgent confirmation that contract Manufacturing is properly conducted at the manufacturing site of the Trustee

(vi) Other matters related to contract Manufacturing

Chapter 8 Self-inspection

Article 15 (Self-inspection)

The general manager shall establish “Self-inspection Procedures” that describe procedures for self-inspection of manufacturing control and quality control of health supplements, and other GMP

operations, and shall have the self-inspection manager perform the operations listed in each of the following items in accordance with the procedures.

(i) Conduct self-inspection of GMP operations, such as manufacturing control and quality control of health supplements at a manufacturing site, in a planned manner or on a temporary basis as necessary.

(ii) Promote correction based on the results of self-inspection.

(iii) Confirm the effect of correction after self-inspection.

(iv) Report in writing to the general manager on the plan and results of self-inspection and the correction after the self-inspection.

Chapter 9 Document Management

Article 16 (Document Management)

The general manager shall prescribe the matters listed in each of the following items concerning the management of documents related to GMP.

(i) Matters related to establishment and revision of documents

(ii) Matters related to preparation and retention of records

(iii) Matters related to approval or deliberation (confirmation)

(iv) Other matters related to document management

(2) Structure and Equipment Standards for GMP for Health Supplements

Chapter 1 General Provisions

Article 1 (Purpose)

The purpose of the Structure and Equipment Standards for GMP for Health Supplements is to provide for standards for structure and equipment of manufacturing sites for health supplements, and thereby to ensure the quality of health supplements.

Chapter 2 Structure and Equipment Standards for Manufacturing Sites

Article 2 (Structure and Equipment Standards for Manufacturing Sites)

The structure and equipment standards for manufacturing sites of health supplements shall be as follows.

(i) The manufacturing sites shall have the structure and equipment necessary for manufacturing products, etc.

(ii) The equipment set forth in the preceding item shall be arranged so as not to hinder smooth and appropriate work, and shall be able to be cleaned or washed and be easy to maintain.

(iii) Workplaces shall conform to the following.

(a) Workrooms shall be separated from places not directly related to the work and from unclean places.

(b) Workplaces shall have an area that is sufficient for work and storage.

(c) Workplaces shall have a structure and equipment to prevent cross contamination.

(d) Workplaces shall have a structure and equipment to prevent dust, insects and rodents.

(e) Daylighting, illumination and ventilation are provided appropriately and cleanly.

(f) Floors shall be made of water-resistant materials, drain well, and be easy to clean.

(g) Interior walls shall be made of water-resistant materials, and have a structure that is easy to clean.

(h) Ceilings, etc. shall be easy to clean, and have a structure that prevents rubbish from falling.

(i) Equipment for cleaning outer packaging of ingredients and packaging materials shall be provided.

(j) Equipment for washing or cleaning equipment, containers, etc. used for manufacturing shall be provided.

(k) Equipment for employees to wash their hands and disinfect their fingers shall be

provided.

(l) Changing rooms or changing boxes whose number is appropriate to the number of employees shall be provided according to the number of employees.

(m) Lavatories shall be provided in the amount appropriate to the number of employees and separated from workrooms.

(n) For water used for manufacturing including washing of manufacturing equipment, equipment that can supply "water for food production" as specified in the standards for foods, additives, etc. shall be provided.

(o) Equipment that comes into direct contact with ingredients, and products, etc. shall be made of materials that are water- and chemical-resistant and that do not degrade the quality of ingredients, and products, etc. with which the equipment comes into contact. Furthermore, the equipment shall be easily washed and can be disinfected as necessary.

(p) Among workplaces, workrooms where weighing work for ingredients, and preparation, filling and closing work for products, etc. are conducted shall conform to the following provisions.

1) Workbenches provided in the workroom shall be designed not to hinder smooth and appropriate work.

2) The workroom shall be constructed so as not to provide a passageway for anyone other than the persons in charge of the work conducted in the workroom.

3) It is desirable that there are no entrances and exits (excluding emergency exits) that directly face the outdoors. Furthermore, if necessary, the workroom shall have a structure and equipment necessary to prevent contamination from the outdoors.

4) Entrances, exits and windows shall be able to be closed.

5) Drainage equipment and equipment required for waste disposal shall have the structure necessary to prevent contamination of the workroom.

6) Equipment in the workroom, such as pipes and ducts, shall have a structure that prevents dust from accumulating on their surfaces. However, this shall not apply when they are easy to clean or wash.

(iv) Storage equipment for ingredients, and products, etc. shall conform to the following provisions.

(a) The area shall be sufficient for the volume handled.

(b) Storage equipment shall be equipped with equipment to maintain the quality of ingredients, and products, etc. handled.

(c) Floors and interior walls shall be made of impermeable materials and have an easy-to-clean structure. Furthermore, drainboards and other equipment shall be provided on the floor surface to prevent contamination.

(d) Entrances, exits and other places that are opened/closed shall be equipped with equipment to prevent the entry of vermin such as rodents and insects.

(v) Equipment and apparatus necessary for testing and inspection of ingredients, packaging materials, and products, etc. shall be provided. However, this shall not apply when testing and inspection are entrusted to other testing and inspection organizations.

II. Explanation of “Voluntary Standards for GMP for Health Supplements”

(1) Control Standards for GMP for Health Supplements (Explanation)

Chapter 1 General Provisions

Article 1 (Purpose)

The purpose of the Control Standards for GMP for Health Supplements is to ensure the quality of health supplements by providing guidelines for manufacturing control and quality control related to the manufacture of health supplements and for accurate and smooth implementation of these controls.

[Explanation of Article 1]

(1) GMP is an indispensable system for ensuring the quality of health supplements, and the Japan Health and Nutrition Food Association uses the two pillars of "Control Standards for GMP for Health Supplements" and "Structure and Equipment Standards for GMP for Health Supplements" as the basis for its voluntary standards for GMP.

These "Control Standards for GMP for Health Supplements" provide guidelines for control, and it is important not only to establish control documents and implement their operations but also to continue them. Therefore, it is necessary to take flexible measures such as reviewing the standards in accordance with changes in internal circumstances and social conditions, and technological improvements.

Article 2 (Responsibility of Business Operators)

1. Business operators who are health supplements manufacturers (hereinafter referred to as "Business Operators") shall endeavor to implement these standards.
2. The Business Operators shall appoint a general manager for each manufacturing site and give the general manager overall authority for GMP control.
3. The Business Operators shall support the general managers so that they can take all possible measures to execute their duties.
4. The Business Operators shall take necessary measures for manufacturing control and quality control when their improvements are required.
5. The Business Operator shall establish "Control Rules for GMP for Health Supplements" and standards, etc. that are suitable for its own manufacturing site in order to comply with the "Control Standards for GMP for Health Supplements" and "Structure and Equipment Standards for GMP for Health Supplements."

