

FDA Compliance

What you need to know to have a compliant facility and be ready for FDA regulation





Alley Background

- First Marijuana Specialist title for a Public Health Authority in the nation. Denver CO.
- Restaurant health inspector before regulating cannabis- CP-FS, CQA.
- Removed contaminated cannabis to ensure public safety.
- Founded Alley Consulting - supporting the industry in safeguarding customer safety while maintaining profits. Denver CO, and Portland OR.
- Instructor at cannabis universities, on company Advisory boards, Denver Cannabis Sustainability Work Group Member, DDPHE Health and Safety Advisory Board, CDPHE Science and Policy Work Groups, CO CHAMP workgroup, ASTM Cannabis advisory Committee.



**THIS TOO
SHALL PASS.**

**IT MIGHT PASS
LIKE A KIDNEY
STONE.**

but it will pass.

Regulations, Crazy Right?

- Regulations exist because something bad happened to someone.
- Regulations are there to protect consumers and companies.
- Understand the “why” is important with regulations.
- Regulators are not to be feared!

Food Safety and Cannabis

- Food safety should be #1 priority to both consumers & companies
- Safe food practices can save a business from liability issues
- Cannabis is given to vulnerable populations - immunocompromised, elderly, and children
- Cannabis can be used as medicine and should be held to higher standards
- All of us, including businesses, share in the responsibility of a safe community



Do your Homework - Buying and Manufacturing



Consumers may not know what's safe

- Most states & counties currently aren't regulating food safety and/or worker safety.
- Retailers should do their homework before selling.
- Manufacturers should follow general regulations for consumable products.
- Ask local health department questions, read regulations, hire a professional, pay attention to recalls – lessons learned!

Cannabis oil

- Contamination
- Shelf Stability – c.bot
- Approved source
- Commercial grade extractors
- Food grade solvents
- Smoking only vs. Edible oil
- Testing and CBD oil - Arsenic, Mercury, Copper, Lead



Ingredient Sourcing



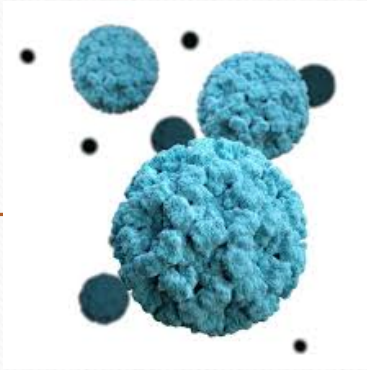
- Unapproved Sources
- Food Grade Ingredients Only
- CBD - Denver approves source in a unique way
- Terpenes
- Flavorings - Essential Oils
- Other Ingredients
- Vaping Additives - Safe?

Facilities

- Smooth easily cleanable surfaces
- Commercial grade kitchen equipment
- Hand washing- hot water, soap, paper towels
- Sanitization- extraction equipment to avoid cross contamination
- Labeling of toxic chemicals
- Employee personal items



Contaminant Dangers



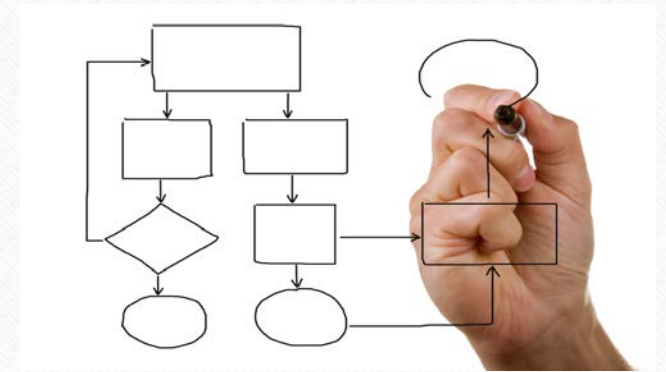
- Bacterial- C. Bot, Listeria, E. Coli, Salmonella
- Viral- Noro Virus, Hepatitis A
- Sick policy in product kitchen
- Molds and Mycotoxins
- Pesticides- Testing, recalls and disposals
- Heavy metals- Chromium, Mercury, Arsenic, Lead, etc.
- Solvents- Butane, ethanol, Pentane, etc.
- Regulatory gap- Hemp isn't regulated fully

cGMP Compliance

- cGMP -Current Good Manufacturing Practice Regulations published by the FDA under the Federal Food, Drug, and Cosmetic Act.
- GMP ensures the quality of drugs, medical devices, dietary supplements and some types of food.
- The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.
- GMP is the proactive part of quality assurance. It is designed to minimize the risks involved in all steps of the manufacturing process.

GMP Includes

- FDA does not certify companies for GMP
- A company must be audited and certified by an accredited certifying body to obtain GMP certification.
- Standard operating procedures- all products and processes
- Food Safety Plan – includes aspects of HACCP Plan
- Emergency action plans
- Logs - lots of them!



Innovative Industry = Interesting Infused Products

- No studies available for the different routes of entry - vaping, lubes, suppositories, etc. Innovation with lack of scientific data.
- Many unstudied cannabinoids and compounds in cannabis.
- Colorado recently added “Audited Products” to regulations for THC products.
- Percentages of terpenes added into products - unnatural levels?
- Hemp - No regulations or testing requirements!
- What about worker safety/OSHA?



Agencies to be Aware of

- Hemp Regulatory Department- Department of Agriculture
- Local health department- Based on County or City
- FDA- Federal in manufacturing, packaging, processing, extraction.
- USDA- Federal Cultivation facilities
- Fire Departments- Extractions with hydrocarbons, CO2, ethanol, etc.
- Building/Zoning/ Local licensing
- OSHA- Federal covers worker safety
- Local department of agriculture- If there is a local jurisdiction
- Your province or town may have additional agencies

What lies ahead?

- More manufacturers are taking responsibility
- More consumers are becoming educated
- More health departments are becoming braver
- More departments are reaching out and learning
- FDA regulation will happen eventually- Hemp soon
- Form good relationships with your regulators



Thank you!

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