E4 Bioscience
The Cannabis Laboratory Experts

BLUE PAPER

Cannabis Laboratory Planning, Design, Licensing, Instrumentation, and Staffing

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Executive Summary

The legislative requirement for laboratory tested cannabis follows legalization of medical and recreational use in every US state to date. Cannabis safety testing is a new investment opportunity within the emerging cannabis market that is separate from cultivation, processing, & distribution, allowing individuals and organizations who may have been reluctant to enter previously a new entry route to the cannabis space. However, many of the costs, operational requirements, and compliance issues are not well understood by people who have not been exposed to laboratory testing.

The purpose of this blue paper is to highlight some of the fundamental strategies and tactics used by clinical diagnostic laboratories that directly apply to cannabis testing laboratories and provide recommendations to avoid common – but expensive – mistakes. The blue paper is not meant to be an exhaustive and detailed review, but rather provide an overview of some of the key points. It will cover:

- Business planning and financial modeling.
- Laboratory planning and design.
- Applying for a cannabis testing license.
- Accreditation, compliance, and regulatory oversight.
- Instrumentation selection.
- Staffing.

Business Planning and Financial Modeling

Business plans help cannabis investors plan for success. While operating a cannabis safety testing laboratory is gaining popularity as an investment vehicle for entrepreneurs and larger investment groups, laboratory testing is complex and expensive. Without prior knowledge about clinical or environmental laboratory testing there is a new set of terminology to learn and many hidden costs. A business plan is an essential document that should not overlooked for the sake of speed. E4 Bioscience believes that a careful examination of the anticipated start up or pre-revenue costs, the ongoing operating costs once the lab is testing samples, and realistic revenue projections will reduce the risk of undercapitalization. By taking the time to understand the scope of the applicable laws, market, financial projections, and operating challenges, investors can better understand the legal, financial, and operational risks of entering into the cannabis laboratory space.

Legal

One key restriction to understand before any work is contemplated is that the legislative intent of many states is to disallow ownership in both safety testing laboratories and cultivation/processing/dispensary businesses. If an investor has current ownership interests in the cannabis space, E4 Bioscience strongly recommends consulting with an attorney to understand the legality of participating in a testing laboratory.

Market Size

Until major legislative changes occur, the market size is determined by the state the laboratory is located in. While states are legalizing cannabis and providing certain business protections, it remains illegal to transport cannabis across state lines. This means that the theoretical market can be estimated by determining the total number of indoor and outdoor square feet permitted for growth, applying constants to estimate the amount of harvested cannabis flower per year, dividing by the state legislated batch size, and multiplying by any mandated replicate testing to derive the potential number of samples to be tested on an annual basis. The potential number of annual samples multiplied by the amount a laboratory believes they can secure for an accredited test is the total theoretical revenue for any given state. If a laboratory can make rudimentary predictions about market share, then total laboratory revenue can be estimated. E4 Bioscience believes that laboratory testing will become a commoditized service, and that over time significant downward pressure on testing reimbursement will occur.

Revenue

We conducted a pricing review of randomly selected laboratories in states that have legalized recreational cannabis use to determine the current average reimbursement for testing. The following terms were entered into a Google search: “Cannabis” and “Laboratory” and “Price” and “List” and “[Full state name with recreational use legalized status]”. All of the first page links (10) were reviewed for pricing information. Laboratory name, state, broad testing category, and a rollup comprehensive state mandated compliance safety test pricing that would mirror the state of CA requirements were charted. E4 Bioscience noted that many labs we expected to appear on the first Google search page did not. We suspect that some prominent labs could significantly improve visibility by better search engine optimization.

It was difficult to compare “apples to apples” as state mandated tests and action limits are different. As currently the state of CA has the most stringent testing requirements nationally, all efforts were to identify the combination of tests that meet CA guidelines to normalize for testing requirements.

Of the 31 laboratories that were identified, only 15 provided pricing information. Using available pricing information, the following testing averages were calculated:

- Flower $ 395.13
- Concentrate $ 389.60
- Edible $ 326.27
- Single Test $ 104.57

That less than half of the laboratories identified posted pricing information is confusing to E4 Bioscience. This approach makes it necessary for cultivators, processors, and manufacturers to contact the laboratory. In an era of transparency and the Internet, not posting testing prices is a surprisingly antiquated business strategy.