[Explanation of Article 2]

(1) The Business Operator (i.e., the president or factory manager, etc.) must appoint a general manager as the person responsible for the overall GMP operations, and if necessary, a deputy general manager to provide full support for the execution of GMP operations.

(2) The Business Operator may delegate to the general manager the appointment of managers or persons in charge necessary for GMP operations and the establishment of the "Control Rules for GMP for Health Supplements" and standards, etc.

(3) A GMP organization is to be built in accordance with the actual conditions of each manufacturing site. However, the Business Operator should pay attention to ensure that the general manager, the manufacturing control manager and the quality control manager are not hindered in the implementation of GMP due to the positional relations with the internal organizations.

(4) The general manager may not concurrently serve as the manufacturing control manager.

(5) The general manager may concurrently serve as the quality control manager if it is unavoidable.

(6) It is not permitted for a person to concurrently serve as the manufacturing control manager and the quality control manager. It is also desirable that the manufacturing control and quality control departments be independent from each other in terms of the persons in charge of work.

Article 3 (Duties of the General Manager)

The general manager shall perform the duties listed in each of the following items.

(i) Supervise GMP operations upon appointment by the Business Operator.

(ii) Appoint and supervise a manufacturing control manager and a quality control manager. In addition, appoint other necessary managers.

(iii) Establish standards, etc. necessary for smooth implementation of GMP.

(iv) Properly evaluate the results of manufacturing control, manufacturing hygiene control and quality control to determine whether or not to ship products.

(v) Operations related to confirmation of validity

(vi) Operations related to response to abnormalities in quality, etc.

(vii) Operations related to GMP education and training for employees

(viii) Operations when manufacturing processes are entrusted to other companies

(ix) Self-inspection operations

[Explanation of Article 3]

(1) The general manager must fulfil his/her duties as the person most responsible for GMP operations.

(2) Other necessary managers in item (ii) vary depending on the size of the company, etc., but they must be appointed with consideration for the necessity for executing GMP operations, and the division of their duties and roles must be clarified.

Furthermore, a GMP organization chart should be prepared to clarify the organization of them.

Other managers include the deputy manufacturing control manager, deputy quality control

manager, manufacturing line manager, warehouse manager, facility manager, testing and inspection manager, education and training manager, self-inspection manager, and validity confirmation manager.

(3) Standards, etc. in item (iii) are as follows:

1) Control Rules for GMP for Health Supplements
2) Product Standards
3) Manufacturing Control Standards
4) Manufacturing Hygiene Control Standards
5) Quality Control Standards
6) Validity Confirmation Procedures
7) Procedures for Response to Abnormalities
8) Education and Training Procedures
9) Control Procedures for Contract manufacturing
10) Self-inspection Procedures
11) Structure and Equipment Standards

However, if contract manufacturing is not implemented or planned, it is not necessary to establish “Control Procedures for Contract manufacturing.”

Furthermore, if necessary, it is desirable to establish rules or procedures to supplement these standards, etc.

(4) Final consumer products and bulk products may not be shipped from a manufacturing site unless the general manager has properly evaluated the results of the manufacturing control status, manufacturing hygiene control status and quality control status, and has determined that the final consumer products and bulk products are allowed to be shipped.

(5) The general manager must meet any of the following qualifications.

1) A person who has knowledge of health supplements, and has been engaged in operations related to manufacturing control or quality control for five years or more.
2) A person who graduated from a university under the School Education Act (Act No. 26 of 1947), a university under the former University Order (Imperial Order No. 388 of 1918) or a professional training college under the former Vocational Training School Order (Imperial Order No. 61 of 1903) after completing a course in medical science, dentistry, pharmacy, veterinary medicine, nutrition, animal husbandry, fishery science, agricultural chemistry or chemistry.
3) A medical doctor, dentist, pharmacist or veterinarian

Article 4 (Product Standards)

The general manager shall establish “Product Standards” for each product that describe the matters listed in each of the following items.

(i) Outline of product

(ii) Standards and test methods for ingredients, packaging materials, and products, etc.

(iii) Standards for labeling

(iv) Manufacturing methods and procedures

(v) Other necessary matters

[Explanation of Article 4]

(1) “Product Standards” standardize the matters necessary for the manufacture of the product item and serve as the basis for manufacturing control and quality control. Therefore, it is necessary to establish “Product Standards” for each product item so that this point is utilized.

(2) Necessary specifications and test methods for intermediate products must also be established and described.

(3) The following information must be described in the Outline of Product in item (i).

1) Pharmaceutical Preparations: Product name, dosage form, descriptions, weight, dimensions

2) Packaging: Form (individual package, inner packaging, outer packaging), volume, quantity

3) Product specifications: Item (when there are individual packages with different numbers of preparations and liquid volumes)

(4) Ingredients in item (ii) include solvents that volatilize due to concentration or drying during manufacturing.

(5) With regard to the labeling in item (iii), necessary matters (expiration date, etc.) must be described in accordance with laws, regulations, administrative guidance, etc.

(6) “Manufacturing methods and procedures” in item (iv) must also include ingredients and their amounts blended, standard preparation amount, standard yield, manufacturing equipment, manufacturing conditions, and process inspection methods.

(7) “Other necessary matters” in item (v) must include matters necessary for the manufacture of the product, such as storage conditions for ingredients, packaging materials, and products, etc.

(8) If testing and inspection are to be conducted at a place of business other than the place of business concerned or at an outside testing and inspection organization, the Product Standards must include a statement to that effect and describe the items to be tested and inspected and specifications and test methods for them.

(9) If testing and inspection (items) are omitted, the details and conditions of the omission must be described.

Chapter 2 Manufacturing Control

Article 5 (Manufacturing Control Standards)

The general manager shall establish "Manufacturing Control Standards" that describe the matters listed in each of the following items concerning the manufacturing control of health supplements.

(i) Precautions when receiving, storing and delivering ingredients and packaging materials

(ii) Precautions when delivering, storing and shipping products, etc.

(iii) Matters related to management of manufacturing processes

(iv) Matters related to management of manufacturing equipment and apparatus

(v) Matters related to changes in ingredients, packaging materials, manufacturing methods, manufacturing equipment, etc.

(vi) Matters related to work control of persons in charge of work

(vii) Other matters necessary for manufacturing control

[Explanation of Article 5]

(1) Manufacturing Control Standards prescribe the manufacturing, storage, etc. from receipt of ingredients and packaging materials to shipment as final consumer products in order to always manufacture health supplements of a certain quality.

(2) "Precautions" in items (i) and (ii) means the following matters.

1) Matters to be observed when receiving and warehousing/delivering ingredients and packaging materials

2) Storage methods that do not cause deterioration in the quality of ingredients, packaging materials, and products, etc.

3) Matters to be observed when warehousing/delivering and shipping products, etc.

