CALIFORNIA CANNABIS INDUSTRY ASSOCIATION

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REPRESENTATIVE SAMPLING AND ITS IMPACT ON DIFFERENCES IN RESEARCH & DEVELOPMENT AND COMPLIANCE DATA

Produced by the CCIA Quality Control Committee

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OVERVIEW

Manufacturers are challenged with creating safe, and consistent products. Formulations need to created in a manner so that they can account for different potency concentrations. Effective General Manufacturing Procedures (GMP) require sample batch testing to confirm operational consistency.

Cultivators and manufacturers typically engage a testing laboratory and conduct R&D testing before compliance testing. The manufacturer will be asked to bring in a representative sample of the product for R&D testing. This testing process can be dramatically impacted if the manufacturer and the testing laboratory have different interpretations as to what constitutes a representative sample.

A common complaint that testing laboratories receive is that a sample submitted for R&D testing passed compliance standards while the same batch submitted for actual compliance testing resulted in a failure. This difference in testing results can be extremely frustrating for the cultivator or manufacturer since the product can no longer enter the legal supply chain without expensive remediation.

The differences between R&D testing and compliance testing that can be minimized by using a consistent sampling method for representative sampling at every point that testing occurs. The sampling method refers to the manner in which a sample is collected for testing and a representative sample is a small sample that accurately represents the characteristics of the whole batch.[1]

CURRENT PROTOCOL

According to the BCC regulations, testing laboratories are required to conduct representative sampling on a batch for compliance sampling. Representative sampling is inherently difficult to conduct given the lack of uniformity of common cannabis goods. Cannabis plant material usually consists of flower, stem, and leaves of varying sizes and proportions, while cannabis concentrates are extremely viscous and difficult to mix. Standard sampling protocols must be employed consistently in order to produce reliable representative samples for testing.

The best protocol for representative sampling involves visualizing the container holding the batch as a grid and assigning location numbers to each part of the grid. A random number generator is utilized to determine which location is sampled and then all the sample increments from those locations are pooled to form the final representative sample. This protocol can be applied towards both cannabis plant material as well as manufactured units. Some of the assumptions made for this protocol is that the batch being sampled is uniform and if there are multiple containers holding a single batch, all the containers are similarly uniform too.[1,2]

Furthermore, the size of the R&D batch vs. the compliance batch can have an impact on data. If a manufacturer produces a small R&D batch, but uses a different process or quantities to produce a much larger compliance batch, the R&D data may not be applicable to the compliance batch.

ISSUES, IF CURRENT PROTOCOL ARE NOT FOLLOWED

When a sample is submitted for R&D testing, it usually consists of a single sample increment taken from a single location in a batch. This sample is also typically much smaller than a compliance sample and does not account for differences at various points of the container.

The differences in compliance and R&D sampling protocols can lead to significant differences in data produced. These differences are more indicative of the non-uniformity of batches rather than inconsistency in laboratory testing.

RECOMMENDATIONS

It is vital to select a laboratory in the same manner as any other supply chain partner. The best way to ensure greater consistency in results is to utilize the same laboratory for batch and compliance testing. Lab shopping is not a viable means of building reliable partnerships in a regulated industry. A manufacturer or cultivator can successfully use a partner laboratory's scientific knowledge to create protocols for conducting representative sampling for R&D purposes in the same manner as compliance.

The best use of R&D testing is to evaluate a product or process before compliance testing. In light of this, it important to stay consistent not only in the sampling method but also the batch size and procedures. This would ensure that the data from the R&D sample is applicable and relevant for decision making. Replicate testing can also be useful in ensuring accuracy of data obtained.

Additionally, when developing new products, it is important to engage a laboratory early in the process and share information about the product. The laboratory may have to conduct internal R&D to develop optimized extraction and sample prep techniques for accurate testing. This can be especially true for novel products or infusion techniques.

In any situation, a transparent relationship between laboratory and manufacturer is important for generating accurate data. It is extremely helpful to provide the laboratory with cannabinoid targets or expected ranges of cannabinoid concentration, or whether a multitude of minor cannabinoids may be present. These factors (especially when dealing with extremely low or extremely high expected values) may have an impact on sample preparation, and subsequently, accuracy of data.

The cannabis industry tends to have an adversarial view towards testing laboratories and this represents a missed opportunity for a more collaborative approach that can help move the entire industry forward as it continues its march towards legitimacy.

CONTRIBUTORS

Dr. Swetha Kaul[1] serves as Chair of the California Cannabis Industry Association's Quality Control Committee, which is responsible for this publication and its content. Other contributing members include Emily Richardson[2], Jeff Kolsky[3], Dr. Reggie Guadino[4], and Gary Ward[5].

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