Start-up costs

Start-up costs for a cannabis testing laboratory can vary widely, but the primary drivers are instrumentation selection, the extent of tenant improvements that are needed, and licensing application preparation costs. Cannabis laboratories are highly specialized and require certain tenant improvements that are not considered for most commercial businesses. The details are discussed in the "Laboratory Planning and Design" section. Cannabis testing requires multiple pieces of highly sophisticated instrumentation. The details are discussed the "Instrumentation" section. And finally, unless an investor has previous regulatory filing experience, an applicant may find the process to be complex, requiring multiple checklists, and discover conflicts between forms, guidance documents, and approved regulation. This is discussed in more detail in the next section, "Applying for a Cannabis Testing License".

Table 1: Estimated start costs for key cannabis laboratory buildout activities

Major startup activity expenses	Low estimate	High estimate
Equipment purchase	$ 450,000.00	$ 2,000,000.00
Tenant improvements	$ 200,000.00	$ 2,000,000.00
Consulting/legal fees	$ 20,000.00	$ 100,000.00
State and municipal license application fees	$ 5,000.00	$ 20,000.00
Inspection fees	$ 5,000.00	$ 15,000.00
Total:	**$ 680,000.00**	**$ 4,135,000.00**

Pre-launch costs

After laboratory construction/tenant improvements are complete and instrumentation has been installed, there will be a period of time when intense focus will be placed on testing validation and other pre-inspection activities necessary for state laboratory licensing. During this time, the laboratory will: need to be staffed at operational levels, consume laboratory reagents, and require all systems be tested for go-live functionality. Many owners and investors find this a frustrating time since the entire laboratory operation needs to be supported without income. The time between buildout and first state compliant sample is measured in months, not weeks, and investors need to ensure there is sufficient capital to cover these operational costs. The principals of E4 Bioscience have owned and operated 3 diagnostic clinical laboratories and suggest this window averages between 6-8 months and is highly dependent on the quality and experience of the analytical staff that has been hired.

Post-launch costs

After the lab is approved by the state and township to accept and test cannabis samples, the operating costs and projected income will ultimately determine long-term viability and profitability. Each laboratory will have a different cost structure, but ensuring a stable supply of samples, coupled with efficient and productive operations, should be a driving business philosophy.

After payroll/labor, which is typically between 30-40% of total expenses, the next largest expense is typically laboratory consumables. These include all of the solutions, solvents, plasticware, QC materials, mass spectroscopy columns, etc... that are used during the testing process and is usually about 10-20% of total expense. Together these two line items account for between 40-60% of the total laboratory expenses.

E4 Bioscience believes that the high cost of analytical instruments, the relatively low reimbursement (average of ~$370/test, table 3), and a shortage of skilled professionals are some of the major factors that will restrain the growth of this market in the coming years.

Table 2: Laboratories identified in Google search.

Laboratory name	State	Website information source
Steep Hill Alaska	AL	www.steephillalaska.com/wp-content/uploads/2017/10/SHA-LSA.pdf
Cascadia Labs	CA	www.cascadia-labs.com
Coastal Analytical	CA	www.coastalanalytical.com/services/pricing
Pharm Labs	CA	www.pharmlabscannabistesting.com
Sequoia Analytical Labs	CA	www.sequoia-labs.com
Agricor Laboratories	CO	www.agricorlabs.com/potency
Agriscience Laboratories	CO	www.app.hubspot.com/documents/2789888/view/36071835?accessId=b4e4ee
Gobi Labs	CO	www.gobilabs.com/services
PhytaTech	CO	www.phytatech.com/test-potency.php
RM3 Labs	CO	www.rm3.us/assets/rm3-labs-informational-packet-061219.pdf
Steep Hill Washington, DC	DC	www.steephill.com/locations/washington-dc
CDX Analytics	MA	www.cdxanalytics.com/index.php/about/laboratory-capabilities
MCR Labs	MA	www.mcrlabs.com/submit-a-sample
ProVerde Labs	MA	www.proverdelabs.com
ACT Laboratories	MI	www.actlaboratoriesinc.com
Iron Laboratories	MI	www.ironlaboratories.com/memberships
PSI Labs	MI	www.psilabs.org/services
The Spott	MI	www.hitthespott.com/wp-content/uploads/2018/03/price-sheet-2017-public.pdf
DigiPath	NV	www.digipath.com/cannabis-testing
MM Labs	NV	www.mmlabtesting.com/departments/
NV Cann Labs	NV	www.nvcann.com/services/summaries-of-tests
Green Leaf Lab	OR	www.greenleaflab.org/services
Iron Laboratories	OR	www.ironlaboratories.com/memberships
Juniper Analytics	OR	www.juniperanalyticsllc.com/services
Rose City Laboratories	OR	www.rosecitylabs.com/forms/index.html
Nutraceutical Science Laboratories	VT	www.nslvt.com/services
Analytical 360	WA	www.archive.analytical360.com/m/products/pricing-packages
Anatek Labs	WA	www.anateklabs.com/wp-content/uploads/pricelistholdingtime/price-list-cannabis.pdf
Confidence Analytics	WA	www.conflabs.com/testing-packages-pricing
Medicine Creek Analytics	WA	www.medicinecreekanalytics.com
Praxis Laboratory	WA	www.praxis-laboratory.com/pricing