4) Measures to be taken in the event of abnormality in the above processes

5) Other necessary matters

(3) "Matters related to management of manufacturing processes" in item (iii) means the following matters.

1) Matters related to lot composition and numbering method

2) Matters to be inspected and confirmed before and after manufacturing work

3) Matters related to manufacturing direction and records such as manufacturing records

4) Measures to be taken in the event of abnormality in the manufacturing process

5) Other necessary matters

(4) "Matters related to management of manufacturing equipment and apparatus" in item (iv) means the following matters.

1) Inspection items for manufacturing equipment and apparatus

2) Matters related to inspection and recovery in the event of failure or abnormality

(5) Item (v) is the case where the ingredients, packaging materials, manufacturing methods, manufacturing equipment, etc. specified in the "Product Standards" are changed. If there is a risk that quality may be affected, the "Product Standards" must be revised after confirmation of validity in accordance with the "Validity Confirmation Procedures."

(6) "Matters related to work control of persons in charge of work" in item (vi) means matters that persons in charge of work must observe when starting work. However, matters related to hygiene control are described in the "Manufacturing Hygiene Control Standards."

(7) "Other matters necessary for manufacturing control" in item (vii) means the following matters.

1) Matters related to restriction of entry by persons other than those in charge of work
2) Status display on main equipment, etc., and display of product names and lot numbers on those in operation
3) Double check in important work

Article 6 (Manufacturing Hygiene Control Standards)
The general manager shall establish "Manufacturing Hygiene Control Standards" that describe the matters listed in each of the following items concerning the manufacturing hygiene control of health supplements.

(i) Matters related to hygiene control of manufacturing equipment (including those related to process inspections; the same shall apply hereinafter)
(ii) Matters related to hygiene control of employees
(iii) Other matters necessary for manufacturing hygiene control

[Explanation of Article 6]

(1) "Manufacturing Hygiene Control Standards" prescribe manufacturing hygiene in a manufacturing site, such as hygienic environment and clothes of employees, in order to prevent contamination of health supplements.

(2) Item (i) "Matters related to hygiene control of manufacturing equipment (including those related to process inspections; the same shall apply hereinafter)" means the following matters.

1) Setting of cleanliness classifications for workrooms, etc.
2) Designation of places, machinery and apparatus to be cleaned in workrooms, etc., and setting of the frequency of cleaning work
3) Procedures for cleaning work, and management methods for chemicals and tools to be used
4) Confirmation methods and status display after cleaning work

(3) Item (ii) "Matters related to hygiene control of employees" means the following matters.

1) Establishment of work clothing standards for employees
2) Establishment of methods for entering and leaving workrooms
3) Understanding of health conditions of persons in charge of work
4) How to wash hands
5) Matters to be observed regarding work clothing

(4) Item (iii) "Other matters necessary for manufacturing hygiene control" means the following matters.

1) Matters related to prohibition of eating, drinking and smoking in workrooms
2) Matters related to prohibition of bringing items not necessary for work into workrooms
3) Matters related to opening and closing of entrances and windows of workrooms
4) Matters related to insect and rodent prevention
5) Matters related to management of water for food manufacture

Article 7 (Duties of the Manufacturing Control Manager)

The manufacturing control manager shall properly perform the operations related to manufacturing control of health supplements listed in each of the following items in accordance with the "Product Standards," "Manufacturing Control Standards," "Manufacturing Hygiene Control Standards," "Validity Confirmation Procedures," and "Procedures for Response to Abnormalities."

(i) Prepare a "manufacturing order" that describes instructions, precautions, and other necessary matters in manufacturing processes.

(ii) Perform the following operations by himself/herself, or have a person designated in advance according to the contents of the operations perform them.

(a) Manufacture health supplements in accordance with the "manufacturing order."
(b) Prepare records concerning manufacturing for each lot.
(c) Conduct proper storage and receipts and disbursements of ingredients, and products, etc. for each lot, and of packaging materials for each control unit, and prepare records of them.
(d) Confirm that manufacturing equipment is clean, and prepare a record of it.
(e) Conduct hygiene control of persons in charge of work, and prepare a record of it.
(f) Periodically inspect and maintain manufacturing of equipment, and prepare a record of it.
(g) When changes are made to ingredients, packaging materials, manufacturing methods, manufacturing equipment, etc., or when there is a risk of affecting quality, confirm the validity in accordance with the "Validity Confirmation Procedures," and then revise the "Product Standards."
(h) Other operations necessary for manufacturing control and manufacturing hygiene

control.

(iii) Confirm that manufacturing control and manufacturing hygiene control are properly implemented according to the preceding items, and report the results in writing to the general manager.

[Explanation of Article 7]

(1) In order to perform the duties in this Article, the manufacturing control manager must appoint a manufacturing line manager, etc. and instruct them to properly control the manufacturing line.

(2) "Instructions, precautions, and other necessary matters in manufacturing processes" in item (i) means the following matters.

1) Person giving the direction, and date of the direction
2) Names and lot numbers of products
3) Names and preparation or usage amounts of ingredients and packaging materials
4) Standard yields of products, etc. in each manufacturing process
5) Manufacturing equipment to be used
6) Work-related instructions or precautions in each manufacturing process
7) Matters related to labeling (expiration date, etc.)

(3) In principle, "manufacturing direction" must be issued for each lot.

(4) "Records concerning manufacturing" (hereinafter referred to as "manufacturing records") in item (ii) (b) must include the following matters.

1) Names and lot numbers of products
2) Date of work, working hours, and names of persons in charge of work
3) Names, lot numbers and preparation amounts of ingredients
4) Names, control numbers, and usage quantities of packaging materials
5) Yields in each manufacturing process
6) Results of process inspections conducted by the manufacturing department during the manufacturing process, and the measures taken when the results were non-conforming or when there were deviations from the manufacturing conditions, etc.
7) Confirmation that each manufacturing process was conducted in accordance with the "manufacturing direction"
8) Confirmation that labeling on products, etc. is appropriate
9) Measures taken during manufacturing operations other than the above
10) Confirmation by the manufacturing control manager that manufacturing control and manufacturing hygiene control are performed properly

(5) The "manufacturing direction" and the "manufacturing records" may be on the same paper as long as the necessary matters are included.

(6) “Proper storage” in item (ii) (c) means as follows.

1) Ingredients, packaging materials, and products, etc. must be stored in accordance with their respective storage conditions so as not to affect the quality.

2) Ingredients, packaging materials, and products, etc. must be stored by item and by lot (or control unit).

3) Ingredients, packaging materials, and products, etc. must be stored using labeling, etc. so that those before and after the testing and inspection can be clearly distinguished.

4) Those determined to be non-conforming as a result of the testing and inspection must be stored clearly separated from others.

(7) “Confirm that manufacturing equipment is clean” in item (ii) (d) means confirming the matters specified in Article 6, item (i).

