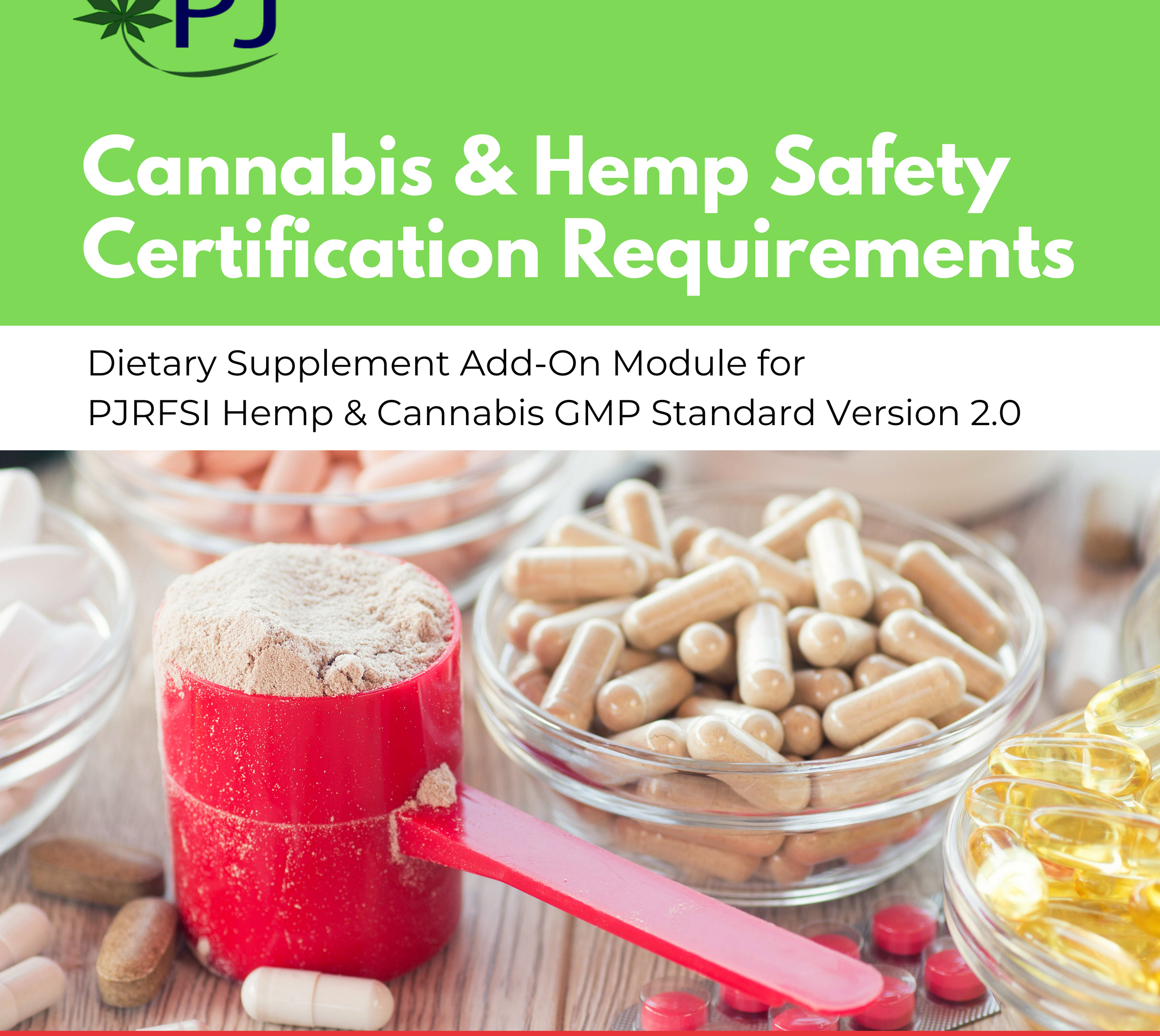
Cannabis & Hemp Safety Certification Requirements

Dietary Supplement Add-On Module for
PJRFSI Hemp & Cannabis GMP Standard Version 2.0



Dietary Supplement Add-On Module. Issued 1/25/2022. Revised n/a. Rev 1.0

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Introduction

Perry Johnson Registrars Food Safety, Inc. (PJRFSI) is committed to providing value-added food safety certification to clients. Our entire team believes that rigor and consistency during audit activities leads to higher levels of customer and end-user satisfaction. PJRFSI is dedicated to uphold the highest standards of professionalism, technical competence and integrity throughout the life cycle of the audit process. We apply the principles of quality management, collaboration and organizational excellence in all of our office and field activities and comply with the requirements set forth by the international standards organizations, accreditation bodies and other affected parties. Through this dedication, we have created and maintain a work environment which provides opportunities and a culture of continual improvement, learning and development for clients, auditors, staff and stakeholders within the food chain.