Table 3: Laboratory pricing

Major startup activity expenses	Flower	Concentrate	Edible	Single test
Coastal Analytical	$ 899.00	$ 899.00	$ 899.00	$ 100.00
Rose City Laboratories	$ 685.00	$ 655.00	$ 700.00	$ 76.00
Iron Laboratories Michigan	$ 575.00	$ 475.00	$ 295.00	$ 245.00
Pharm Labs	$ 483.00	$ 520.00	$ 520.00	$ 100.00
Iron Laboratories Oregon	$ 450.00	$ 475.00	$ 440.00	$ 230.00
RM3 Labs	$ 450.00	$ 450.00	$ 450.00	$ 50.00
Juniper Analytics	$ 410.00	$ 410.00	–	$ 108.00
Steep Hill Alaska	$ 360.00	$ 360.00	$ 360.00	$ 92.00
The Spott	$ 360.00	$ 360.00	$ 360.00	$ 50.00
Agriscience Laboratories	$ 315.00	$ 315.00	$ 330.00	$ 65.00
Medicine Creek Analytics	$ 265.00	$ 265.00	$ 265.00	$ 265.00
Praxis Laboratory	$ 265.00	$ 265.00	$ 225.00	$ 42.50
Confidence Analytics	$ 190.00	$ 190.00	–	$ 50.00
Analytical 360	$ 120.00	$ 105.00	$ 50.00	$ 50.00
Anatek Labs	$ 100.00	$ 100.00	–	$ 45.00
ACT Laboratories	–	–	–	–
Agricor Laboratories	–	–	–	–
Cascadia Labs	–	–	–	–
CDX Analytics	–	–	–	–
DigiPath	–	–	–	–
Gobi Labs	–	–	–	–
Green Leaf Lab	–	–	–	–
MCR Labs	–	–	–	$ 50.00
MM Labs	–	–	–	–
Nutraceutical Science Laboratories	–	–	–	–
NV Cann Labs	–	–	–	–
PhytaTech	–	–	–	–
ProVerde Labs	–	–	–	–
PSI Labs	–	–	–	–
Sequoia Analytical Labs	–	–	–	–
Steep Hill Washington, DC	–	–	–	–
Average:	**$ 395.13**	**$ 389.60**	**$ 326.27**	**$ 104.57**

Laboratory Planning and Design

Because commercial structures are widely different, cannabis testing laboratories are always a custom build. Good laboratory design creates a safe and efficient workflow that contemplates many different needs. Some of the planning points include:

Key Design Points

- Minimizing staff movement.
- Providing for common and limited access areas.
- Separate areas for enclosed sample receipt, accessioning, sample storage, chemical and biological waste storage.
- Laboratory instrument infrastructure including power (220V and 110V), industrial gas (N2) generation and venting, HVAC systems for venting, benches, water for sinks, showers, eye wash stations.
- DNA extraction, pre-amplification, and post-amplification rooms for molecular testing that addresses unidirectional airflow recommendations.
- Comprehensive security plan for camera placement and limited access.
- Breakrooms and changing areas.
- Administrative offices.
- Sufficient parking.

