# Quality Assurance in New Jersey's Cannabis Industry

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**Introduction**

While Quality Assurance (QA) is not well understood in the world of cannabis, it is critical to the development and delivery of high-quality and safe products to consumers. This lack of understanding is unfortunate, since cannabusinesses can use QA as a competitive differentiator in their branding and promotion. Conversely, the sale of inferior or unsafe products can lead to health, enforcement and political problems within the industry.

**The Current State of Affairs**

According to Marianne Bays, Ph.D., a cannabis industry consultant, there is a severe shortage within the cannabis industry of rigorous QA programs, especially along each phase of the "seed -to-sale" process. "It is just cost-effective to have a stringent QA process in place – it allows you to avoid costly problems, including recalls and the loss of customer trust. Further, customer expectations are based on their experience with pharmaceuticals and food industries – they want and deserve to know that packages actually contain what it says on the label."

**QA Comes to the Cannabis Industry**

With regulation comes standardization, then testing procedures to ensure compliance. According to Jennifer Worringer, principal, Green Sea Consulting, this process (which is now common in the pharmaceutical and food/beverage industries) will soon become a standard way of life in the cannabis space. Although a strict QA program is needed at every phase of the cannabis delivery process, specific QA procedures differ according to the operation the business is performing.

However, in all cases, it is imperative to have a QA officer responsible for the development of QA procedures and overseeing compliance with those procedures. Accurate data collection and retrieval is also mandatory; in the event a problem arises, it will be necessary to back-track the sample to its source.

Cannabusinesses will need to employ QA specialists; those best qualified probably be found in the pharmaceutical or food industries. Larger players will invest heavily in testing equipment and a staff of QA professionals to develop protocols and ensure adherence to internal standards. Smaller companies will implement less rigorous programs, typically as part time staff functions. Others will out-source the QA function to the extent possible, while still striving to deliver high quality products to consumers.

**QA is Just a Good Business Practice**

From a business perspective, QA is critical for several reasons:

- Implementing a rigorous QA program avoids serious problems, many of which can lead to lost revenue. For example, a tainted product recall will result in unnecessary expenses and a potential public relations nightmare.
- Delivering (and promoting) high quality products can be an integral part of a company's branding and messaging, reflecting an image that resonates with potential clients, serving as a competitive differentiator.

**The Impact of Regulations on QA**

New Jersey's Alternative Treatment Center (ATC) applications required applicants to describe quality assurance, quality control and testing protocols used to assess "medicinal marijuana" for potential contamination as part of questions on Cultivation Operations and Processing Operations. No guidance has been provided regarding effective ATC quality assurance. Likewise, the specific testing standards currently in use in NJ have not been publicly distributed, but we can speculate that the presence of several contaminants is measured on a pass/fail basis. These substances may include bacteria, mold and pesticide. Incidentally, each state has established its own criteria for types of contaminants and acceptable levels. These standards also may vary by the "root of administration", e.g., whether the product is taken orally, smoked, or applied to the skin. The existing standards are said to be currently under review; they will expire on December 19, 2018 and need to be replaced.

On the federal side, we can expect that various government agencies will become involved in the future – including the FDA, DEA, the Department of Agriculture, and the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF). Companies will be held responsible for maintaining "good manufacturing and laboratory practices". Further, their operation will be subject to unannounced inspections from any federal agency.

**Conclusion**

A word to the wise is sufficient. In many cases, cannabis entrepreneurs and even existing cannabusinesses are unaware of the enormous impact QA has on their company. They should make QA an integral part of their planning from the very start – and treated with as much importance as security, staffing, product tracking or compliance with state regulations.

**Marianne Bays,** PhD is a Cannabis Industry Analyst at Kalyx Development Inc., Managing Director of Mingleridge Business Resources, LLC. and Vice President of the NJ Cannabusiness Association.

**Jennifer Worringer** is a molecular biologist with more than a decade of experience in the quality control and assurance of globally regulated pharmaceutical drug products with ImClone, Eli Lilly and AmerisourceBergen.