(8) “Hygiene control of persons in charge of work” in item (ii) (e) refers to the matters specified in Article 6, item (ii).

(9) “Periodically inspect and maintain” in item (ii) (f) means periodic inspection and repair other than the daily cleaning and inspection set forth in item (ii) (d). For instruments, adjustments after calibration must also be included in the periodic inspection and maintenance.

Chapter 3 Quality Control

Article 8 (Quality Control Standards)

The general manager shall establish “Quality Control Standards” that describe the matters listed in each of the following items concerning the quality control of health supplements.

(i) Matters related to methods for specimen collection

(ii) Matters related to quality control of ingredients, packaging materials, and purchased bulk pharmaceutical preparations

(iii) Matters related to implementation of testing and inspection and judgment of results

(iv) Matters related to reporting and communication of judgment results to the general manager and the manufacturing control manager

(v) Matters related to collection and management of stored samples of products, etc.

(vi) Matters related to handling of long-term stock items

(vii) Matters related to inspection and maintenance of equipment and apparatus for testing and inspection

(viii) Matters related to implementation of testing and inspection

(ix) Other matters necessary for quality control

[Explanation of Article 8]

(1) “Quality Control Standards” prescribe the methods for specimen collection, implementation of testing and inspection, and methods for evaluating and communicating test results in order to conduct appropriate quality control.

(2) “Methods for specimen collection” in item (i) must describe matters related to specific collection methods for collecting specimens that are representative of lots or control units for ingredients, packaging materials, and products, etc. so that accurate test judgments can be made. For example, the timing of specimen collection, the amount of specimen collected, precautions necessary to prevent quality degradation and contamination when collecting specimens, methods for collecting specimens that are representative of lots or control units so that accurate test judgments can be made, etc. must be described.

(3) Matters related to judgment of results of testing and inspection in item (iii) include measures to be taken in the event of abnormality in testing and inspection, such as retest and reinspection.

(4) “Reporting of judgment results” in item (iv) must be made in writing.

(5) “Stored samples of products, etc.” in item (v) means samples of products, etc. to be stored for the purpose of following up the quality of products, etc.

(6) The provisions for reevaluation to determine whether or not to use ingredients, packaging materials and intermediate products that have been stored for a long period of time as stated in

item (vi) must be clarified.

However, this does not apply to bulk products and final consumer products, since this involves change in their best-before dates.

(7) "Matters related to implementation of testing and inspection" in item (viii) must include the following matters as necessary.

1) Matters related to quality assurance of reference standards and reagents/test solutions, etc. to be used in testing and inspection

2) Matters related to methods for conducting stability testing

3) Matters related to handling when retest and reinspection are required

(8) If testing and inspection are to be conducted at another place of business of the manufacturer concerned or at an outside testing and inspection organization, precautions for the method of sending specimens, etc. must be described.

(9) "Other matters necessary for quality control" in item (ix) must specify matters related to quality evaluation when manufacturing conditions, etc. of products are changed.

Article 9 (Duties of the Quality Control Manager)

The quality control manager shall systematically and properly perform the operations related to quality control of health supplements listed in each of the following items in accordance with the "Product Standards," "Quality Control Standards," "Validity Confirmation Procedures," and "Procedures for Response to Abnormalities."

(i) Perform the following operations by himself/herself, or have a person designated in advance according to the contents of the operations perform them.

(a) Collect specimens necessary to conduct testing and inspection for each lot or control unit of ingredients, packaging materials, and products, etc., and prepare records of them.

(b) Test and inspect the collected specimens for each lot or control unit, and prepare records of them. When testing and inspection results provided by suppliers of ingredients and packaging materials are used, one's own manufacturing site may omit its testing and inspection. However, for ingredients that act as or contain active ingredients, at least one confirmation test to identify them must be conducted.

(c) For products, etc., store the amount necessary for a prescribed test for each lot under appropriate storage conditions for the required period as stored samples of products, etc., and prepare records of them.

(d) Periodically inspect and maintain equipment and apparatus for testing and inspection, and prepare a record of it.

(e) Specify expiration dates for use of reagents, reference standards, etc. used in testing, and properly manage them.

(f) If one's company's test method is not officially approved, establish a reliable analytical method.

(g) Evaluate the impact on quality when changes are made to manufacturing conditions, etc. of products.

(h) For products, etc. in tablet, capsule or other forms, a separately specified disintegration test must be conducted for each lot.

(i) Other operations necessary for quality control.

(ii) Judge the results of testing and inspection, and report the results in writing to the general manager and the manufacturing control manager.

[Explanation of Article 9]

(1) "Perform the following operations by himself/herself, or have a person designated in advance according to the contents of the operations perform them" in item (i) means, in principle, a person in charge of the quality control department. However, "a person designated in advance"

in sampling may be a person form another department who has received preliminary education and been designated by the quality control manager.

(2) "Records of specimen collection" in item (i) (a) may be written on the same paper together with the records of testing and inspection in item (i) (b).

(3) "Records of testing and inspection" in item (i) (b) must include the following matters.

1) Specimen name, and lot number or control number

2) Testing and inspection items, date of testing and inspection, person who conducted the testing and inspection, and testing and inspection results

3) Judgment of testing and inspection results, date of judgment, and name of the judge
However, the judge must be the quality control manager.

(4) "When testing and inspection results provided by suppliers of ingredients and packaging materials are used, one's own manufacturing site may omit its own testing and inspection" in item (i) (b) means that the quality control manager may omit testing and inspection at his/her own manufacturing site on his/her own responsibility in the following cases.

1) When using ingredients delivered in accordance with the standards for health supplements or food additives specified by the Japan Health and Nutrition Food Association or the ingredient standards provided in the official compendiums of the Japanese Pharmacopeia, etc.

2) When test results of suppliers of ingredients, packaging materials and purchased bulk preparations are reliable based on past results.

(5) "Confirmation test to identify" in item (i) (b) means a qualitative test to confirm identity, which means confirmation by chemical and physical means.

(6) "Appropriate storage conditions" in item (i) (c) usually means room temperature without artificial control.

(7) "Periodically inspect and maintain equipment and apparatus for testing and inspection" in item (i) (d) means periodic inspection and maintenance of the matters set forth in Article 8, item (vii), and for instruments, adjustment after calibration must also be included.

(8) "Reagents, reference standards, etc." in item (i) (e) are important samples for evaluating testing and inspection results, and the periods specified by their manufacturers are the periods until the packages are opened, so it is necessary to set the expiration dates for use after the packages are opened in accordance with the company's actual usage records.

(9) In principle, all items of testing and inspection of products, etc. must be conducted for each lot, but for items which have reasonable grounds, their testing and inspection may be conducted at a specified frequency.

(10) Testing and inspection may be conducted at another place of business of the manufacturer concerned or at an outside testing and inspection organization. In this case, the testing method

must be specified.