If sufficient funding is available, it is worth the additional cost to improve the internal laboratory appearance. Many clients will want to conduct a laboratory site visit and a good looking, well kept space will help to demonstrate professionalism and sell its services. Furthermore, the first appearance will orient auditors to degree of concern the laboratory places on details.

While there are several architectural firms throughout the US with cannabis laboratory design and construction, E4 Bioscience has worked with Pumford Construction, LLC[1] and Pathangay Architects, LLC[2] and highly recommends both.

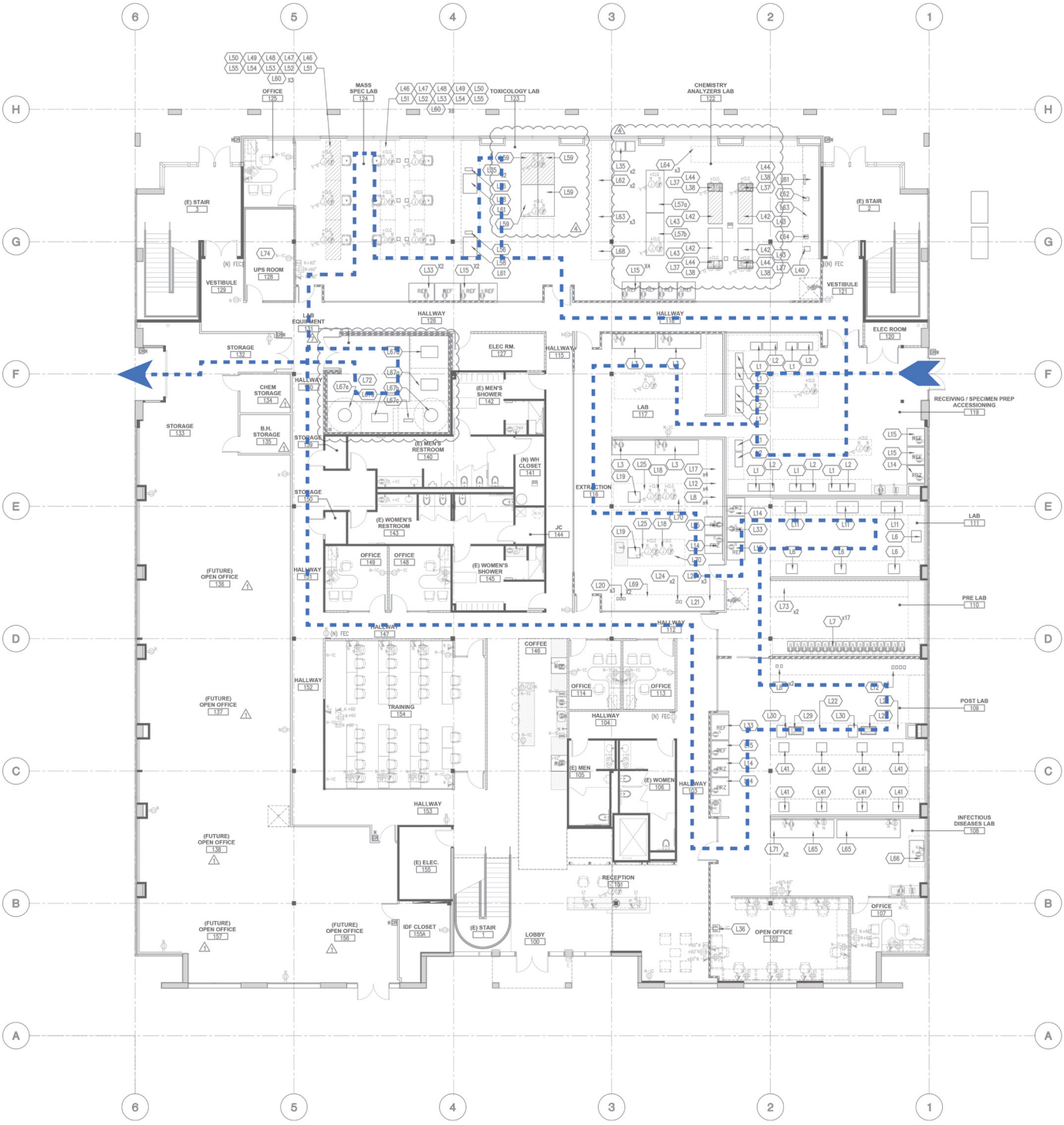
Workflow

Workflow is often overlooked in spaces that are being converted from general use into a laboratory. Ideally, a good laboratory design would a single path workflow in which samples and people move in a manner that limits retracing steps and with minimal distance between and in areas where the different pre-analytical, analytical, and post-analytical steps occur. Apart from complicating the limited access plan, it is not ideal for staff have to move potentially hazardous chemicals or to have to move from a "clean" lab area through a "dirty" lab area.

Figure 1 shows an example of a unidirectional workflow in a laboratory E4 Bioscience helped design. Samples arrive in a gated area through secure doors (F1) and are then transferred into an accessioning area (F2). Here they are divided into portions for microbial testing and analytical chemistry testing. Microbial samples pass into a staging area (F3). Once technicians are ready to test, they move in succession through a DNA extraction room (E3), pre-amplification room (E2), and amplification room (D2/C2). Once results are available, samples are moved out of the testing area to a waste storage area (F4/F5) and are ultimately transferred out of the building. Mass spectroscopy samples follow the other independent pathway and are joined with samples in waste storage for removal from the facility.

[1] http://www.pumford.com
[2] https://www.pathangayarchitects.com/cannabis/

Figure 1: Example of a laboratory with unidirectional workflow



Applying for a Cannabis Testing License

While cannabis testing may provide exciting financial possibilities, the pathway to opening a laboratory begins with obtaining a license. Licensure may seem like a straightforward process, but the reality is that obtaining a cannabis safety testing laboratory license is an expensive, time consuming, and challenging task. Cannabis safety testing is not a business that is "figured out as you go", rather, the application process demands a thoughtful, written plan that requires substantial upfront effort and supporting document preparation.

Application Sections/Information

