A2LA and ASA Joint Program Update

Ensuring cannabis quality is an important issue in states where cannabis has been legalized, whether for medical use, adult use, or both. Implementing quality control measures, however, has created a practical dilemma for these states in terms of what activities need to be regulated and how to regulate them. One of the main challenges lies in deciding what steps are necessary to ensure that this product does not harm their citizens. For most other consumables, the US Food and Drug Administration (FDA) provides the regulations, guidelines, and enforcement necessary to ensure that products are safe and contaminant-free. Cannabis, however, is unique in that it remains federally illegal. As such, the gaps in oversight are increasingly being addressed by widely accepted nongovernmental requirements.

To help support product quality in states where cannabis is legal, A2LA has developed sector-specific criteria to accredit cannabis laboratories, and has now partnered with **Americans for Safe Access (ASA)** to offer a joint assessment program that allows cannabis laboratories to become accredited to both ASA and A2LA standards as part of a unified process. This partnership creates a clearer and more direct path for cannabis laboratories to achieve the highest product safety standards.

AmericansFor SafeAccess
Advancing Legal Medical Marijuana Therapeutics and Research

Since the legal liability for producing an unadulterated product ultimately is a shared responsibility between the state, growers, and dispensaries, having a legally defensible and consistent approach to quality assurance is paramount. For most other products, this is accomplished by a combination of state and federal regulatory requirements for ensuring that product safety label claims are met, usually through third party independent laboratory testing. However, the lack of FDA involvement has created a vacuum where adequate federal guidance on acceptable practices is unavailable. For other consumables, laboratory quality control and safety testing follow a relatively straightforward approach, in which the laboratory demonstrates that they have appropriate facilities, necessary testing and measurement equipment, and competent staff to perform the appropriate type of analysis. In many regards, the cannabis testing laboratory community is indistinguishable from any other competent laboratory organization. However, the process diverges from the norm mostly due to a lack of standard methods, lack of available proficiency testing and, as noted above, federal regulations.

An emerging and broadly accepted solution (and one that also creates legal defensibility and a baseline consistency) is to use standardized nongovernmental requirements. For testing laboratories in general, the standard is ISO/IEC 17025:2017 (General Requirements for the Competence of Testing and Calibration Laboratories). This is a globally accepted standard of quality for testing laboratories, which aims to ensure a quality management system is implemented to improve a laboratory's ability to produce consistent results. A2LA offers accreditation not only to the generalized ISO/IEC 17025 standard, but to cannabis sector-specific criteria derived from the American Herbal Products Association (AHPA) Recommendations for Regulators – Cannabis Operations (Laboratory Operations) document. These requirements supplement the ISO/IEC 17025:2017 requirements and help to ensure that processes such as appropriate security and safety, data management, reporting, sample handling, chain of custody, and disposal are in place. These and other key processes also form the basis of the Americans for Safe Access (ASA) Patient Focused Certification (PFC) program module for laboratories.

A2LA and ASA use the same additional specific criteria, and now have an exclusive relationship to assess jointly to these criteria. Laboratories seeking both an accreditation by A2LA and a PFC laboratory certification by ASA using these cannabis-specific criteria can achieve both with a single comprehensive assessment. Laboratories indicate interest when they apply to A2LA for accreditation and submit the combined ISO/IEC 17025:2017/ ASA checklist and other associated quality documentation and records.

The rest of the process works as follows:

- A2LA will supply the assessors to perform the assessment and then complete follow-up review of corrective actions for any deficiencies cited. Once the assessment review is complete, the assessment package is sent to A2LA's Accreditation Council as well as to PFC for review by their certification review committee.
- Once approved, the laboratory will receive an A2LA Scope and Certificate of Accreditation and a separate Certificate from PFC regarding their PFC certification.
- ASA and A2LA will also put out a press release regarding the certification and add this to our social media feeds.
- PFC will provide the laboratory with a graphics package for them to print out PFC materials for their clients that include their company logo. The PFC certification also has a training component to it that covers cultivation, manufacturing, dispensing and laboratory operations, as well as law enforcement interactions and patient education. It also connects PFC certified businesses to give cannabis business operators the ability to work with other businesses that have been vetted by the 3rd party certification process.
- A2LA and PFC's services also include pre-accreditation/pre-certification assessments which can help assure clients that they have the most optimum systems in place to reduce the stress of required assessments and reduce the chances of a difficult assessment.

A2LA and ASA are pleased to be the first and only organizations to jointly offer this type of combined, comprehensive cannabis testing accreditation/certification program. We feel this will help move the testing industry toward addressing the concerns related to quality and consistency of the analytical data. Most importantly, with a more multi-faceted approach to cannabis laboratory certification and accreditation, we hope to be a key factor in supporting product quality and public confidence.