cGMP Certification for Cannabis Businesses

Be a Leader in the Industry

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Want to know what cannabis companies already have certifications?

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How can your facility prepare for the upcoming FDA regulations, get a competitive advantage, and ensure a safe and consistent product for consumers?

That answer is easy---The first step is cGMP Certification.

What is cGMP?

- cGMP stands for current Good Manufacturing Practices. The regulations were created by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act and cover manufacturers of food, dietary supplements, cosmetics, medical devices, and prescription drugs.
- cGMP regulations require a systematic quality approach to manufacturing, including the development and implementation of procedures and documentation for the design, monitoring, and control of all manufacturing processes. This quality management system helps to ensure products are made consistently and reliably to product specifications for identity, strength, quality, and purity. Not only does cGMP help businesses prevent hazards such as contamination or errors, it ensures that products are safe for consumers, every time.

Why is cGMP certification important?

- **Consumer Safety:** cGMP certification helps protect the consumer from purchasing ineffective, contaminated, or inaccurately labeled products. Consumers have an expectation of safety when buying products, and cGMP certification helps increase brand confidence. In the wholesale food manufacturing world no one will even buy your product if your company doesn't have this basic certification.
- **Brand/Investment Protection:** cGMP certification helps protect the manufacturer and brand from FDA enforcement such as warning letters, cease and desists, product seizures, or recalls. This is the number one risk mitigation for all brands, partners, and investors alike.
- **Marketing Tool:** cGMP certification can be a powerful marketing tool that sets compliant businesses apart from the competition. This certification can be advertised on your website to let consumers know that your business follows a high standard for safety and quality, making your business among the best of the best in the industry.

What's the difference between "cGMP Compliant" and "cGMP Certified"?

A BIG difference! Any business can say they are "cGMP compliant", but without the certification to back that up, that statement is hollow. Achieving cGMP certification is an arduous process that demonstrates and proves a facility's deep respect for product quality and consumer safety. cGMP certification can only be achieved by passing an audit from an accredited certifying body.

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What are the steps to gain cGMP Certification?

Due to potential conflicts of interest, the FDA and all other government bodies cannot certify companies for cGMP. As a consulting agency, we too cannot certify companies for cGMP. However, we can provide hands-on assistance with documentation, training, and audits of your business to prepare your business for the final certification audit.

Step 1: Gap Analysis
To begin the process, Allay Consulting will conduct a gap analysis of the facility to get a baseline idea of what the facility already has in place and what it may still need to complete the certification process. The gap analysis consists of a facility evaluation to determine if all required fixtures are in place (hand sinks, for example), as well as a SOP/documentation evaluation to determine the scope of the existing quality management system.

Step 2: Choose a cGMP Certifying Body
The second step is to choose a cGMP certifying body who will conduct the certification audit and issue the certification. Allay Consultants will look at all options available and will work with you to choose the certifying body that works best for your company. Currently, Allay works regularly with six accredited certifying bodies and can help your company choose the best fit.

Step 3: Create SOPs and Documentation
The third step is creating the large number of SOPs and documentation required for certification. Allay Consultants will evaluate and update all existing documentation, and work with your staff to create newly needed documentation. Approximately 50 different SOPs and/or documents are required for cGMP certification, and this can take anywhere from six months to two years to complete, depending on your business's timeline and budget.

Step 4: Train Staff
The fourth step is training staff to implement all the SOPs and documents. Allay can train on site or create training for your company that your staff can conduct themselves.

Step 5: Additional Gap Analysis
The fifth step is to have an Allay Consultant conduct an additional gap analysis to ensure your business is 100% ready for the final certification audit. If so, Allay will schedule the certification audit with the certifying body.

Step 6: Certification Audit
The sixth step is the certification audit---the day you've been waiting for! An Allay Consultant can be at the facility with your staff to answer questions and take notes while the auditor is on site. If there are any nonconformities or violations, your Allay Consultant will try to correct the issue while the auditor is on site, or if it cannot be corrected on site, a corrective action plan will be submitted after the audit. If too many nonconformities were found during the certification audit, a second certification audit may be required, but this is rare when working with Allay Consulting.

