

Quality is not an act, it is a habit"

-Aristotle

Perry Johnson Companies

Headquarters – Troy, MI

Family of 72 companies

Global Offices in Europe, Asia, and the Americas

Offering services in Food Safety, Cannabis/Hemp, and all other ISO manufacturing types.



Importance of Food Safety in the Hemp and Cannabis Industry

Why does it matter?

\$14



5 Classic Points of GMP

- ▷ Premises
- ▷ People
- ▷ Products
- ▷ Procedures/Processes



Premises

Security- Consistency, checks, video Outside-Perimeter, pests, trash, Inside- Entries, employee flow, visitors EMP- Environmental Monitoring Plan Testing for Ecoli, salmonella, listeria, etc. Is your testing lab capable of these? Receiving- Ingredients, doors, inventory Shipping/Warehouse

Premises

- 2.3.3 The plant must be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good repair; drips or condensate from fixtures, ducts and pipes may not contaminate the product, product contact surfaces, or product-packaging materials; aisles or working spaces provided between equipment and walls must be unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating the product, product-contact surfaces, or product-packaging materials with clothing or personal contact.
- 2.3.4 Lighting in the plant must be adequate and appropriate for sanitation, inspection and processing tasks being performed.
- 2.3.5 Adequate ventilation or control equipment must be provided to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate the product.
- 2.3.6 Walls, doors, and overhead doors must be adequately pest-proof.

Warehouse Premises

- 2.18.1 There must be a written procedure for the inspection of delivery vehicles. This will also apply to receiving and shipping. Procedures must define when carriers are to be rejected.
- 2.18.2 There must be a written procedure for the inspection and receipt of ingredients, raw materials, and packaging. 2.18.3 Raw materials, ingredients, packaging and finished product must be stored separate, secure and protected in storage.
- 2.18.4 Storage temperatures must be controlled and monitored. 2.18.5 Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of the product, as well as against deterioration of the product and the container.
- 2.18.6 Refrigerated and/or frozen truck temperatures must be monitored prior to loading and unloading. Record of these temperatures must be kept.

Sanitation

• Sanitation 2.5.1 All processing, storage, warehouse, and employee welfare areas as well as processing and food handling equipment should be appropriately clean.

2.5.2 The facility should have documented standard cleaning procedures or Sanitation Standard Operating
Procedures (SSOP's) that include what to clean, frequency, chemicals to be used, and dismantling instructions. The
Master Sanitation Schedule (MSS) should include all facilities, buildings, and equipment, and should include
cleaning and/or sanitation records.

Environmental Monitoring

2.6.1 A risk-based environmental monitoring/microbial control program should be in place with roles and responsibilities documented.

2.6.2 The program should include a sampling plan or schedule, as well as pass/fail criteria for samples or swabs.

2.6.3 Environmental/microbial testing results should be monitored, and corrective actions implemented where unsatisfactory trends are observed in a timely manner.

2.6.4 Records should be maintained.

Pest Control

- 2.7.8 The methods and responsibility for pest preventions shall be documented and effectively implemented. Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present. Records of all pest control applications and corrective actions shall be maintained.
- 2.7.9 Pest Control Contractors must meet the following: a.) licensed and approved by the local relevant authority,
 b.) use only trained and qualified operators who comply with regulatory requirements, c.) use only approved chemicals and have labels and SDS on file, d.) provide a pest control management program including site maps of all devices, e.) provide a written report of their findings and the inspections and treatments applied.
- 2.7.10 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against pests.

People

- Training/Onboarding: What are your proceedures?
- How do you qualify them? State requirements
- How are they promoted to more technical obligations
- What is your philosophy?
- What if someone is sick?
- Jewelry, clothing, security(water bottles)

People

- . 2.1.3 A written dress code for all employees (including new and part-time), visitors, vendors, and contractors must be documented. Employees must wear clean clothing and shoes appropriate for their working conditions.
- 2.1.4 The facility must require the use of hair restraints and facial hair restraints. False fingernails, fingernail polish, jewelry (e.g. rings, exposed body piercings, bracelets, etc.), or watches are not to be worn.
- 2.1.5 Hands must be thoroughly washed (and sanitized if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
- 2.1.7 Eating, drinking, spitting, chewing or using tobacco products must only be permitted in designated areas.