(11) The details of cases where testing and inspection are omitted and where other testing organizations are used must be described in the Product Standards.

(12) “Reliable analytical method” in item (i) (f) is, for example, an analytical method that has been studied and established by referring to methods for confirmation of validity of analytical procedures, etc.

(13) Evaluation items in item (i) (g) include the following.

1) At least the first three lots manufactured or tested after the implementation of change.

2) Possible effects on the expiration date of a change in important manufacturing conditions. If necessary, relative comparison tests, etc. must be conducted on lots before and after the change.

(14) Regarding item (i) (h), health supplements are food products processed with the intention of expressing functions. Since one of the important matters for products, etc. in tablet, capsule or other forms, among the health supplements, is that they disintegrate in the body after they are ingested, disintegration tests must be conducted for each lot.

Chapter 4 Confirmation of Validity

Article 10 (Validity Confirmation Procedures)

The general manager shall establish "Validity Confirmation Procedures" that describe the procedures for confirming validity in processes of manufacturing health supplements, and have the validity confirmation manager perform the operations listed in each of the following items in accordance with the Procedures.

(i) Confirm the validity of the manufacturing processes listed below.
  (a) When manufacturing of a new product is started
  (b) When the quality of products is significantly affected by changes in manufacturing equipment, manufacturing conditions, etc.
  (c) When the constancy of the manufacturing process of existing products is evaluated
  (d) Other cases where it is deemed necessary to properly conduct manufacturing control and quality control of products

(ii) Prepare and confirm a "validity confirmation implementation plan" that describes instructions, precautions, and other necessary matters in manufacturing processes, and report them in writing to the general manager.

(iii) Prepare "validity confirmation procedures," judge the results, and report them in writing to the general manager.

[Explanation of Article 10]

(1) Confirmation of validity in health supplements means to verify in accordance with the validity confirmation procedures that the structure and equipment, manufacturing procedures, processes, and other manufacturing and quality control methods at a manufacturing site are appropriate and that products of a certain quality can be always obtained, and to put this in writing. It is a work to verify validity based on the concept of confirmation of validity.

(2) The validity confirmation manager prepares a validity confirmation plan and a report, and reports them to the general manager after they are confirmed by the manufacturing control manager and the quality control manager. However, the validity confirmation manager may concurrently serve as the manufacturing control manager.

(3) In the case of item (i) (a), it is preferable to conduct the confirmation of validity before and during actual production. Furthermore, in the case of (b) and (d), it is preferable to conduct the confirmation of validity during actual production again at the time of change.

However, in the case of (a) and in any of the following cases, it is allowed to conduct the confirmation of validity during actual production only.

1) When manufacturing by improving a process whose validity has already been confirmed

2) When manufacturing using a method similar to that used to manufacture similar products

3) When confirmation in daily process control, such as fermentation process, is important

In the case of (c), it is desirable to evaluate the manufacturing process based on past manufacturing data, but reconfirmation of validity during actual production may be periodically conducted if necessary.

(4) For item (i) (c), in order to evaluate the stability of the manufacturing process based on past manufacturing data, accumulated test results and manufacturing records must be evaluated for the established manufacturing process using statistical methods, etc. The evaluation is conducted using consecutive data of about 10 to 20 lots. However, a smaller number of lots is acceptable if there is a good reason.

(5) "Other cases where it is deemed necessary to properly conduct manufacturing control and quality control of products" in item (i) (d) means control of changes related to ingredients (selling manufacturer, etc.), specification (specification for ingredients and products), test methods (analytical methods, etc.), labeling and packaging materials, etc.

(6) Confirmation of validity before actual production means identifying variable factors (operating conditions, etc.) that are thought to affect the quality at the time of development or trial manufacture, and confirming whether products that conform to the intended quality over the entire range of variable factors can be manufactured, preferably at the scale of actual production.

(7) When confirming validity during actual production, variable factors (operating conditions, etc.) that are thought to affect the quality must be within allowable conditions. In other words, it must be confirmed through process control, etc. that the operating conditions set at the time of trial manufacture, etc. are appropriate. In principle, it is desirable to examine the first three lots carefully.

(8) The manufacturing control and quality control departments involved in manufacturing, testing and inspection must conduct manufacturing, testing and inspection in accordance with a "validity confirmation implementation plan," and prepare "validity confirmation report."

(9) "Instructions, precautions, and other necessary matters in manufacturing processes" in item (ii) means the following items.

1) Implementation plan No.

2) Purpose of confirmation of validity

3) Processes to be covered

4) Equipment to be covered

5) Expected results

6) Lots for implementation

7) Scheduled implementation period

8) Department in charge of implementation

9) Department in charge of testing and inspection
10) Specific verification method
11) Seals of confirmer and approver and dates
12) Other necessary matters

(10) “Validity confirmation implementation report” in item (iii) must include the following items.
1) Implementation report No.
2) Purpose of confirmation of validity
3) Implementation plan No.
4) Processes to be covered
5) Equipment to be covered
6) Lots for implementation
7) Implementation period
8) Person in charge of implementation
9) Person in charge of testing and inspection
10) Results of implementation
11) Conclusion
12) Related records
13) Seals of confirmer and approver and dates
14) Other necessary matters

Chapter 5 Response to Abnormalities in Quality, Etc.

Article 11 (Procedures for Response to Abnormalities)

The general manager shall establish “Procedures for Response to Abnormalities” that describe how to respond in the event of any of the following abnormalities.

(i) Abnormalities at the time of receipt of ingredients and packaging materials and during acceptance testing and inspection

(ii) Abnormalities in processes

(iii) Products cannot be shipped

(iv) Complaints

(v) Recall

[Explanation of Article 11]

(1) “Procedures for Response to Abnormalities” clarify measures to be taken for abnormalities in all processes from the receipt of ingredients and packaging materials to the shipment of products, etc. to minimize the impact of such abnormalities on others, and describe measures to be taken to prevent recurrence of such abnormalities. Furthermore, the Procedures are also intended to be used to respond promptly and appropriately to external complaints and recalls after the shipment of products, etc.

(2) For items (i), (ii) and (iii), it is necessary to clarify the relationship between the Procedures and the responses specified in other standards.

(3) For handling of complaints in item (iv), the following matters must be noted.

1) Information received as complaints must be treated as useful information related to manufacturing and quality control, and must be used for control at one’s company. If there is a complaint about quality, etc., “manufacturing records” and “test records” must be inspected and confirmed and testing of stored samples, etc. must be conducted as necessary to determine the cause of the complaint, such as whether it is based on the product design, caused by the manufacturing process, or due to storage, handling, etc. in the distribution process, and based on the results of such inspection and confirmation, appropriate measures must be taken.

In order to promptly handle complaints, it is necessary to develop a complaint handling system and also to establish a certain handling method.