PJRFSI Dietary Supplement Add-On Module is based on FDA CFR 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. This add-on module covers the manufacture of cannabis products that conform to the dietary supplement requirements. It is an add on module only and must be audited in accordance with Cannabis/Hemp Safety Standard for Manufacturing which includes the requirements set forth in the Management System and GMP Requirements & Other Pre-Requisite Program sections.

Dietary Supplement Add-On Module Requirements

1.0 Audit Requirements

1.1 Context of the Organization

1.1.1 Individuals responsible for quality control (QC) have been identified. Responsibilities relating to quality are distinct and separate from operations.

1.2 Leadership

1.2.1 Management conducts a review of the quality system to assess its suitability and efficacy at least every two years.

1.**2.2** Individuals responsible for supervising sanitization activities have been have been assigned by the organization. These individuals are qualified to oversee the activities in question based on experience and/or training.

1.**2.3** Competent supervisory personnel responsible for overseeing transportation operations have been identified within the organization and have received appropriate training.

1.3 Planning

1.3.1 A hazard analysis has been conducted for each type of dietary supplement in order to identify and evaluate known or foreseeable hazards and to determine if specifications or process controls are required to address them.

1.**3.2** Production processes are designed to ensure the quality of the product and these control systems have been approved by Quality Control management.

1.**3.3** A crisis management plan has been developed to manage significant disruptive events (such as prolonged power outages or natural disasters) that may impact the manufacturer's ability to deliver safe product.

1.4 Support

1.**4.1** A master site plan or facility diagram/floorplan has been created for the site. The plan/diagram accurately reflects the current layout of the building.

1.**4.2** In areas of the facility where product containers are open and exposed to the environment, there are adequate measures taken to protect product against contamination. These may include protective coverings, skimming equipment, or proper storage/location practices.

1.**4.3** There are appropriate controls in place to ensure the function of electronic, automated, or mechanical equipment used in manufacturing according to its intended use (e.g. back-up power for critical systems). These controls have been approved by Quality Control personnel.

1.**4.4** Changing rooms and areas to store personal belongings are provided to staff. These areas are sufficiently removed from operations or are otherwise controlled to avoid a risk of contamination to product or product contact surfaces.

1.4.5 Pest control procedures have been established and include the appropriate use of pesticides, fungicides, fumigants, or rodenticides to be used.
1.4.6 Lighting suspended or located above exposed materials or equipment use safety-type bulbs, or facility is otherwise constructed to adequately prevent contamination from glass.
1.4.7 Controls are in place to verify the backgrounds of new, contracted, seasonal, and temporary employees before they are hired.
1.4.8 Job descriptions are available for all personnel, and these individuals have received food safety, GMP, and other trainings appropriate for their functions.
1.4.9 All records relating to the receiving, testing, manufacturing, or shipping of product are maintained for at least one year after that production batch's shelf life, or at least two years beyond the date of distribution of the last batch associated with those records.
1.4.10 Backup electronic files are maintained for current software programs, outdated software programs needed to retrieve past records, and data. These records are complete and secure against alteration.

1.5 Operation

1.5.1 All utensil surfaces are comprised of corrosion-resistant, nontoxic materials that are easily cleaned. Surfaces are inspected at regular intervals for signs of wear or damage.
1.5.2 Logbooks are maintained for each piece of equipment. Logs contain the date of use and documentation of any cleaning/sanitation or maintenance activities. Documenting this information in batch records is acceptable.
1.5.3 Documentation is maintained of the controls used to ensure equipment is functioning properly and in accordance with its intended use.
1.5.4 Procedures are on file for cleaning the manufacturing plant.
1.5.5 Surfaces that do not come into direct contact with components or dietary supplements are cleaned at a defined and effective frequency to prevent contamination.
1.5.6 Procedures for maintenance, cleaning, and sanitizing all equipment, utensils, and contact surfaces are established, with records of sanitation activities maintained.
1.5.7 Cleaning procedures are established for cleaning and sanitizing all filling and packaging equipment and utensils.
1.5.8 Cleaning compounds and sanitizing agents used at the facility are both adequate and safe for their intended use.
1.5.9 Equipment, utensils, and contact surfaces used for holding low-moisture components or dietary supplements are ensured to be dry and in sanitary condition before use.
1.5.10 Contact surfaces are cleaned and sanitized before use and after any interruptions during which the surface may have become contaminated.
1.5.11 A foreign supplier verification program (FSVP) has been effectively implemented for all direct importers of components, bulk dosage forms, or dietary supplements from foreign suppliers.
1.5.12 There is a planned deviation process established to expedite approval of raw materials, packaging materials, and other component suppliers on an emergency basis.
1.5.13 Records are maintained to show that water used as a component in a dietary supplement or any contact surface used in its manufacture complies with applicable Federal, State, and local requirements.
1.5.14 A written procedure is in place for retesting materials to extend shelf life.