Step 7: Corrective Action Plan Submittal
The final step is submitting the corrective action plan to the certification body for the correction of any nonconformities that could not be corrected during the audit. Allay can assist your company in writing the corrective action plan. Once this is submitted and reviewed, the certifying body will determine if your business is granted a certification.

Step 8: cCMP Certification Approval
If the corrective action plan was approved by the certifying body, your business will receive the cGMP certificate. Congrats!

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Are there other certification options besides cGMP?

Yes! There are several other certifications that Allay Consulting can assist your business with:

- ISO 9001: This is the international standard for a quality management system ("QMS"). The standard is used by organizations to demonstrate their ability to consistently provide products and services that meet customer and regulatory requirements and to demonstrate continuous improvement. Due to the overlap between ISO 9001 and cGMP certifications, Allay Consulting recommends that these two certifications be achieved at the same time.

- ISO 22000: This is a food safety management standard to help organizations identify and control food safety hazards, at the same time as working together with other ISO management standards, such as ISO 9001. Applicable to all types of producers, ISO 22000 provides a layer of reassurance within the global food supply chain, helping products cross borders and bringing people food that they can trust.

How does Allay Consulting's services work and how long will it take for certification assistance?

12-Month Contract: Allay provides 12-month contracts for ongoing compliance and cGMP or ISO certification assistance. Allay can provide anywhere from 5-40 hours per month depending on bandwidth, your company budget, and deadline goals. The hours per month go towards anything the company requires when it comes to compliance. This includes full Quality Management System implementation, SOP/ Document development, process evaluation, label compliance, Food Safety plans, HACCP Plans, Hazardous Communication Plans, Employee training, ongoing compliance audits, etc.

Gap Analysis: A one-time audit of a facility consists of full FDA/ GMP evaluation at a flat rate. Allay will schedule and conduct the audit and within 72 hours of the end of the audit will provide your company with a full report including all violations observed, concerns, and talking points. This audit is designed to evaluate the facility, find the compliance pitfalls that might exist and see where your company is at compliance wise. This can give you an idea of where your company is at and how you want to move forward. If a contract for a 12-month contract is signed this will be the first visit that will take place during the first month of the contract.

Completion of the cGMP certification process typically takes 155-191 billable hours; therefore, Ally Consulting recommends at least 20 billable hours per month to start the process. This will ensure that your company is moving at a good pace and seeing results. If your business needs or timeline changes, Allay Consulting's contracts are flexible and you can choose to increase or decrease the hours per month (with proper notice).

For pricing please reach out to Allay Consulting at www.allayconsulting.com.

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Why should I hire Allay Consulting to assist my business with this?

Allay's expertise is unrivaled: Allay is comprised of former Denver public health cannabis regulators with over 31 years of collective, hands-on regulatory experience that has provided lessons learned for our THC Cannabis and Hemp clients. We have the high level of experience and expertise needed to interpret cGMPs and painlessly get through the certification process. Allay Consulting has completed the cGMP process with various cannabis businesses already and is always open to assist truly good companies in the industry.

Saves you time: The hectic pace of running a successful cannabis business sometimes means that you can't stop and create numerous SOPs, much less implement a robust quality management system. Allay Consulting can do all of this for you, while you maintain normal business operations, with just needing to answer operational questions for Allay instead of having to write everything yourself.

If you have any questions, please feel free to reach out. Thank you for considering Allay Consulting for your cGMP certification needs.

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ABOUT

With offices in Colorado and Oregon, Allay Cannabis Consulting guides companies through the hazards of the budding cannabis industry by navigating compliance pitfalls, ensuring best practices, and ultimately making sure the product you create ends up in stores, and not disposed of.

Allay is comprised of previous marijuana/hemp regulators. We understand how difficult compliance can be for such a young industry... think of Allay as a support buffer between the industry and regulators. We Provide a variety of services including Licensing assistance, New facility planning and build outs, and routine compliance audits. Allay covers many compliance areas including your State and local cannabis regulations, FDA compliance, assistance with GMP Certification, Assistance with ISO Certification, OSHA regulations, and Fire code regulations. We provide a variety of retainer packages for long term compliance support, SOP/document development, Equipment evaluation, and product packaging evaluations, etc.