2) Even if a manufacturing site has a complaint handling system in place, it will not function adequately unless an overall system for collecting and communicating complaints, etc. as a manufacturer is in place. Therefore, it is necessary to develop a company-wide system as well as a complaint handling system at a manufacturing site.

(4) With regard to handling of recalls in item (v), the flowing matters must be noted.

1) When a recall of the product is decided due to reasons related to the quality, etc., it is necessary to develop a recall handling system as a manufacturing site and to establish cooperation with the company's overall crisis management system in order to promptly report to administrative agencies, provide information to the Japan Health and Nutrition food Association, etc., make a public announcement to the press, investigate the exact cause, understand the status of recall, and take appropriate remedial actions, with the primary purpose of preventing health hazards to consumers.

2) In the case where there is a complaint about quality and only the product that is the subject of the complaint is taken back (however, only when it is confirmed that the complaint is a spot issue and does not affect the entire lot), it does not fall under recall handling.

3) In the case where products whose expiration date for use has expired are taken back, it does not fall under recall handling.

Article 12 (Duties of Responsible Persons in Relation to Response to Abnormalities)

1. If any abnormality (including abnormalities in testing and inspection results) is found at the time of receiving ingredients or packaging materials, the manufacturing control manager shall determine whether or not the ingredients or packaging materials in question can be used, and if they cannot be used, he/she shall take appropriate measures to prevent the ingredients or packaging materials in question from being used. If necessary, decisions shall be made after consultation with the quality control manager and the general manager.
2. The manufacturing control manager shall contact the supplier of ingredients or packaging materials to provide them with information on abnormalities, and request them to investigate the cause and prevent recurrence.
3. When any abnormality is found in the manufacturing process or when products cannot be shipped, the manufacturing control manager shall instruct the supplier to take measures for the products in question, investigate the cause of the abnormality, and strive to prevent its recurrence. Furthermore, measures to be taken for the ingredients or packaging materials in question shall be decided after consultation with the quality control manager and the general manager as necessary.
4. The quality control manager shall take the following measures in response to complaints from customers, trustees, etc.
   (i) Instruct the department that caused a complaint to investigate the cause of the complaint
   (ii) Responses to complainants
5. The general manager shall take prompt and appropriate actions in the event of recall.
   (i) Report information on whether or not recall is necessary to the Business Operator, and if

necessary, to administrative organs and the Japan Health and Nutrition Food Association, and make a final decision.

(ii) Give appropriate instructions to the department that deals with the recall.

(iii) Report the progress and results of the recall to the Business Operator in a timely manner, and if necessary, to administrative organs and the Japan Health and Nutrition Food Association.

(iv) Report the recall plan, and the progress and results of the recall to the Japan Health and Nutrition Food Association.

[Explanation of Article 12]

(1) The person responsible for the department where an abnormality occurred must take responsibility for promptly and appropriately managing the abnormal product, determining the cause, and taking countermeasures.

(2) The person responsible for the department where an abnormality occurred must contact and consult with the relevant departments to prevent the abnormality from affecting other lots and products.

(3) For external complaints in Paragraph 4, the point of contact at one's company and the point of contact at the manufacturing site must be clarified. It is preferable that the quality control manager should be the point of contact at the manufacturing site.

(4) Since the recall in Paragraph 5 has a significant impact on the outside of the company, the general manager must take appropriate measures in accordance with instructions of the Business Operator and in cooperation with the relevant departments.

Chapter 6 Education and Training

Article 13 (Education and Training Procedures)

The general manager shall establish "Education and Training Procedures" that describe procedures for providing education and training for employees, and shall have the education and training manager perform the operations listed in each of the following items in accordance with the procedures.

(i) Plan and implement education and training for employees on manufacturing control, quality control and related matters.

(ii) Report in writing to the general manager on the plan and implementation status of education and training.

[Explanation of Article 13]

(1) Education and training on manufacturing control and quality control include the following items according to the type of work.

1) Outline of the Japan Health and Nutrition food Association's "GMP Guidelines for Health Supplements"

2) Food-related laws and regulations, etc.

3) Standards, etc. at the manufacturing site concerned

4) Matters related to the work to be actually performed (including on-the-job training)

5) Outside education (including education on general matters related to health supplements, and general matters related to manufacturing control, quality control and manufacturing hygiene control)

(2) "Plan and implement" in item (i) means to periodically implement education and training at least once a year after evaluating the effectiveness of the education and training. Furthermore, extraordinary education and OJT must also be provided according to circumstances.

(3) "Report" in item (ii) includes the following items.

1) Date of implementation

2) Details of education and training

3) Names of persons who received education and training

4) Names of persons who provided education and training

Chapter 7 Commissioning Manufacture

Article 14 (Contract Manufacturing)

The general manager who has a manufacturing site of another manufacturer (hereinafter referred to as "Contract acceptor") perform part of the manufacturing process of health supplements shall establish "Control Procedures for Contract Manufacturing" that describe the arrangements on the matters listed below in order to ensure appropriate implementation of manufacturing control, quality control, etc. at the Contract acceptor, and shall perform the operations in accordance with the procedures. Contract Manufacturing to another manufacturing site of one's company shall be treated the same.

(i) Scope of commissioning manufacture

(ii) Matters related to manufacturing control and manufacturing hygiene control pertaining to contract Manufacturing

(iii) Matters related to quality control pertaining to contract Manufacturing

(iv) Methods of quality control during transportation and delivery

(v) Timely or urgent confirmation that contract Manufacturing is properly conducted at the manufacturing site of the Contract acceptor

(vi) Other matters related to contract Manufacturing

[Explanation of Article 14]

(1) Contract manufacturing) under GMP means "having a manufacturing site of another manufacturer (hereinafter referred to as "Contract acceptor") carry out part of health supplement manufacturing processes. For example, if all of the preparation processes are carried out by another company and packaging of bulk preparations is carried out by one's company, the preparation processes are not considered contract manufacturing under GMP when bulk preparations are packaged by one's company, but the purchase or transfer of bulk preparations.

(2) It is not permitted for a Contract acceptor to further contract manufacturing to another manufacturer.

(3) Contract Manufacturing to another manufacturing site of one's company must be treated the same as contract to another manufacturer.

(4) Arrangements must be made in the form of a "contract agreement" or an equivalent document.

(5) "Scope of contract manufacture" in item (i) means the content of manufacturing processes to be contracted and the scope of responsibilities to be shared for the contracted processes.

(6) "Manufacturing control" and "quality control" in items (ii) and (iii) means the following matters.

1) Matters related to "Product Standards"

2) Matters related to "Manufacturing Control Standards" and "Manufacturing Hygiene

Control Standards”

3) Matters related to “Quality Control Standards”

(7) Item (v) means confirming on a timely basis that manufacturing by the Contract acceptor is conducted by appropriate manufacturing control and quality control. Furthermore, urgent confirmation must be conducted in the event of the occurrence of abnormalities, etc.

