Newly regulated industries, such as cannabis, must deal with establishing standardized protocols with the prospect of regulations changing quickly and evolving as the industry expands. With the legalization of cannabis in Canada in October 2018, labs needed to be ready for an influx of customers and ensure the products going to market were safe for consumers.

In 2017, with the intent to mainly serve hemp and cannabis customers, Kaveh Kahen co-founded Sigma Analytical Services in Toronto with Ashton Abrahams. “There was this big opportunity to address the needs of that market,” says Kahen. “And considering my past experience with analytical instrumentation, particularly within cannabis markets, I decided to start a lab and it has been very successful.”

When first working to get the lab up and running, before even beginning to establish testing protocols, they needed to acquire all the necessary licenses from the Canadian government.

“In our case, getting all the licenses took much longer than expected,” he says. “There was a new division under Health Canada that was created to focus on the cannabis market, and it took us almost a year to get our cannabis license. We actually got our controlled substances and pharmaceutical licenses much faster, so we could work in those areas.”

**Accelerating Method Validation**

Kahen explains that their first year was spent setting up the lab and validating methods—during which Sigma Analytical Services didn’t bring in any revenue, putting pressure on establishing both cannabis, hemp, and controlled substances methods quickly.
“Although I was very familiar with the instrumentation, the methods, and the market, it still took us a year to validate all our methods,” he explains. “That’s the part that many new entrepreneurs who jump on this don’t know. It takes a lot of time to validate methods.”

But by gaining insights from other cannabis industry experts, the lab was able to establish a robust workflow.

“Through PerkinElmer’s experience in pesticide testing and cannabis testing, we were able to accelerate ramping up our lab,” he says. “Working with them was really helpful for us because they are one of the pioneers in the cannabis industry so they had experience in the U.S. we could relate to.”

By the time PerkinElmer began working with Sigma Analytical Services, they already had collaborations with laboratories in California and Oregon, two of the first states in the U.S. that legalized cannabis.

Ensuring Compliance in a Complex Environment

In a highly regulated industry like cannabis, labs need to keep compliance in the front of their minds when building their business. At Sigma Analytical Services, Kahen says that with their three licenses, they have several audits a year, each requiring different protocols and information to be gathered. Using instruments that keep logs both in the cloud and on their server facilitates this process immensely.

The cannabis and hemp industries are also complex and have diverse products—labs must be able to test anything from a CBD-infused drink to a CBD-infused bath bomb. And while the protocols for testing those two products will be different, they all must comply with Canada’s laws and good manufacturing practice (GMP).

“We are one of the go-to labs when you are dealing with very difficult samples,” says Kahen. “This market is challenging because every day there is a new product that’s being infused with CBD—sports drinks, toothpaste, bath bombs—in addition to the typical vape pens and edibles we see. We are GMP compliant in all of these categories despite all these challenges.”

Relying on Experience

When establishing a new company in a newly regulated industry, Kahen trusted PerkinElmer as an experienced authority in application and method development and validation to help Sigma Analytical Services not just get off the ground, but as reliable experts to return to in the future.

“All my major analytical equipment is PerkinElmer,” he says. “Our experience with the IR platforms and the NexION ICP-MS platform were spectacular. The service engineer and application scientists who helped train our team all were highly competent and knew exactly what they were doing. The software is 21 CFR part 11 compliant and this is important. It has been a world class experience. I don’t think any other instrument manufacturer can meet this—and that was just in the first year.”

PerkinElmer with more than 70 years of experience developing and supporting analytical instruments and solutions are an invaluable partner in setting up any new laboratory, whether it is a laboratory under significant regulation such as Sigma’s Analytic Services to research laboratory in academia to a QA/QC laboratory in industry.