ASTM INTERNATIONAL
Cannabis Standards and Services

FREE Global Workshop on Cannabis Quality

Part One - America and Europe

Virtual Event
December 7 - 8, 2022
8 a.m. - 12:15 p.m. ET; 2 p.m. - 6:15 p.m. CET

Register: go.astm.org/d37workshop

The United National Drug Control Conventions permit the cultivation, production and utilization of cannabis for medical and scientific use. However, national regulations for cannabis-based product manufacture and quality control vary widely across countries, states, and territories. Similarly, requirements for importation and dispensing of cannabis-based products differ.

Industry and regulators face common challenges resulting from test methodologies that are not validated, inaccurate label claims for cannabinoid content (e.g., CBD and THC), and varying limits for microbial and chemical contamination. Likewise, emerging concerns related to synthetic minor cannabinoids (e.g., Δ8-THC) and impurities demand attention. Public standards that set specifications for identity, cannabinoid content, limits for contaminants and other quality attributes, are fundamental to meet these challenges and to conduct the necessary tests for quality attributes.

Addressing common challenges through harmonization and alignment of quality standards across jurisdictions would protect patients, promote research, and improve public health across the globe. Standards Development Organizations (SDOs) such as the US Pharmacopeia (USP), ASTM International, and the European Pharmacopeia (Ph. Eur.) are working to develop laboratory test methods and guidelines to help address pressing topics like quality specifications, packaging and labeling standards, operational best practices and more. Resources from other organizations such as the U.S. Food and Drug Administration (FDA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), European Medicines Evaluation Agency (EMEA), World Health Association (WHO), and Food and Agriculture Organization (FAO), and national monographs provide relevant information on quality attributes and risk-based testing.

This workshop will discuss standards and guidelines from USP, European Pharmacopeia, ASTM International, and other relevant organizations to help address the challenges related to cannabis quality. Science-based resources from these groups will be considered as we explore opportunities to harmonize the varying national requirements for cannabis quality for products intended for medical use and scientific research.

Toward the harmonization of cannabis product quality attributes – a workshop exploring existing data and identifying gaps to inform standards organizations, policymakers, and regulators.

Register Today!
go.astm.org/d37workshop

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DAY 1

REGULATORS PANEL — 8 a.m. to 10 a.m.
Opening Remarks
Chair: **Julio Sánchez y Tépoz,** M.Scs, JD, former Head Commissioner of COFEPRIS (Mexican Ministry of Health)

The panelists will present information on the regulatory framework for medical cannabis quality in their jurisdiction and the experiences in implementing the requirements (15 minutes each) followed by a panel discussion and Q&A on the challenges and gaps about medical cannabis quality (50 minutes).

Andrew Waye, Ph.D., Health Canada
Gillian Schauer, Ph.D., MPH, Cannabis Regulators Association, U.S.
Joao Perfeito, MSc, Brazilian Health Regulatory Agency (ANVISA), Brazil
Werner Knoess, Ph.D., Head of German Cannabis Agency BfArM (Federal Institute for Drugs and Medical Devices)

BREAK (15 MINUTES)

STANDARDS PANEL — 10:15 a.m. to 12:15 p.m.
Chair: **Robin J. Marles,** Ph.D., Health Canada

The panelists will present information on the standards resources (monographs, reference standards, guidelines) and the current priorities for cannabis quality from their organizations (15 minutes each) followed by a panel discussion and Q&A on the stakeholder needs and opportunities for harmonization of standards (50 minutes).

Nandu Sarma, Ph.D., US Pharmacopeia
David Vaillencourt, MSc, Vice Chair, ASTM Committee D37 on Cannabis
M.J. van de (Marco) Velde, Ph.D., Dutch Office for Medical Cannabis, the Netherlands
Jaume Sanz-Biset, Ph.D., Ph. Eur., European Pharmacopoeia (EDQM), France

DAY 2

INDUSTRY PANEL — 8 a.m. to 10 a.m.
Chair: **Holly Johnson,** Ph.D., American Herbal Products Association

The panelists will present information on the industry experiences in meeting regulatory requirements and in utilizing the available standards for medical cannabis quality (15 minutes each) followed by a panel discussion and Q&A on the current gaps and industry needs for standards and whether (and how) harmonization of standards will help industry and public health (50 minutes).

Alan Sutton, Jazz Pharma, UK
Tjalling Erkelens, Bedrocan, the Netherlands
Marcel Bonn-Miller, Ph.D., Canopy, Canada
Prof. Giovanni Appendino, Indena, Italy

BREAK (15 MINUTES)

LABORATORY PANEL AND DISCUSSION ON KEY ISSUES
10:15 a.m. to 12:15 p.m.
Chair: **Martin Woodbridge,** PGC.PHC, DPH, MPHC, Woodbridge Research

The panelists will present information on the practical implications of standards for cannabis quality from a laboratory perspective (15 minutes each) followed by a panel discussion and Q&A on the challenges identified for laboratory services.

Mahmoud ElSohly, Ph.D., University of Mississippi, U.S.
Chris Hudalla, Ph.D., ProVerde Labs, U.S.
Remco Vree Egberts, Ph.D., Ofichem, the Netherlands

A wrap-up discussion, with all panel chairs and the organizers on the key issues identified during the previous three panel discussions, to help determine the next steps to achieve the workshop objectives (50 minutes).

Objectives

- Obtain awareness of the existing data, regulatory framework, and public policy for cannabis quality, public quality standards, and policy guidance documents on defining cannabis product quality attributes globally – initially from an American and European perspective.
- Understand the scientific basis for standards to explore potential harmonization amongst the standards groups.
- Facilitate discussions between stakeholders to identify needs and challenges related to cannabis quality.
- Identify areas of global data gaps to inform future standards and research needs.

Who should attend?

- All cannabis industry stakeholders, professionals, and regulators will benefit from joining this workshop as they are all affected by quality requirements.
- Quality control and quality assurance professionals, scientists, researchers, laboratory personnel, healthcare practitioners, consultants, and regulators will gain invaluable insight on cannabis quality and standards.