Lanton Law Blogcast



Lanton Law presents our latest Blogcast with David Vaillencourt, the CEO and Founder of The GMP Collective.

David will be answering questions about the cannabis industry. What are the main challenges? Lessons learned from his experiences in the industry. What are the emerging regulatory interests?

The GMP Collective, is a leader in helping to create and maintain standards, strategies and compliance for cannabis companies.

DAVID VAILLENCOURT, M.SC., FOUNDER AND CEO OF THE GMP COLLECTIVE

What are the main challenges that cannabis stakeholders face from a compliance standpoint?

There is no shortage of challenges cannabis stakeholders face from a compliance standpoint. They especially vary between jurisdictions. However, there are two fundamental challenges we always see:

- 1. The ability to understand and confidently interpret the regulations
- 2. The awareness of the regulations that apply to their business as regulatory compliance is much more than just the state cannabis board

First, interpreting and understanding the regulations. Most people don't grow up spending their time reviewing law and understanding the difference between statutes and regulations let alone interpreting them. Many people take their best guess, and do largely okay. By the time they've successfully been licensed and operational for a year - most reflect on how much of a learning curve it was to dissect the language and nuance. It's always easier to pass an inspection the first time. Re-inspections allow opportunities for inspectors to pick up on other things they may have missed the first time (they aren't perfect either!). If you are unlucky enough to end up with

an inspector or code enforcer on a bad day, he or she can delay your opening by months if not years.

Word of advice - retain good legal counsel, hire people who have navigated this before, and commit yourself to learning enough to make informed decisions.

Not knowing and truly understanding the regulatory and statutory world leads me to my next point - cannabis compliance is not just meeting the requirements laid out by your state cannabis board! Most building and fire codes are managed at the local (i.e. not state) level. The Environmental Protection Agency (EPA) and Occupational Safety and Health Administration (OSHA) are also two big federal players that carry significant weight and discretion to enforce and fine businesses. The Food and Drug Administration (FDA) has issued numerous warning letters to cannabis and CBD companies (known as 483 warning letters). Just because cannabis is still considered federally illegal because of the Controlled Substances Act does not mean federal agencies aren't turning a blind eye to enforcing. After all, fines can be a significant revenue stream for agencies amidst continuous budget constraints. If you are still not convinced, just remember the three lettered agency that is arguably the biggest benefactor financially from state cannabis markets, to the tune of billions of dollars per year -- the IRS.

The takeaway - Do your due diligence and work with a seasoned business and law firm that can keep you on the right side of compliance with all rules and regulations, not just your state cannabis board!

What important lessons have you learned from the industry being in Colorado?

Many people are surprised to learn that the majority of our team's work has been outside of the State of Colorado, despite calling Colorado home. Some of our biggest projects have been internationally - most notably in Canada and COlombia. This is nothing against the Colorado market - it has its own merits and challenges just like any other market. Colorado is unique in that, being one of the oldest regulated markets relatively speaking (tied with Washington state for the first recreational cannabis market in the US), it has developed into a thriving craft and small business friendly market although market maturity and consolidation continues to change. The regulations were not developed with product quality and good manufacturing practices in mind, and revising statutes is a slow process once established. States with more recent legalization efforts have learned from this and incorporated requirements of Good Manufacturing Practices, including Florida and Michigan. With more states adopting these best practices every day, we continue to watch companies struggle to shift cultures and adopt these best practices. It's not going to be an easy road. MPG Consulting and the University of Colorado Boulder Leeds School of Business published a report in the fall of 2020 on the state of the cannabis market in Colorado, which can be found on the state's website for free here.

To answer the question more directly, I would say that I have learned that culture runs deep, the majority of the people that work in the industry do so out of passion and pride, not just because it is a job. And, while difficult to quantify, you cannot discount the safeguards that are put in place when you know your team is committed and passionate about the product you are making - whether it be a widget or a cannabis product. As the industry continues to grow and mature, I am optimistic that the passion will continue to drive improvement in product quality, safety, and adoption of best practices - something which the industry continues to struggle with.

What advice would you give to an emerging cannabis stakeholder?

First, ask yourself WHY. Why do you want to be a cannabis stakeholder? Why are you here? What do you have to offer? This is not to discourage anyone, but rather to make sure they think critically. This is not just another job or another opportunity. There are certainly no shortage of publicly traded companies recruiting with promises of significant wealth and opportunity. However, almost all have cash negative operations without a proven and viable pathway to profitability. Do your homework. Join industry groups. Ask questions. Build your network and team with skillsets that complement yours and fill the gaps you have.

Start with the end in mind. What is your goal and your 5-year plan. Do a market assessment and know what will differentiate you and your brand. Look to other industries to understand where the future of cannabis is likely to be. Beer, wine, and consumer packaged goods are 3 industries that everyone should understand at a fundamental level. For example - MolsonCoors is successful, but so aren't the thousands of craft brewers. The craft beer industry works hard to differentiate their products. They collaborate with other breweries, have strict controls in place, carefully source their raw ingredients such as hops and grains to make unique products, and they seek data on their consumer preferences.

This could be boiled down to - collect and review data - all the time! It will help you make informed decisions.

What are some of the emerging regulatory entities a cannabis stakeholder should be aware of?

Keep your eyes and ears tuned to the federal agencies such as the FDA and DEA. In the ASTM International, a 120-year old globally recognized consensus standards development organization formed the D37 Committee on Cannabis in 2017, providing a balanced forum for all interested stakeholders to develop standards for industry adoption. With over 1000 members across 30 countries - it is only a matter of time before regulators across the nation and world codify into law these consensus standards, solving the challenges of international trade and product safety. For businesses looking to demonstrate compliance and stay ahead of regulations, ASTM has launched its Cannabis Certification Program with support of several regulatory and enforcement agencies. Operators can now become certified with a mark of trust that shows due diligence and risk mitigation - which benefits business bottom line and can be the difference between a major inspector fine and leeway because the systems are in place to rapidly correct accidental violations.

In the meantime - the DEA and FDA have developed robust frameworks for developing, vproducing, and distributing controlled substances for various medical and research purposes. If companies truly want to be positioned for the long haul in the medical cannabis space, they should be familiar with the FDA's document published in 2016 - Botanical Drug Development: Guidance for Industry.

Again, it's common that we hear frustrations from the industry about these guidance documents -- that they are too vague or not helpful. For someone new to the world of the FDA, of course they are vague and difficult to understand! Refer back to my comments in question number one. Every day, companies and researchers successfully navigate this process and follow the guidelines of the FDA and DEA. It is an investment, but when put in context of the amount cannabis companies have invested in unproven technologies and other mistakes, it is one that will pay off significantly.

Regardless of whether medical cannabis is your path or not, be an informed member of the industry. Attend workshops and webinars, ask questions of other experts, and do your market research. Vet your consultants and future employees, ask for references, and most importantly, enjoy the ride!