1.5.15 Both weighing operations and sample collection are conducted in a controlled area that does not present an opportunity for contamination.
1.5.16 Master manufacturing records are prepared for each unique formulation and batch size of dietary supplement.
1.5.17 The batch production record accurately follows the master manufacturing record with all steps being performed along with relevant production information. These records must be maintained according to good record retention practices.
1.5.18 Master manufacturing records, batch logs, or other records identify the process lines and major equipment used during manufacturing to indicate their contents; this includes the name of the dietary supplement, the specific batch or lot number, packaging material used, and the phase of manufacturing.
1.5.19 Packaging and labels are controlled for issuance and reconciled after use. (This excludes cut or rolled labels that are examined 100% by electronics or equipment.)
1.5.20 Processes are established to identify unlabeled materials that will be held for future labeling operations.
1.5.21 Procedures have been established for packaging and labeling, and for assigning a lot or batch number to each lot of packaged and labeled dietary supplements. These materials are confirmed to match the master manufacturing record before use.
1.5.22 Procedures have been established for disposing of obsolete or incorrect labels and packaging materials.
1.5.23 When a process deviation occurs that could result in the adulteration of a dietary supplement or a mislabel, the items are placed under a QC hold, and are only reworked, reprocessed, or treated to correct the deviation under the approval and supervision of QC personnel.
1.5.24 Reprocessed materials are required to meet their original specifications.
1.5.25 The final disposition decision is determined by QC personnel. Records of material reviews and disposition decisions are on file and scientifically valid.
1.5.26 Dietary supplements, their components, in-process materials, labels, and packaging are held under appropriate conditions of temperature, humidity, and light so as not to lead to deterioration, contamination, or mix-up.
1.5.27 Written procedures are in place for transportation operations. Steps are being taken to prevent dietary supplements from becoming unsafe during transport.
1.5.28 Product distribution records are adequately maintained and are retained according to good record retention practices.
1.5.29 Procedures have been implemented for the handling of returned dietary supplements. They include appropriate quarantine procedures until a QC disposition for destruction or salvage and reprocessing has been determined.
1.5.30 If the reason for a return implicates other batches, an investigation should be performed to determine if those batches comply with specifications.
1.5.31 Records are maintained for material reviews and product dispositions of returned products. These should include all testing results and reevaluations by the QC unit for reprocessed materials.

1.5.32 Representative samples of each batch of repackaged or relabeled dietary supplements are examined to determine if they conform to specifications.
1.5.33 The aforementioned records are maintained for at least one year past the shelf life date, or two years beyond the date of distribution of the last batch in the records.

1.6 Performance Evaluation

1.6.1 Reserve samples are maintained by the site and held under appropriate conditions that will not lead to a mix-up, contamination, or deterioration.
1.6.2 Dietary supplement ingredients are sampled, tested, and released prior to use in production. Unless exempted by the FDA, these methods include at least one test or examination to verify the identity of the dietary ingredient.
1.6.3 Scientifically-valid testing methods are used in these assessments, such as organoleptic, macroscopic, microscopic, and/or chemical analysis.
1.6.4 Parameters have been set for laboratory controls such as testing methods, sampling plans, and criteria for examination and reference materials.
1.6.5 Product complaints are reviewed by qualified personnel in order to determine if the complaint resulted from a failure of the dietary supplement to meet any of its specifications or quality.
1.6.6 The decisions to investigate complaints as well as the final decision as a result of the investigation (including corrective actions) are approved by QC personnel.
1.6.7 Records of product complaints and investigations are on file and maintained according to good record retention practices.

1.7 Improvement

1.7.1 Procedures are established for a corrective and preventative action (CAPA) program for the handling of all non-conformances identified within the scope of the standard.