(8) It is desirable to specify the following matters in “Matters related” in item (vi).

1) Matters related to contact points of both parties

2) Matters related to procedures for making changes to manufacturing methods, conditions, etc.

3) Matters related to preparation and retention of records necessary for manufacturing control and quality control

4) Matters related to reporting when an abnormality occurs in the contracted process

5) Matters related to the handling of complaints

Chapter 8 Self-inspection

Article 15 (Self-inspection)

The general manager shall establish “Self-inspection Procedures” that describe procedures for self-inspection of manufacturing control and quality control of health supplements, and other GMP operations, and shall have the self-inspection manager perform the operations listed in each of the following items in accordance with the procedures.

(i) Conduct self-inspection of GMP operations, such as manufacturing control and quality control of health supplements at a manufacturing site, in a planned manner or on a temporary basis as necessary.

(ii) Promote correction based on the results of self-inspection.

(iii) Confirm the effect of correction after self-inspection.

(iv) Report in writing to the general manager on the plan and results of self-inspection and the correction after the self-inspection.

[Explanation of Article 15]

(1) “Conduct self-inspection in a planned manner” in item (i) means to inspect the following items for consistency with actual conditions in a planned manner in order to evaluate whether “manufacturing control and quality control of health supplements” are appropriately conducted.

1) “Control Rules for GMP for Health Supplements,” standards, procedures and related documents for the operations of these standards
2) Product Standards
3) Duties of the general manager
4) Operations related to manufacturing control (including manufacturing hygiene control)
5) Operations related to quality control
6) Operations related to confirmation of validity
7) Operations related to response to abnormalities
8) Operations related to education and training
9) Operations related to contract manufacturing
10) Operations related to self-inspection

(2) “Self-inspection on a temporary basis” in item (i) means temporary self-inspection conducted as necessary in the event of abnormality, occurrence of complaints, recall, etc.

Chapter 9 Document Management

Article 16 (Document Management)

The general manager shall prescribe the matters listed in each of the following items concerning the management of documents related to GMP.

(i) Matters related to establishment and revision of documents

(ii) Matters related to preparation and retention of records

(iii) Matters related to approval or deliberation (confirmation)

(iv) Other matters related to document management

[Explanation of Article 16]

(1) Since documents related to GMP are indispensable for implementing GMP, provisions on their establishment must be clearly stipulated.

(2) Documents should be revised as appropriate according to improvements in management conditions, changes in social conditions, advances in science and technology, etc., and provisions on revision must also be stipulated.

(3) Records must be kept on the distribution of documents, collection of old versions at the time of revision, etc. to ensure that they are of the latest versions.

(4) Records of GMP implementation must be prepared, and records must be kept, in principle, for three years or a period until the expiration date plus one year, whichever is longer.

(5) Set a retention period for old versions, and in principle, retain them for five years.

(6) The management and registration of signatures, seals, etc. to be used for approval, deliberation (confirmation), etc. of documents and records must be described.

(7) Documents include “Structure and Equipment Standards” of Structure and Equipment Standards for GMP for Health Supplement.

(2) Structure and Equipment Standards for GMP for Health Supplements (Explanation)

Chapter 1 General Provisions

Article 1 (Purpose)

The purpose of the Structure and Equipment Standards for GMP for Health Supplements is to provide for standards for structure and equipment of manufacturing sites for health supplements, and thereby to ensure the quality of health supplements.

[Explanation of Article 1]

(1) These "Structure and Equipment Standards for GMP for Health Supplements" provide guidelines for structure and equipment, which is the other one of the bases stated in [Explanation of Article 1] of "Control Standards for GMP for Health Supplements," and require flexible measures such as reviewing the standards in accordance with changes in internal circumstances and social conditions, and technological improvements.

Chapter 2 Structure and Equipment Standards for Manufacturing Sites

Article 2 (Structure and Equipment Standards for Manufacturing Sites)

The structure and equipment standards for manufacturing sites of health supplements shall be as follows.

(i) The manufacturing sites shall have the structure and equipment necessary for manufacturing products, etc.

(ii) The equipment set forth in the preceding item shall be arranged so as not to hinder smooth and appropriate work, and shall be able to be cleaned or washed and be easy to maintain.

(iii) Workplaces shall conform to the following.

(a) Workrooms shall be separated from places not directly related to the work and from unclean places.

(b) Workplaces shall have an area that is sufficient for work and storage.

(c) Workplaces shall have a structure and equipment to prevent cross contamination.

(d) Workplaces shall have a structure and equipment to prevent dust, insects and rodents.

(e) Daylighting, illumination and ventilation are provided appropriately and cleanly.

(f) Floors shall be made of water-resistant materials, drain well, and be easy to clean.

(g) Interior walls shall be made of water-resistant materials, and have a structure that is easy to clean.

(h) Ceilings, etc. shall be easy to clean, and have a structure that prevents rubbish from falling.

(i) Equipment for cleaning outer packaging of ingredients and packaging materials shall be provided.

(j) Equipment for washing or cleaning equipment, containers, etc. used for manufacturing shall be provided.

(k) Equipment for employees to wash their hands and disinfect their fingers shall be provided.

(l) Changing rooms or changing boxes whose number is appropriate to the number of employees shall be provided according to the number of employees.

(m) Lavatories shall be provided in the amount appropriate to the number of employees and separated from workrooms.

(n) For water used for manufacturing including washing of manufacturing equipment, equipment that can supply "water for food production" as specified in the standards for foods, additives, etc. shall be provided.

(o) Equipment that comes into direct contact with ingredients, and products, etc. shall be made of materials that are water- and chemical-resistant and that do not degrade the quality of ingredients, and products, etc. with which the equipment comes into contact. Furthermore, the equipment shall be easily washed and can be disinfected as necessary.

(p) Among workplaces, workrooms where weighing work for ingredients, and preparation, filling and closing work for products, etc. are conducted shall conform to the following provisions.

1) Workbenches provided in the workroom shall be designed not to hinder smooth and appropriate work.

2) The workroom shall be constructed so as not to provide a passageway for anyone other than the persons in charge of the work conducted in the workroom.

3) It is desirable that there are no entrances and exits (excluding emergency exits) that directly face the outdoors. Furthermore, if necessary, the workroom shall have a structure and equipment necessary to prevent contamination from the outdoors.

4) Entrances, exits and windows shall be able to be closed.

5) Drainage equipment and equipment required for waste disposal shall have the structure necessary to prevent contamination of the workroom.

6) Equipment in the workroom, such as pipes and ducts, shall have a structure

that prevents dust from accumulating on their surfaces. However, this shall not apply when they are easy to clean or wash.

(iv) Storage equipment for ingredients, and products, etc. shall conform to the following provisions.

(a) The area shall be sufficient for the volume handled.

