

To ensure that the health and wellbeing of Customers and the safety of the public is maintained, Botanica will strictly comply with Quality Control/Chain Of Custody, and enforce a multi-pronged series of protocols for Quality Control and Quality Assurance safeguards through its Quality Management System (“QMS”) with three (3) specific goals:

1. to implement a system that ensures all marijuana products provided to its Customers are safe, effective and meet or exceed the highest standards of healthcare professionals, the Massachusetts Cannabis Control Commission (“CCC”) and related regulatory agencies;
2. to establish and maintain strict protocols for developing and utilizing an effective monitoring and control system for product quality and process performance; and
3. to pinpoint and implement product quality and process improvements, include innovations and new to the marijuana quality system to effectively and consistently safeguard customer needs.

Following well-accepted Best Practices in the Pharmaceutical Industry for Quality Control and Quality Assurance (“QA/QC”), and specifically adhering to the standards set by the state of Massachusetts where applicable and not in conflict with CCC requirements, Botanica’s team of marijuana industry veterans, pharmaceutical and medical professionals, has prepared a Quality Management System (“QMS”) focused on authenticating the source of products, their freshness, the authenticity of lab results provided and chain-of-custody from the source supplier. Security, storage, sanitation and safety, and inventory control SOP’s ensure all products provided to a qualified customer at Botanica’s facility are unaltered from the provider and safe for their intended use. A strict set of protocols for handling Adverse Events, employee and customer education are also outlined below.

### **Process Performance and Product Quality Monitoring System**

To ensure a maintained state of control, Botanica has enacted a plan to monitor process performance and product quality of the supplier product suppliers with whom it deals. Utilizing quality risk management (“QRM”) in order to establish a control strategy, Botanica encourages relevant and effective corrective and preventive actions (“CAPA”).

Internal audits play a key role in Botanica’s QMS protocols. Consistent audits allow Botanica to continuously review its own processes and procedures, help to uncover any potential gaps in its system, streamline operations and assess the state of compliance and QMS. A QMS that has an integrated audits feature that can schedule regular audits of various departmental and operational areas and link the results of these audits to the “corrective action” feature is a major benefit to Botanica. Botanica’s QMS links directly to corrective actions from any audits automatically triggering required action.

Complaint handling/adverse event tracking is critical to measuring the effectiveness of its QMS. Another aspect prevalent in Botanica’s QMS is seeking and recording feedback on product quality from both Botanica employees along with Customers. Specifically, Botanica’s QMS features an easily accessible "complaints handling" feature providing Customers immediate opportunities to

provide feedback on products. This handling in compliance with FDA guidelines. It records all feedback, specifically seeking information regarding the experience using the product from packaging to application through effects and keeps records of these events which Botanica will monitor monthly for the improvement of customer experience.



MasterControl™

feature manages complaint



Another key feature of Botanica's QMS is its dedication to supplier management. Specifically, supplier quality plays a major

role in ensuring the safety and efficacy of adult use marijuana products. To enhance its QMS, Botanica has implemented a "supplier" rating system which rates supplier's based upon compliance with CCC regulations, Botanica SOP's, quality of the products being provided, customer satisfaction, diversity of products, availability of products, timeliness of responses to inquiries, and the complaints received from customers. Through use of a QMS's "supplier rating" feature, Botanica will be able to rank supplier suppliers based both on quantitative and qualitative criteria throughout the quality process and recommended corrective actions resulting from noted deficiencies. Understanding and recognizing supplier qualifications and ratings is extremely important to choose the most cooperative suppliers. These ratings also apply to ancillary product and service providers giving Botanica the analytics necessary to maintain an efficient QMS and improve customer service.

Botanica will employ a QMS-specific automated system designed and overseen by MasterControl, a custom off-the-shelf ("COTS"), configurable, and easy-to-use solution that combines industry best practices with the flexibility to meet the demands of the ever-changing adult use marijuana industry. This will be a "closed loop solution" separate and apart from Botanica's utilization of Biotrack's seed-to-sale system and Baker Management Platforms which will be operated in accordance with CCC guidelines and regulations.

MasterControl's experience in pharmaceutical medical marijuana document control, employee training, corrective and preventive action, and quality control with some of the world's leading cannabis companies is a perfect partner. It is the world's first Compliance Quality Management Software System to become 21 CFR Compliant and specifically handles the following:

- Document Control
- Training
- Supplier Management
- Corrective & Preventive Action System
- Change Control
- Quality Audit Management
- Bill of Materials ("BOM") Handling
- Forms-Based Process Automation

- Complaint Management

More than 1,000 companies worldwide, including 3 of the top 5 life science providers, rely on Master Control's easy-to-use platform that combines industry best practices with flexibility.

Botanica's automated QSM protocols allow information to be stored within a single, cohesive platform making the search and retrieval of data almost instantaneous. Further, since Botanica's encrypted cloud-based data archiving and recordkeeping functions will utilize Amazon Web Services ("AWS") for data its IT Director has developed and will implemented a comprehensive protocol set that Inactive records will be archived using Amazon Glacier, which is part of AWS. Following strict cybersecurity protections all QSM will be compliant with CFR 21 Part 11.

### CAPA system

Botanica will establish and maintain procedures for implementing a corrective and preventive action ("CAPA") system as part of its QMS protocols. CAPA is divided into two distinct but related functions: (1) Corrective Action requires a Root Cause Analysis ("RCA") to determine the root cause, of the undesirable situation AND taking action directed at



eliminating the root cause or error; (2) Preventive Action is an action taken by the organization and prevent the reoccurrence of the undesirable situation. Botanica's SOPs require investigation of complaints, rejection of products, non-conformance, audits, as well as trends from product quality monitoring, and analysis of all processes using a risk based approach to statistically rank the severity of the risks. The Risk ranking will determine the severity of the issue and whether a CAPA will be adopted. Risks which may potentially negatively affect the quality of adult use marijuana products available to customers require a CAPA under Botanica SOPs.

