

Global Workshop on Cannabis Quality: Part One – America and Europe

Sponsored by ASTM International and United States Pharmacopeia

December 7-8, 2022

Key Highlights

During the workshop we heard from several esteemed regulatory, industry, laboratory, and standards development organization representatives from nearly a dozen countries. Getting several sub-sectors of the cannabis industry from so many countries to come together to discuss medical cannabis quality is a historic feat in itself. But what we learned was invaluable. After listening to the speakers, it was clear that global regulators and cannabis stakeholders recognize the need for harmonization when it comes to cannabis quality attributes, but all realize it is a challenging task. We discussed what we can do to overcome it.

Julio Sánchez y Tépoz told us it may be easier to converge and the first step to convergence is a scientific discussion. Similarly, Dr. Robin Marles compared a barbershop quartet to how we can collaborate globally to ensure cannabis quality—everyone may not all be singing the same notes, but we can sing in harmony. And as Dr. Holly Johnson simply put it, we can “call a scientist!” The workshop also highlighted how far we have come to be able to give access to safe cannabis products. We have far more data, consensus standards, and monographs to inform regulation and policy than we had years ago. Further, the workshop provided many opportunities for the cannabis industries of the world to converge on a scientific basis and continue to advance cannabis quality through best practices.

Regulatory Perspectives

In the first panel, we were joined by regulators from Mexico, Canada, Germany, and Brazil. We learned each nation has its own approach to regulating medical cannabis. For example, Health Canada does not consider medical cannabis products to be approved therapeutic drug products. Therefore, cannabis products in Canada, unless approved as a therapeutic drug, must comply with [Good Production Practices \(GPP\)](#), rather than Good Manufacturing Practices (GMP) that are followed by the pharmaceutical industry. Germany and Brazil, along with several other countries, differ in this approach, as they require adherence to GMP for all medicines, including cannabis.

We found out there were similarities between the different countries as well. All the nations represented recognize monographs in official pharmacopeias for establishing limits for impurities and reporting of dominant cannabinoids and require utilization of validated methods for quality control testing of final products prior to release.

International Standards and Pharmacopeias

The second panel included two leading Pharmacopeias (USP and European Pharmacopoeia, EDQM), international standards development organization ASTM International, and the Dutch Office of Medical Cannabis. We were educated on the structure of a pharmacopeial standard,

which is legally binding in many countries, and learned about the existing work, standards, and monographs from the USP, EDQM, ASTM International's [D37 Committee on Cannabis](#), and the Netherlands. This includes the over 48 published ASTM standards for the cannabis industry, the Dutch Office for Medical Cannabis ([OMC Monograph for Cannabis Flower](#)), the USP's proposed [Cannabis Species Inflorescence monograph in the Herbal Medicines Compendium \(HMC\)](#), and the EDQM's [draft monograph on Cannabis flos \(3028\)](#) (the latter two were open for comments in late 2022). These resources will continue to provide the industry with more direction and consistency. Despite many similarities, key differences were discussed including microbial testing requirements, use of water activity, and whether or not to require the testing for terpenoid content.

Perspectives from Industry

Day 2 began with perspectives from producers of medical cannabis products from around the world, describing the challenges and costs associated with bringing safe and quality cannabinoid-based products to market. Key differences in chromatographic profiles of semi-synthetic versus botanically-derived cannabinoid-based medicines were discussed. We saw characterization and testing data from approved pharmaceutical cannabinoid-based medicines such as Epidiolex®, which outlined the challenges of standardizing botanical starting materials given the inherent heterogeneity of the cannabis plant. To help overcome this challenge and create reliable herbal pharmaceutical products for Dutch patients, we learned about Bedrocan's new practice for medicinal cannabis cultivation, known as [Good Medicinal Cannabis Cultivation Practices \(GMCCP\)](#).

The need for risk assessments to characterize the likelihood of impurities and contaminants and to determine the concentration of minor cannabinoids and terpenoids was also considered as an important means for ensuring products are safe and consistent regardless of genetic origin. Additionally, we discussed health claims on labels and a recent wave of products containing cannabinoids other than D9-THC that are known to be inebriating (e.g., D8-THC).

Testing Laboratories, Research, and the U.S. State-by-State Approach

To wrap up an information-packed two days, we considered the challenges and discrepancies that analytical testing laboratories and academic researchers have seen, and how differences in state regulations have complicated the issue in the US. In stark contrast to national approaches in the rest of the world, US states have not been required to use pharmacopeial or consensus standards, which has resulted in dozens of unique regulatory frameworks and labs using different testing methods. During this final panel we took a deep dive into the issues of representative sampling and development and validation of test methods. We also looked at how testing panels and permissible contaminant limits differ widely amongst US states.

What's Next?

We hope the workshop inspired you to get involved in ensuring the safety and quality of cannabis globally!

Learn more about ASTM International's work in cannabis at www.astmcannabis.org

Learn more about USP's work in cannabis at <https://www.usp.org/dietary-supplements-herbal-medicines/cannabis>