Products

- 1.6 Allergen Management Program 1.6.1 A documented allergen control program should be implemented to include management of raw ingredients, processing aids, lubricants, rework and finished goods.
- 1.6.2 Ingredients containing allergens must be clearly identified as such and properly controlled, segregated in storage, production, or batching areas to prevent cross contamination.
- 1.6.3 Controls should be identified to prevent allergen cross-contamination to include: scheduling, utensil/equipment segregation or sanitation requirements between allergen non-allergen runs and etc.
- 1.6.4 Sanitation controls must be identified as part of the allergen control program to ensure removal of allergen residue is effective and has been validated. Records of validation should be maintained.
- 1.6.5 Labeling for allergen-containing products shall meet legal and customer requirements.
- 1.6.6 Allergen awareness/control training must be completed annually.

Products

- Ingredients- COA(Certificates of Analysis)-
- Oils/THC Content
- In 2004, the FDA passed the Food Allergen Labeling and Consumer Protection Act (FALCPA)
- It meant that manufacturers were required to label food packaging if their foods contained one of the <u>eight most common food allergens</u>. These eight allergens are
 responsible for <u>up to 90 percent</u> of all allergic reactions related to food.
- The "Big Eight" are:
- milk
- eggs
- fish
- shellfish
- tree nuts
- peanuts
- wheat
- soybeans

Products

- RECALLS
- Recall Plan 1.12.1 The documented recall plan must contain:
- Defined roles and responsibilities
 Contact lists for external notification (regulators, customers, public)
- Lot identification and verification information •
- Product disposal procedures •
- Effectiveness check procedures to be used during a recall

Processes/Proceedures

- Be consistent
- How are you documenting?
- Spreadsheets, Software, cyber security
- Who is in charge of what?
- Meetings and updates for the team documented(Internal Audits and Management Reviews)

Product Process Documentation

- 2.14.1 Record of batch must be documented and maintained to contain:

 Grower information Raw material testing In processing and finished product testing results for purity, contaminants, cannabinoid quantifications Name of product Strength Concentration Weight or measure of each THC product for each batch size List of ingredients used and amounts The identity and measurement of THC levels in product that will be declared on the label Description of the packaging
- 2.14.2 Work instruction must be documented and implemented at each processing step requiring quality control to be monitored to ensure quality of the cannabis product and labeling accuracy.
- 2.14.3 Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that product-packaging materials are safe and suitable.



Product Testing Concerns

Cannabis and Hemp Testing

- How is the sampling conducted?
- Frequency of testing
- What credentialing does lab have (State Approved or ISO 17025)?
- What tests are conducted (potency, terpenes, pesticides, heavy metals, micro/pathogens, yeast/molds)?

CONTAINS THC

Cannabis Packaging

- Adherence to current packaging requirements
- Proper labeling
 - THC level of product
 - Name & address of production facility
 - Name of the infused product and ingredients by descending weight
 - Product cannot be a shape, color, package, or labeled to appeal to minors age 17 and under
 - Child-resistant packaging



Cannabis/Hemp Certification

Audit Types and Steps to Certification

PJRFSI Cannabis cGMP Standard

- Applicable for Cannabis and Hemp growers
- Accredited by ANSI
- Based off of existing Federal, Food Industry and Code of Federal Regulations requirements.
- State-specific requirements also included



How to be Audit Ready

- Pre-assessment
- Review and implement Requirements
- Train Employees
- Internal Audit
- Implement Corrective Actions



Benefits of Certification

- Mitigate risks to public health and safety
- Promote your products with an added layer of confidence
- Increase consumer confidence
- Stay ahead of the competition when it comes to government requirements
- Reduce recalls and save money
- Insurance companies are discounting for companies that have GMP and or ISO certs

The 10 Golden Rules of GMP

- 1. Get the facility design right from the start
 - 2. Validate processes
- 3. Write good procedures and follow them
 - 4. Identify who does what
 - 5. Keep good records
 - 6.. Train and develop staff
 - 7. Practice good hygiene
 - 8. Maintain facilities and equipment
- 9. Build quality into the whole product lifecycle
 - **10.** Perform regular audits

Download the Standard

▷ We are offering a free download of the standard from our website



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Cannabis

FREE Download - Cannabis Safety Standard for Manufacturing

We now offer specialty certifications that cover all facets of the Cannabis Industry. PJRFSI has created new Cannabis programs based on our successful food, agricultural, and pharmaceutical safety certifications. Whether you are growing/harvesting, producing/extracting, or creating MIP's (Marijuana Infused Products), we have resources for you that are streamlined and effective. PJRFSI Cannabis certification program is based on Good Manufacturing Practice (GMP) guidelines and are State specific.



Have questions? Reach us at <u>www.pjrfsi.com</u> and bmcmillen@pjrfsi.com

