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THOUGHT LEADERSHIP

QUALITY ASSURANCE & QUALITY CONTROL IN CANNABIS

by Garrett Cropsey

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THE STATE OF QA/QC IN CANNABIS

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Quality Assurance and Quality Control, collectively "QA/QC," encompass the overarching strategies and methods used to prevent and identify issues within a given process. These terms, commonly used within large-scale production and manufacturing environments, play a crucial role in maintaining compliance in operations as well as the overall success of the company.

These practices, described in full as part of the International Organization for Standardization's ISO 9000 family of quality management systems, are a foundational element of Good Manufacturing Practices ("GMP") here in the United States and abroad. Yet the current dichotomy between federal and state cannabis laws currently prevents the enforcement of these standards on cannabis businesses because GMP standards are enforced by the FDA, which still holds cannabis to be a Schedule 1 illegal drug.

Currently, each state-regulated medical, or adult-use cannabis program has some form of quality management standards that licensees must follow. These standards rarely look alike from state to state and all fall short of the full requirements for GMP operations. Here we will explore how cannabis businesses can familiarize themselves with QA/QC principles and implement new procedures in their businesses, bringing themselves closer to GMP standards of operations.

Cannabis businesses in Canada and other countries with a nationally unified stance on cannabis are already familiar with GMP and QA/QC as requirements for their continued operations. However, these subjects are much less familiar to cannabis businesses currently operating within the United States, who would do well to familiarize themselves with what will surely become the standards to which they are held.

Given the fact that the owners of any business are reticent to adopt additional costs without a clear explanation of benefits, it's important to note at this point that the implementation of QA/QC principles provide a variety of tangible benefits.

Among them are:

- increased process efficiency and consumer confidence
- decreased likelihood of recalls, compliance violations, and license forfeiture
- decreased costs to comply with GMP guidelines upon federal legalization

We will cover:

- the difference between quality assurance and quality control
- QA/QC principles for cannabis businesses
- cannabis quality management in the future (and benefits of adopting these procedures now)

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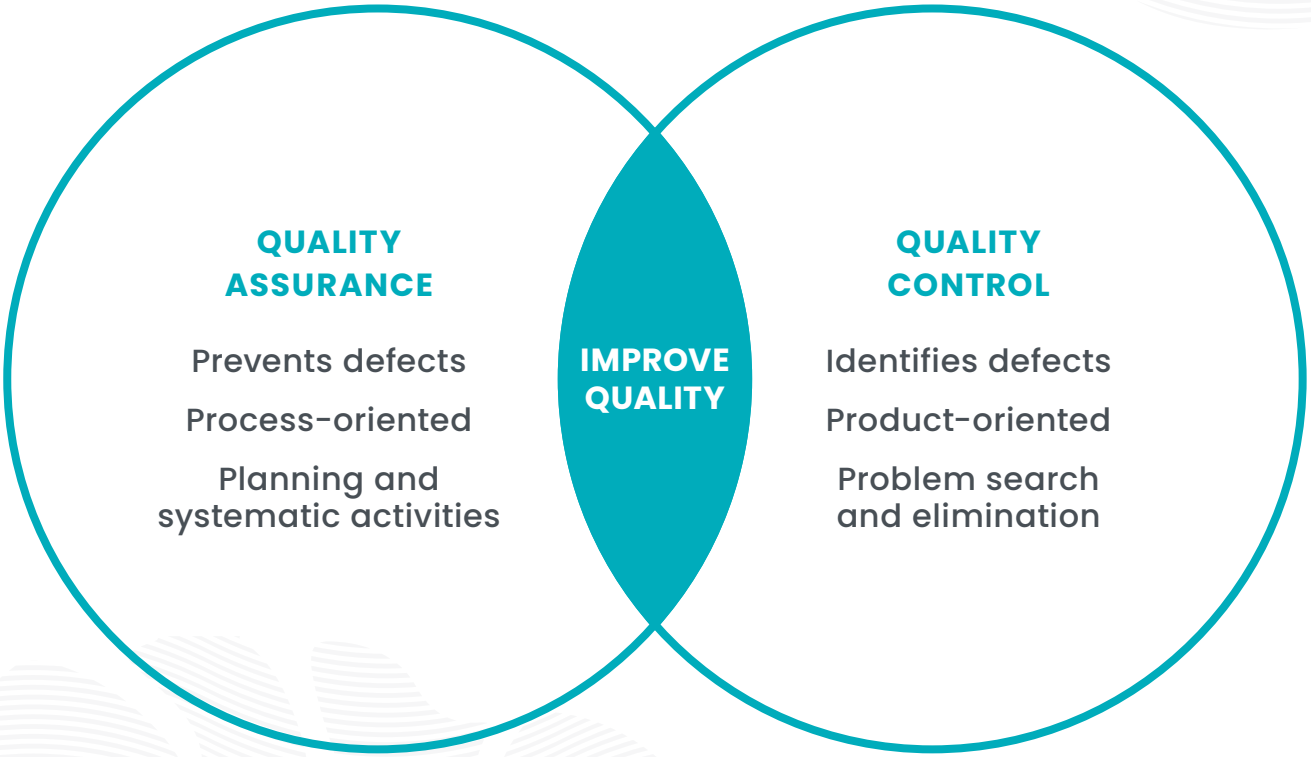
THE DIFFERENCE BETWEEN QA/QC

