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Outline

- Company Background
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 - History
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- Status of Cannabis Testing in US
- Gap Analysis
- Working Together

Company Background

The Problem...

As states legalized cannabis use for medicinal and personal use, several mandated that some or all cannabis products must undergo quality control testing (QC) to ensure product safety and efficacy, however...

- Federal Government prohibits marijuana usage, therefore, states could not turn to the FDA for guidance in setting up rules and regulations for QC labs.
 - All DEA licensed laboratories, such as toxicology, pharmaceutical, environmental, etc., are barred from servicing the marijuana market
- The few “licensed” third-party labs in existence are having difficulty working with states to set “harmonized” testing standards.
 - Current laboratories are not equipped with suitable testing methods to meet quality control (QC) state regulations

Leaves public vulnerable to low quality and unsafe marijuana products



History

Connecticut

- Obtained Drug Control License in 2013 (first such license in US)
- Conducted over 20k R&D tests
- Collaborate with Department of Consumer Protection and Health Department
 - Heavy Metal
 - Pesticides
 - Microbiology
 - Water Activity
 - Storage and handling of baked goods
- Provide testing services to 3 of 4 production facilities

Florida

- Submitted initial public comments to Health Department in 2014
- Participated in multiple “stakeholders” meetings
- Helped draft testing regulations for Amendment 2
- Provide testing services to CHT Medical

Quality Control Testing Services

Microbiology

Mycotoxins

Water Activity

Pesticides

Heavy Metals

Residual Solvents

Terpenes

Cannabinoids



Microbiology Laboratory

- CT Health Department BSL2 Certified
- USP <1111> (pharmaceutical grade)
 - Pharmaceutical grade
 - Total Aerobic Microbial Count
 - Total Yeast and Mold
 - Specific Organisms
 - *Pseudomonas aeruginosa*
 - *Staph. Aureus*
 - Gram negative
- Mycotoxins
 - Aflatoxin B1, B2, G1, G2
 - Ochratoxin A
- Water Activity



Inorganic Chemistry Laboratory

- Inductively Coupled Plasma Mass Spectrometry (ICP-MS)
 - Heavy metal contamination
 - Cadmium
 - Lead
 - Mercury
 - Arsenic



Organic Chemistry Laboratory

- High Performance Liquid Chromatography (HPLC)
 - Cannabinoid content analysis (potency)
- Gas Chromatography Mass Spectrometry (GC-MS)
 - Terpene content analysis
 - Residual solvent analysis
- Tandem Mass Spectrometry (MS/MS)
 - Pesticide residue analysis



Team Members

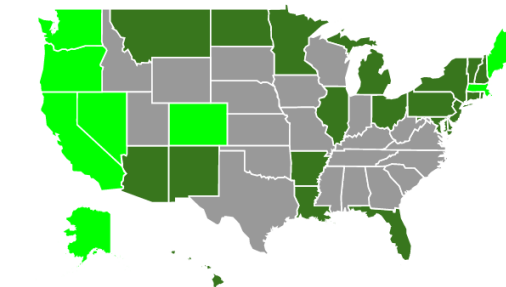
- Jennifer Beaty; Administrative Assistant (UCONN)
- Ashley Clemens; Microbiology (UCONN)
- Lorena Tamayo; Microbiology (UCONN)
- Ewelina Pliszka; Organic Chemistry (UCONN)
- Hillary Galanos; Organic Chemistry (CCSU)
- Raina Boyle; Organic Chemistry (CCSU)
- Linbin Zhang; Inorganic Chemistry (Chinese Academy of Sciences, Beijing, China)
- Melanie Fensick; Operations Manager (University of Hartford)

Mission

“Our mission is to deliver accurate and expeditious results to our customers by applying hi-tech analytical tools and technologies, employing highly qualified personnel, and focusing on patient safety, customer service, research, and education.”

Status of Cannabis Testing In US

State	Testing Required?	Lab Type	Products Tested	Type of Testing
Arizona	No	No testing is required	None	N/A
California	No	No testing is required	None	N/A
Delaware	?	Independent Laboratory/State Laboratory	Infused Ingestibles / Extracts / Usable Flower	DHHS may select a random sample for testing. Results will compare to results obtained by producer. Producer chooses what to test for. Pesticide use if prohibited. DHHS will test facility for pesticide contamination
Florida	Yes	Internal Laboratory	Infused Ingestibles / Extracts	Producer chooses what to test for. Third-party lab audits batch records only.
Hawaii	?	Independent Laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination
Maine	No	No testing is required	None	N/A
Michigan	No	No testing is required	None	N/A
Montana	No	No testing is required	None	N/A
New Jersey	Yes	State Laboratory	Infused Ingestibles / Extracts / Usable Flower	MAY INCLUDE: Potency / Homogeneity / Contamination
North Dakota	?	Independent Laboratory	Infused Ingestibles / Extracts / Usable Flower	DHHS may select a random sample for testing. Results will compare to results obtained by producer. Producer chooses what to test for. Pesticide use if prohibited. DHHS will test facility for pesticide contamination
Rhode Island	No	No testing is required	None	N/A
Vermont	No	Independent Laboratory	Infused Ingestibles / Extracts / Usable Flower	Testing only when there is a customer complaint



Marijuana Legalization Status

- Medical marijuana broadly legalized
- Marijuana legalized for recreational use
- No broad laws legalizing marijuana

<http://www.governing.com/gov-data/state-marijuana-laws-map-medical-recreational.html>

State	Testing Required?	Lab Type	Products Tested	Type of Testing
Connecticut	Yes	Independent Laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contaminants; no third-party accreditation
Colorado	Yes	Independent Laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination
Massachusetts	Yes	Independent Laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination
Minnesota	Yes	Independent Laboratory	Extracts	Potency / Homogeneity / Contamination
New Hampshire	Yes	Independent Laboratory	Extracts / Usable Flower	Potency / Homogeneity / Contamination; Inadequate sampling protocols may compromise results
New Mexico		Independent Laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination; Inadequate sampling protocols may compromise results
New York	Yes	Independent Laboratory	Extracts / Usable Flower	Potency / Homogeneity / Contamination; Inadequate sampling protocols may compromise results
Oregon	Yes	Independent Laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination; Inadequate sampling protocols may compromise results
Washington	Yes	Independent Laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination; Inadequate sampling protocols may compromise results

State	Testing Required?	Lab Type	Products Tested	Type of Testing
Alaska	Yes	Independent laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contaminants
Illinois	Yes	Independent laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination
Maryland	Yes	Independent laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination
Nevada		Independent laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination
Pennsylvania	Yes	Independent laboratory	Infused Ingestibles / Extracts / Usable Flower	Potency / Homogeneity / Contamination;

Gap Analysis

What Is Missing...

- Lack of defined parameters
 - Sampling guidelines
 - Batch Size guidelines
 - Standards
 - USP, FDA, EPA, USDA
- Lack of accountability
 - Third-party accreditation
 - ISO/IEC 17025
 - National Environmental Laboratory Accreditation Program (NELAP)
- Communication deficiencies
 - Inter-Lab Proficiency Testing
 - Lab and grower/producer
- Training
 - Quality Control
 - Quality Assurance
- Education
 - Conferences
 - Seminars



Working Together

Validation of testing methods

Laboratory accreditation

Focus on patient needs and **not** on THC levels

Establish focused guidelines

Accurate and reliable results

Prevent "race to the bottom"

Guarantee Patient Safety!
(avoid lawsuits)

Questions