(b) Storage equipment shall be equipped with equipment to maintain the quality of ingredients, and products, etc. handled.

(c) Floors and interior walls shall be made of impermeable materials and have an easy-to-clean structure. Furthermore, drainboards and other equipment shall be provided on the floor surface to prevent contamination.

(d) Entrances, exits and other places that are opened/closed shall be equipped with equipment to prevent the entry of vermin such as rodents and insects.

(v) Equipment and apparatus necessary for testing and inspection of ingredients, packaging materials, and products, etc. shall be provided. However, this shall not apply when testing and inspection are entrusted to other testing and inspection organizations.

[Explanation of Article 2]

(1) "Shall be arranged so as not to hinder smooth and appropriate work, and shall be able to be cleaned or washed and be easy to maintain" in item (ii) means the following.

1) For the arrangement of each workroom, consideration must be given to prevention of contamination from outside and contamination of other products during work.

2) For the arrangement of equipment and apparatus in workrooms, consideration must be given to prevention of confusion and mistakes during work and easiness of cleaning, washing and maintenance.

3) Workrooms must have a structure that is difficult for foreign materials and dust to accumulate and easy to clean.

(2) "Places not directly related to the work and unclean places" in item (iii) (a) means places that may cause contamination by dust or organisms and microorganisms, such as office rooms, break rooms, power machinery rooms, power distribution rooms, supply sheds, cooking places, bathrooms, lavatories, garbage dumps, and drain sewers.

(3) "An area that is sufficient for work and storage" in item (iii) (b) includes space for easy maintenance, inspection and cleaning.

(4) When there is a risk of cross contamination as mentioned in item (iii) (c), it is desirable to have one machine per room. However, if this is not possible, appropriate cross contamination measures or control must be taken.

(5) Regarding "daylighting, illumination" in item (iii) (e), lighting must be bright enough for work

by using windows through which natural light comes in in the case of daylighting, and by using artificial lighting in the case of illumination.

(6) "Floors" in item (iii) (f) must have smooth surface made of concrete, tile, mortar, etc. with no gaps and have a structure that is easy to clean.

(7) "Equipment for employees to wash their hands and disinfect their fingers" in item (iii) (k) means hand-washing equipment with running water provided with invert soap, disinfectant solution, etc.

(8) "Constructed so as not to provide a passageway for anyone other than the persons in charge of the work" in item (iii) (p) (2) means that the workroom is arranged so as not to be used as a passageway to go to other workplaces or workrooms.

(9) "Shall be able to be closed" in item (iii) (p) (4) means door locks, etc. as a measure to prevent people, insects, birds, dust, etc. from entering from outside.

(10) "Other testing and inspection organizations" in item (vi) means other manufacturing sites of one's company and external testing and inspection organizations.

Association Profile

Association Profile

Name	Japan Health and Nutrition Food Association
Address	2-7-27 Ichigaya-sadohara-cho, Shinjuku-ku, Tokyo 162-0842, Japan TEL: +81-3-3268-3134 FAX: +81-3-3268-3136 E-mail: jhnfa@jhnfa.org Website: https://www.jhnfa.org
Director General	YAJIMA Tetsuya, M.D., Ph.D.
Date of foundation	April 1, 1985: Founded as Incorporated Foundation, Japan Health Food Association (approved by the then Minister of Health and Welfare) July 1, 2011: Certified as Public Interest Incorporated Foundation, Japan Health and Nutrition Food Association
Executives	22 trustees, 20 board directors, 2 auditors
Basic assets	259 million yen
Number of members	627 companies (As of Aug.31, 2025)
History	October 1, 1979: Established as Incorporated Foundation, Japan Health Food Research Association April 1, 1985: Founded as Incorporated Foundation, Japan Health Food Association (approved by the then Minister of Health and Welfare) July 16, 1992: Merged with Japan Dietetic and Enriched Foods Association, and renamed to Japan Health and Nutrition Food Association July 1, 2011: Certified as Public Interest Incorporated Foundation, Japan Health and Nutrition Food Association
Objectives	Our association promotes public health by establishing standards for health foods and operating certification programs, such as the JHFA mark, GMP for health foods, and In-house Safety Assessment for health foods. We collect relevant information, conduct research, and disseminate accurate knowledge on Foods with Health Claims and Foods for Special Dietary Uses. As for the nutrition labeling in accordance with the Food Labeling Standards, we encourage proper nutrition labeling practices in accordance with the intent of the Food Labeling Act, thereby supporting the sound development of our members and related industries.
Outline of business	1. Establishment of standards for health foods and implementation and promotion of the JHFA certification programs 2. Implementation and promotion of the GMP certification programs for health foods 3. Implementation and promotion of the In-house Safety Assessment certification program for health foods 4. Support for application and dissemination of Foods for Specified Health Uses and Foods for Special Dietary Uses 5. Support for notification and dissemination of Foods with Function Claims 6. Consultation on Foods with Nutrient Function Claims and nutrition labeling in accordance with the Food Labeling Standards 7. Research and dissemination of appropriate knowledge about health foods 8. Training and certification of Food Quality Adivisers 9. Publication of academic journal 10. Collection and analysis of domestic and international information on health foods and general food products and provision of relevant information and insights to our member companies

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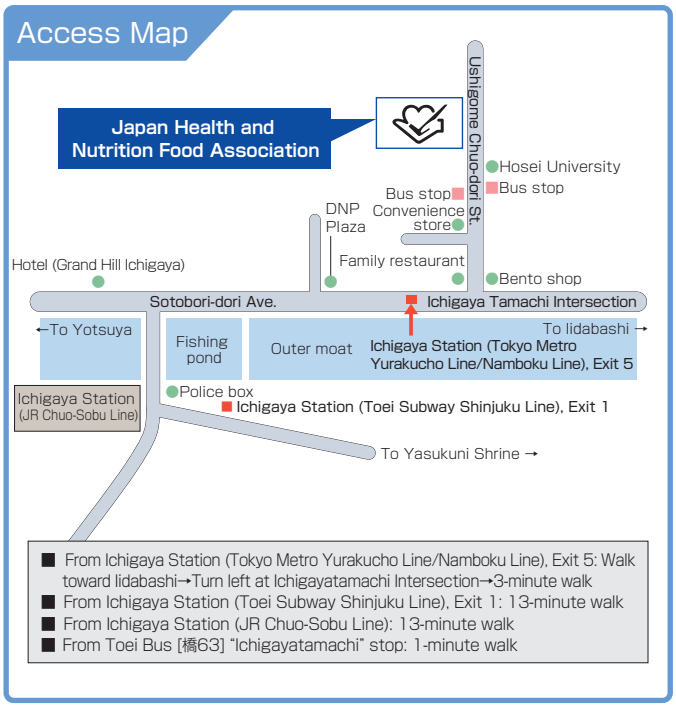
Access Map



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