WHAT IS THE DIFFERENCE BETWEEN QUALITY ASSURANCE AND QUALITY CONTROL?

Both QA and QC are concerned with how quality is defined for a given product or process, as well as how quality is ensured and repeated across batches of that product or iterations of that process. While they are often discussed in tandem, QA and QC are actually two different departments, with QA activities overseeing QC activities. The two create feedback loops of process review and amendments that, over time, refine the process in question to reduce issues and improve results. Both are dependent upon a robust and holistic set of standard operating procedures ("SOPs") for the product or process in question.



In fact, the procedures for both QA and QC themselves will be standardized within the same body of SOPs. Because QA and QC have very different goals, it is important that they are performed by different groups within an organization in order for them to remain objective and reduce bias. In this sense, the seeming redundancies between the two programs are also a means of ensuring quality. On the following page, we will discuss each in more detail, in order to better understand their differences.

WHAT IS QUALITY ASSURANCE?

The Oxford English Dictionary defines quality assurance as, *"the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production."* Quality assurance is process oriented and focused on issue prevention. It asks, "how do I design my process to ensure quality is maintained?"

A foundational tool in quality assurance is known as the PDCA cycle, for "Plan, Do, Check, Act." First, you must define what objectives must be met to ensure the quality of your product or process, then develop a **plan** to deliver on those objectives. Next, **do** the plan you developed in a small-scale, controlled environment, measuring outcomes and gathering data. Then, **check** the plan you developed by reviewing the results measured in the second step, identifying differences and similarities your results have from your desired outcome to establish the root cause. Finally, **act** on the root causes identified in the previous step to adjust your plan from step one to avoid deviations you measured in the previous step.

Once the process has been established and implemented, use the same PDCA cycle to review the act of making the product or the process itself in action, continuously revising and optimizing SOPs, including those SOPs for QC itself. It is integral for QA measures to include oversight of QC measures in order to ensure that the quality of QC measures themselves are maintained.

WHAT IS QUALITY CONTROL?

The Oxford English Dictionary defines quality control as, *"a system of maintaining standards in manufactured products by testing a sample of the output against the specification."* Quality control is product oriented and focused on issue identification. It asks, "is the process operating within the parameters set to maintain quality?"

Quality control involves observing the process, taking measurements of key parameters, and checking those measurements against the standards for quality set by QA and embedded within SOPs. These SOPs also will also include instructions for when measured parameters deviate from quality thresholds, including mitigation steps to bring the process back into specifications or for ceasing and resetting the process if mitigation is not possible. In the same way that separation between QA and QC groups is necessary to maintain objectivity, so too is the separation between the QC group and manufacturing or operations groups as well. This is to eliminate the opportunity for manufacturing or operations groups to hide deficiencies or other lapses in quality in order to avoid blame as part of root cause analysis.

Employees would often rather sacrifice the entire product batch or the success of the activity in question in order to avoid personal blame. Since it is impossible to eliminate user error or self-interested acts of obfuscation through even the most robust SOPs, the solution is instead to separate the two groups and clearly define all activities in SOPs, along with forms to record the employees completing those activities.