Preparing to submit a cannabis safety testing application is a lengthy process. Even though states are highly motivated to approve applications to reduce the bottleneck in sample testing, a complete, accurate, and detailed application is a legal requirement. States and townships are working hard to provide support and guidance to applicants, however, E4 Bioscience has observed that minor modifications to application documents are common. Therefore, it is imperative to always download the most current application forms, or better, submit an electronic application when possible.

Because regulations are currently created by states, variations in application specific requirements are expected, but two general categories of information are common: 1) a pre-qualification phase that includes legal and financial disclosures, business background checks, and demonstration of financial security, and 2) a physical description of the facility and operations plan. In addition to state licensing, there is also likely to be township/municipal licensing requirements. Fortunately, the application information tends to closely mirror state applications. The pre-qualification phase is relatively straightforward as it relies on preexisting information. The second phase is future thinking and often requires the applicant to describe their plan.

The facility and operations sections commonly request demonstration of the following:

- Building zoning requirements.
- Architect stamped floorplan schematics.
- Security plan including limited access areas.
- Hazardous waste management plan.
- Quality management plan.
- Marketing and advertising plan.
- Standard operating procedures.
- Instrumentation/equipment.
- Staffing plan that includes credentialed and trained employees.

Timeline

It takes about 3-6 months of consistent effort to prepare and submit both the state and municipal applications. Some of the key determinants of time include: 1) the ability of business owners to produce documentation of their business history, financial strength, and litigation history. 2) prior experience and/or access to template documents that can be used as a writing roadmap. While obviously self-serving, E4 Bioscience believes that working with a knowledgeable consulting group will reduce the timeline by helping to decipher regulations and organize a prioritization plan for document procurement and preparation.

Accreditation & Compliance

Cannabis safety testing laboratories are highly regulated and require accreditation. Accreditation is the formal recognition from an agency or organization that provides oversight that a laboratory is able to produce accurate and defensible analytical data. An accredited laboratory has the technical proficiency to conduct an identified scope of work through standard procedures and protocols to meet defined quality standards. Accreditation requires a thorough evaluation of a laboratory's quality system, facilities and equipment, test methods, records, reports, and staff.

