

Cannabis and CBD

Good Manufacturing Practice (GMP) Regulations

We can assist your organization with GMP compliance



The **U.S. Food and Drug Administration (FDA)** carefully monitors drug manufacturers' compliance with its Good Manufacturing Practice (GMP) regulations. The mandated and required GMP regulations help the FDA protect consumers by confirming the safety, quality, and effectiveness of drugs. GMP regulations ensure products are produced consistently in a controlled manner according to quality standards, such as ISO 9001. Companies that produce cannabis and cannabidiol (CBD) products should comply with GMP regulations, including having the necessary facilities, equipment, methods, controls and the ability to manufacture, process, and pack their products.

BENEFITS OF GOOD MANUFACTURING PRACTICES

- ✓ Ensure consumer safety
- ✓ Comply with federal and statutory laws and regulations
- ✓ Ensure product safety, quality and effectiveness
- ✓ Improved structure, processes and procedures internally
- ✓ Better internal controls, which will improve operations and reduce risks

GOOD MANUFACTURING PRACTICE (GMP) OVERVIEW

- ✓ Subpart A – General provisions
- ✓ Subpart B – Organization and Personnel
- ✓ Subpart C – Buildings and Facilities
- ✓ Subpart D – Equipment
- ✓ Subpart E – Control of Components and Drug Product Containers and Closures
- ✓ Subpart F – Production and Process Controls
- ✓ Subpart G – Packaging and Labeling Control
- ✓ Subpart H – Holding and Distribution
- ✓ Subpart I – Laboratory Controls
- ✓ Subpart J – Records and Reports
- ✓ Subpart K – Returned and salvaged drug products

CLIENT TESTIMONIAL

“The responsiveness and communication provided by The ISO 9001 Group throughout our project was great. We liked the their approach on the technical support and guidance that was provided during the implementation sessions. Overall, the project went well and the meetings with our consultant were very helpful.”

*Ramesh Gopalakrishna
Saint-Gobain*

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