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QA/QC PRINCIPLES FOR CANNABIS BUSINESS

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QA/QC principles can be readily applied to all types of cannabis businesses but the specifics of these strategies and practices vary between license types. As stated previously, all QA/QC activities are based upon a robust and holistic set of SOPs.

If you are not sure where to start, start there! When assigning QA/QC activities to employees, always remember the need for separation between those performing tasks and those designated to monitor their performance. For facilities with enough resources, the simplest solution is to establish separate QA and QC departments within your company. Short of that, the next logical solution would be to place an upper-management employee in charge of QA and a management-level employee, who is not involved directly in the activity they monitor, in charge of QC.

For example, a Chief Compliance Officer would oversee QA activities for the cultivation facility, with the Director of Cultivation overseeing QC activities, with the cultivation process itself being performed by their subordinate Cultivation Managers, Assistant Cultivation Managers, and Cultivation Associates.

In this section we will explore the quality management concerns of the three major license types of cannabis businesses. While these are some of the primary aspects of quality for cannabis licenses, all should seek to monitor and ensure quality across all activities, including: inventory monitoring, record keeping, packaging, labeling, security, storage, sanitation, human resources, and vendor/client relationships, amongst others.

CULTIVATION

The primary concern of cultivation licensees is the quality of the cannabis they cultivate. The following are a few of the primary quality outcomes of concern for cannabis cultivators:

- **POTENCY:** Cannabis strains have a range of potency. Plants of the highest quality for any strain express their highest possible potency.
- **YIELD:** Cannabis strains also have a wide range of yields. Plants of the highest quality for any strain yield the most possible flowers.
- **TRIMMING:** Cannabis strains have different leaf density and flower structures. Plants of the highest quality are trimmed and manicured to present the flowers at their maximum potential.
- **CURE:** Cannabis strains require different curing conditions. Plants of the highest quality are cured to maximize their flavor profile and express all characteristics strongly.
- **TESTING:** Finished cannabis flowers should pass all testing requirements for the state or country in question. Testing facilities themselves are a higher-level quality control body for a cannabis regulatory market.
- **CONDITION:** Cannabis strains produce different size flower buds. These buds are delicate and proper handling preserves the structure of their cannabinoid-containing trichome structures. Plants of the highest quality are handled in a way that maintains the size and overall integrity of their flowers.

Implementing quality standards and control procedures for each of these concerns will subsequently maximize the quality of cannabis flower your facility produces. As they say, “the proof is in the pudding!” and this proof will ensure your flower fetches top-dollar, while companies without proper quality management practices are stuck explaining their deficiencies as they argue over pricing.

PROCESSING

The primary concerns of processor licensees is the quality of the cannabis concentrates they extract and the quality of the infused products they manufacture, if applicable. The following are a few of the primary quality outcomes of concern for cannabis processors:

- **YIELD:** The amount of extract produced in each run (yield) is dictated by the quality of the source material but also depends on how the machine is operated. Extraction runs of the highest quality extract the highest percentage of cannabinoids and/or terpenes possible, while simultaneously limiting the inclusion of other undesired plant compounds.
- **POTENCY:** Potency of cannabis extracts and infused products can vary based upon the quality of source material. Cannabis extracts and infused products must meet the potency standards, set by the company or dictated by regulations, in order to be sold.
- **HOMOGENEITY:** It is easy for cannabis concentrates and infused products to separate within their mixture, causing inconsistency in potency across the same batch or even within one product. Cannabis extracts and infused products of the highest quality are homogeneous such that they express the same potency throughout the entire product, within a strict margin (e.g., ~100mg edible, 10 servings, ~10mg each).
- **PURITY:** The extraction process often concentrates other plant compounds within the resulting extract, as well as cannabinoids, which then must be separated out via post-processing methods like winterization or rotary evaporation. Purity is important in infused products as well, ensuring that contaminants do not enter the manufacturing process. Cannabis extracts and infused products of the highest quality are free from impurities, passing all required testing.