### A Change Management System.

Botanica fully recognizes that the best QA/QC and QMS protocols require remaining current with changes in regulations and the evolving adult use marijuana industry. Thus, whether change is prompted by the CCC, Botanica's own risk assessments, educational developments or other sources, to ensure continual improvement in customer care and the adult use marijuana industry Botanica's QMS includes a change management system that focuses on product safety and quality. Using the custom "change management" feature, Botanica can initiate a change based on customer feedback, non-conformance, an audit, a corrective action or any similar quality event. By incorporating quality into the change management process through the Master Control platform, Botanica ensures that nothing gets overlooked, and product quality and safety is effectively maintained.

To implement any change in its QMS, Botanica's SOP's require that the request for a process change shall be documented in a Change Request which will include the justification for the change and the circumstances giving rise to it. Botanica's Chief Operations Officer ("COO") and Chief Compliance Officer ("CCO") shall evaluate the merits of the proposed change and determine the actions necessary to address and implement the intended changes. Wherever it is deemed essential,

other departments will be consulted about proposed changes contained within the Change Request. This may include discussions with the Security Director, Public Health Director, Director of Dispensary Compliance and Retail Director, consultants, or other relevant parties prior to according approval for the proposed change. If the Change Request is deemed necessary, the COO and CCO will ensure that all necessary impact assessments are completed; all risks and outcomes identified during the review processes are addressed to the utmost satisfaction; and proposed changes comply with regulatory and legal requirements. At this time the proposed change will be submitted to the CCC for necessary approvals including submission of current SOP's governing the subjects covered by the Change Request as redlined and updated where necessary, a new SOP will be specifically crafted and submitted to the CCC for review and approval.

Once approved by the CCC or any other required regulatory body, all affected personnel will be informed of the changes and adequately trained prior to implementation. All training will be documented and archived by Botanica.

Upon implementation of change, the COO and CCO shall verify: Implemented changes are as intended; Documentations are complete pertaining to changes; and changes are communicated to the applicable regulatory and legal requirements are fulfilled.

### **Adverse Events**

Effective QC/QA and QMS require protecting customer and public health and safety through minimizing the possibility of Adverse Events. Thus, effective methods for detecting Adverse Events are required as well as strict protocols for reporting same. Botanica's employees will be thoroughly, and routinely trained on how to identify, document, and report an Adverse Events as well as provide immediate emergency assistance when required.

Botanica will maintain formal policies and procedures for Adverse Events requiring immediate preparation of a written or typed report documented on the organization's Adverse Event/incident form. ALL employees will be trained annually on Adverse Event detection and reporting protocols beginning with their initial training upon hiring. Employee training will include advising customers on expectations and effects of adult use marijuana and on possible Adverse Event occurrence. The Adverse Event/incident form template will guide customers through a clear and understandable information gathering process to facilitate an investigation and promote safety. Further, reminders to report and record Adverse Events will be part of daily instructions provided to ALL employees. For the planning, tracking, controlling and communication phases, Botanica will utilize the BioTrack's Inventory Tracking System.

ALL communications regarding a report or documentation of an Adverse Event will be simultaneously provided to the supplier from which the adult use marijuana product implicated by the Adverse Event was received.

Botanica will prepare a report as a result of any Adverse Event related to adult use marijuana consumption and/or use reported to Botanica by a customer. While not controlling, Botanica believes that the MedWatch Form FDA 3500 authored by the FDA sets forth appropriate criteria for triggering Adverse Event reporting and will incorporate same into its SOP's. Accordingly, Botanica will require employees to report any Adverse Event, product problems or product use errors involving:

- adult use marijuana regardless of form
- Devices used for the delivery of adult use marijuana products such as vaporizer pens and
- Combination products (adult use marijuana & devices).

Botanica will also require employees to document reports of problems from customers and caregivers concerning the quality, performance of or safety concerns such as: suspected counterfeit product, suspected contamination, defective components, poor packaging or labeling.

Botanica will train its employees to immediately report a perceived Adverse Event defined as “serious” when the customer outcome is:

- Death
- Life-threatening
- Hospitalization - initial or prolonged
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events).

As indicated, Botanica will utilize the most of to date version of Form FDA 3500 along with Botanica’s proprietary Adverse Event /incident form template. Documentation of Adverse Events will address:

- Diagnosis information
- Whether the Adverse Event was life threatening/severe/moderate/mild
- Whether the Adverse Event was serious and suspected or unexpected
- Causality assessment: how product was administered, stored, secured, and interacted.
- Actions taken following use of the product
- Whether dosage differed from previous dose
- Whether the Adverse Event was resolved/not resolved/resolved with sequel Adverse Event. Adverse Event required or extended hospitalization
- Whether the Adverse Event caused persistent or significant disability/incapacity

Dispensary employees will contact their immediate supervisor as soon as possible after the incident is reported and follow SOP’s for Adverse Event reporting but no later than the date employee received the Adverse Event report. The Dispensary Director will notify the CCC of this report within twenty-

four (24) hours and provide any information and/or documentation requested. The Dispensary Director will also immediately notify the supplier responsible for providing the product related to the Adverse Event. Botanica will retain copies of Adverse Events/incident reports in accordance with CCC regulations and for up to three (3) years.