ISO 17025

The International Organization for Standardization (ISO) is an internationally recognized accreditation organization that sets standards that are meant to be applied consistently, irrespective of geographic location. In the analytical laboratory space, ISO 17025 is a widely recognized accreditation used in many industries including food safety testing and environmental testing. Every state that has approved cannabis use has also passed legislation requiring safety testing[1]. Although several cannabis laboratory accrediting organizations exist, many states have chosen to defer to ISO 17025 accreditation as the key requirement to transition from a temporary license to a full license. Furthermore, many clients will not work with laboratories that don't have ISO accreditation, even though they are legally allowed to offer testing services.

ISO 17025 can be summarized as a process for a laboratory to show that a quality system exists that can reliably detect and/or quantitate analytes of interest. In a cannabis laboratory examples include the percentage of THC and/or other cannabinoids, pesticides, heavy metals, residual solvents, microbial pathogens, moisture content, etc. ISO 17025 and subsequent accreditations are typically difficult to obtain, involve substantial labor, effort, and documentation, and require maintaining a high level of expertise and compliance post-accreditation.

AOAC International

AOAC International[2], formerly the Association of Official Analytical Chemists, develops voluntary consensus standards in accordance with the U.S. National Technology Transfer and Advancement Act of 1995 (PL 104-113) and U.S. Office of Management and Budget Circular A-119. AOAC provides a helpful guidance document that effectively interprets ISO 17025 guidance, "AOAC International Guidelines for Laboratories performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals – An Aid to the Interpretation of ISO/IEC 17025" (ALACC Guidelines)".

AOAC International has organized a new initiative, the Cannabis Analytical Science Program, to provide a forum where the science of hemp and cannabis, and the development and maintenance of cannabis standards and methods can be discussed. The CASP analytical community is comprised of government, academic, and contract laboratories; technology providers; private sector organizations; and allied associations[3].

ASTM

ASTM International[4], formerly known as the American Society for Testing and Materials, is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. ASTM formed Committee D37 on Cannabis to develop standards for cannabis, its products and processes[5]. The activities are focused on meeting the needs of the cannabis industry, addressing quality and safety through the development of voluntary consensus standards. Subcommittees will focus on the development of test methods, practices and guides for cultivation, quality assurance, laboratory considerations, packaging and security.

1 www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
2 www.aoac.org
3 www.aoac.org/AOAC_Prod_Imis/AOAC/SD/CASP/AOAC_Member/SDCF/CASP/CASP_Main.aspx
4 www.astm.org
5 www.astm.org/COMMITTEE/D37.htm

Culture of Compliance

A strong culture of compliance forms a solid foundation upon which a successful, safe, and respected laboratory can function. Common compliance activities include:

- Preparing for new accreditations, inspections, and audits.
- Writing, following, and documenting standard operating procedures (SOP's).
- Ensuring a safe working environment.
- Collecting, analyzing, summarizing, and sharing operational data.
- Performing regular proficiency testing.
- Investing in staff education and training.

A successful compliance program requires a daily commitment from everyone in the organization. It is essential that the executive management team and technical leaders of any laboratory are familiar with the expectations of, and fully support the time and cost of, a comprehensive compliance program. Unfortunately, compliance is not a revenue generating service line, so it is not uncommon, particularly during the "Pre-Launch Phase", for the executive team to want to take shortcuts with compliance activities. Failure to understand the basic safety and documentation rules is a key – and obvious – flag for external auditors. Most examples of cannabis license denial, suspension, or revocation can be directly linked to this major shortcoming. An audit violation becomes part of the laboratory permanent record and takes more time to fix retroactively than it does to do it correctly the first time. E4 Bioscience strongly recommends a laboratory hire an experienced and dedicated QA/QC manager and take the additional time whenever needed to prepare robust compliance documentation to avoid receiving a major audit violation.

Finally, large clinical diagnostic laboratories (>$10B valuation) such as Quest and LabCorp, have been operating for decades and can provide valuable guidance for the cannabis testing laboratory space. There is consistent overlap in their cost structure, operational requirements, and compliance needs that can be directly applied to cannabis testing. Cannabis safety testing labs would be wise to learn from clinical diagnostic laboratories. These laboratories often perform detailed mock inspections using external assistance to identify areas to strengthen before a live audit occurs.