The same is true for cannabis extracts and infused products as it is for cannabis flower; implementing quality standards and control procedures for each of these concerns will ensure you produce consistently high-grade products. Those who fail to adequately control these quality concerns waste time and resources remediating products, throwing away batches, and reducing profit margins in order to find buyers for sub-par products.

DISPENSING

The primary concerns of processor licensees is the quality of the cannabis concentrates they extract and the quality of the infused products they manufacture, if applicable. The following are a few of the primary quality outcomes of concern for cannabis processors:

- **PRODUCTS:** The overall quality, diversity, and availability of products at a dispensary are arguably of the greatest importance. Dispensaries of the highest quality offer high-quality products, a diverse range of products, and ensure those products are available continuously, without any lapses in offerings.
- **CLEANLINESS:** Dispensaries, much like other retail establishments, present themselves in different ways based upon their location and target customers. But despite their differences, dispensaries of the highest quality present a clean and sanitary facility in order to retain their customers.
- **ORGANIZATION:** The way in which and degree to which a dispensary is organized have a large effect on the efficiency of the sales process and the customer's perception of the dispensary itself. Dispensaries of the highest quality ensure their products and sales process are highly organized to reduce transaction times and present themselves professionally.
- **IDENTITY VERIFICATION:** A dispensary's identity verification policies (including age, medical patient status, veteran status, disability status) are of the utmost concern for their continued operations. Dispensaries that fail to appropriately verify their customers age and, if necessary, medical marijuana patient card status risk heavy penalties and possible revocation of their license. Dispensaries of the highest quality have procedures in place that clearly define identity verification requirements for all types of customers to ensure against lapses in compliance.

While the quality concerns for dispensaries are different than those for cultivation and processing licensees, the quality of products sold at the dispensary are ultimately dependent upon the quality of the supplier. By selecting products from vendors of quality, dispensaries set the foundation of their own public perception as well. In addition to product quality, the overall quality of the dispensary's atmosphere and operations will ensure they build a strong customer base that are willing to go out of their way to get the quality of products and service offered.

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CANNABIS QUALITY MANAGEMENT IN THE FUTURE

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As stated earlier, the implementation of and adherence to QA/QC procedures for cannabis businesses in the United States is currently limited to the specific requirements of the state in which a business operates and not as part of FDA-regulated, GMP standards of operation.

However, while the implementation of quality management standards is not mandatory, using these methods is still inarguably beneficial. The list of quality management concerns presented in the last section should already be under scrutiny for licensees with only limited quality management systems in place, simply given the fact that ignoring them would mean failure for their business.

So, by taking what are only loosely held concerns at present and applying clear quality standards, detailed SOPs for staff to follow, and assigning QA and QC oversight roles, it is possible to close the gap between where the majority of cannabis businesses operate currently and all other FDA-regulated, GMP certified businesses.

If one works from the understanding that federal legalization of cannabis within the United States will happen in the relative short term, and the FDA will gain oversight of all cannabis operations, then implementing QA/QC procedures now only makes more sense.

Since the upfront cost of implementing QA/QC procedures can be large, depending on the size and complexity of the business, many business owners balk at the prospect and question the value of such extensive changes. While this is true, the argument remains that doing so will only benefit the business long-term.

Such benefits include:

- Front- and back-end savings from increased yields, potency, and/or sales as a result of process efficiency improvements;
- Increased consumer confidence in products and/or services offered;
- Decreased likelihood of recalls or compliance violations as a result of detailed SOPs, constant process oversight, and quality management;
- Decreased likelihood of fines and/or license revocation; and,
- Decreased costs to ultimately comply with FDA GMP guidelines upon federal legalization.

For these reasons and more, there is no better time than now for cannabis businesses within the United States to implement thorough quality assurance and quality control standards – saving themselves from wasted time and resources as well as unnecessary stress, while simultaneously pushing the cannabis industry and public perception further towards legitimacy.

ABOUT THE ADVISOR

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Garrett brings his hard-science background together with his work in cannabis operations, logistics, and supply chain management to provide foundational support for clients in planning their business and applying for competitive cannabis licenses. He has managed client projects in 19 states, plus Canada, and serves on the Scientific Advisory Committee of the National Cannabis Industry Association.

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