

Hemp & CBD: Analytical & Industry Updates



Presented by
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March 15th, 2022

Agenda

Testing Considerations

- Adapting to Industry Needs
 - Low Level Cannabinoids Testing
 - CDPHE Certification
 - GMP for APIs and OTCs
- Choosing a Reputable Lab

Industry Updates & Involvement

- US Hemp Authority
- Hemp Feed Coalition Efforts
- Hemp Industries Association



Testing for Cannabinoids

Standardized Method of Cannabinoid Analysis

- AOAC International announced the approval of Official Method 2018.11 for detecting and measuring cannabinoids in hemp in April 2020
- Initially created and validated for dry weight cannabis flower
- Additional validation and approval to be used to evaluate all plant materials of hemp

Adapting to Industry Expansion

- Method extension to other matrices: oil, tincture, finished products, meal, topicals, gummies etc.
- LC/MS Validated Method for Lower Level Detection (especially for THC)
- LOQ of 1ppm or 0.0001% for 15 cannabinoids

CDPHE Certification

Pesticide Challenges

- Complexity of matrices
- Full pesticide panel as per 6CCR 1010-21, 21.7
- LOQs

Other contaminants

- Heavy metals
- Mycotoxins
- Residual Solvents



GMP/OTC - OTC Lifecycle



21 CFR 210. Current Good Manufacturing Practice in Manufacturing Processing, packing, or Holding of Drugs
 21 CFR 211. Current Good Manufacturing Practice for Finished Pharmaceuticals

Quality Management System

Validated Software Systems and Equipment

State-of-the-art technology and systems to comply with 21CFR Part 11

Test Methods

Determine test suitability per matrix and verify through controls and proficiency testing

Measurements Traceability

Reference standards and materials enable us to establish controls that verify performance

Teams

Members demonstrate a track record of scientific excellence and a breadth of industry insights and experience

- ✓ Validated systems
- ✓ Centralized IT infrastructure
- ✓ Redundancy
- ✓ **One Quality System**



Choosing a Reputable Testing Lab

Transparency

- Audit your lab
- Ask questions

Quality

- Written QA Manual & SOPs
- Method Validations for your specific matrices

Consistent Turn-around-time

- Confirm KPI for meeting stated TATs
- Confirm no capacity issues

Accreditations and Licenses

- ISO 17025
- DEA
- CDPHE

Support Services

- Technical Support for Troubleshooting
- Consulting and Regulatory Guidance

Red Flags

- Price is too good to be true
- Not sharing information

Industry Involvement



U.S. Hemp
Roundtable



USHA Certification Program

Program Standard 4.0 Coming Soon!

“The U.S. Hemp Authority® Certification Program is our industry's initiative to provide high standards, best practices, and self-regulation, giving consumers and retailers confidence in hemp and CBD products.”



Hemp Feed Coalition

First ingredient application in the US submitted for hemp to be federally approved as a feed ingredient for laying hens



The submission is a culmination of a two-year long effort, consisting of an ingredient investigation of hemp seedcake and meal and a clinical trial to demonstrate the safety and efficacy of hemp for laying hens.

Hemp Feed in Trials

- Colorado State University –Hemp seed meal to lambs
- Kansas State University –CBD Flower to beef cattle, and spent biomass for rumen (microbiome)
- Oregon State University –Spent biomass to lambs, poultry, dairy cattle, and horses
- North Dakota State University –Hemp seed meal to beef cattle
- Tuskegee University –Hemp seed meal to goats
- North Carolina State University –Hemp seed oil to horses
- Tarleton University –Hemp seed meal to rabbits
- Central State University –Hemp heart protein to Rainbow Trout

Hemp Industries Association



**A purpose-driven trade association with
Business & Farming members who support ethical, sustainable,
and transparent trade practices**

HIA is governed democratically by its members, which includes setting the organization's nonprofit mission:
To advance the hemp economy and educate the market for the benefit of our members, the public and the planet.

Thank You!



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