Instrumentation

Cannabis and cannabis derived products generally require testing for the presence of five groups of compounds: pesticides, heavy metals, residual solvents, cannabinoids (THC primarily), and microbial pathogens. The instruments used to perform the first four categories of tests are predominantly based on spectroscopy technology, while microbial pathogens can be identified by traditional microbiology and/or molecular biology instrumentation/techniques. Choosing the appropriate instrument vendor/make/model for a particular test can be a daunting task, but several standard considerations will recur during most conversations with laboratory equipment manufacturers including: price, sensitivity, sample throughput, consumable cost, vendor support, maintenance downtime and difficultly, anticipated time to failure, software, and ease of use.

Mass spectroscopy cost vs. sensitivity vs. maintenance

Because it is common for new cannabis laboratories to significantly underestimate start-up costs, price is often cited as the primary consideration in instrument selection. As with most financial decisions, there is a performance trade-off for low or lower cost instrumentation. Some vendors can provide an analysis of state specific testing analytes, minimum action levels, and appropriate instrument pairing. In many states, this is not the most expensive alternative. When available, manufacturer refurbished and warrantied instruments are an excellent and cost efficient way to reduce equipment expense.

E4 Bioscience recommends purchasing the most sensitivity that can be afforded for any instrument. Lower cost invariably leads to lower sensitivity and throughput, faster time to failure, and more frequent maintenance. Higher sensitivity allows additional sample dilution, which provides for a cleaner sample being loaded onto the instrument. A cleaner sample leaves less matrix residue, which in turn reduces instrument maintenance. The goal of any laboratory is to reduce maintenance to a minimum, since any time maintenance is being performed testing is not. Furthermore, when limits of quantitation (LOQ's) are close to the low end of sensitivity, it is more difficult to validate a new method and the likelihood of reporting a false negative or false positive increases.

Vendors and support

Another important consideration is the level of vendor support. While vendors are willing to provide very helpful preventative maintenance plans or perform installation qualification and operational qualification (IQ/OQ), both are expensive and IQ/OQ is not necessary. While these technical support options can be useful, any assistance in method development and validation also has an inherent value. Developing new test methods is a complex and time-consuming task even for highly trained analytical chemists and microbiologists. Therefore, a high value should be placed on any intellectual assistance a vendor can provide. Of particular interest are boilerplate methods that can be followed and used as a foundation for SOP's, access to control material, educational seminars, and in-person training.

Several spectroscopy instrument vendors are positioning themselves for the cannabis laboratory safety testing market. The current market leaders include:

- Agilent: www.agilent.com/en/promotions/cannabis
- Perkin-Elmer: www.perkinelmer.com/category/cannabis-analysis
- Sciex: www.sciex.com/applications/food-and-beverage-testing/cannabis-testing
- Shimadzu: www.GrowYourLab.com

Staffing

Like any business, staffing is always a challenge. Staffing a cannabis laboratory shares many of the same issues that clinical diagnostic laboratories encounter. An important concern is that not unlike clinical diagnostic laboratories, because of technical, licensing, and accreditation requirements, a cannabis testing laboratory always works under the threat of being forced to temporarily cease operations if it doesn't have the required technical staff.

The key technical hires are highly educated, expensive, and hard to recruit. From a hiring standpoint, there are several position requirements that decrease the available pool of qualified applicants and increase the demand (and therefore cost) for their skill sets:

- Previous scientific and laboratory training with a specific emphasis on analytical chemistry and, separately, molecular microbiology.
- Analytical thinking and independent decision-making skills.
- Knowledge of compliance, quality, and regulatory framework.
- Leadership and management capabilities.
- Proximity to the testing facility: these staff cannot work remotely.
- A willingness to work in a start-up/new company environment.
- Acceptance of the risk and stigma associated with cannabis.

Critical laboratory hires

E4 Bioscience believes that all accredited cannabis laboratories will need two critical lead technologists: 1) a PhD trained (preferably) or MS trained analytical chemist with substantial experience in spectroscopic techniques and 2) a microbiologist, preferably with molecular biology training. While it may be tempting to reduce payroll cost by merging the two positions, the likelihood of finding a person with dual training is remote. Furthermore, the testing process is time consuming and it is unrealistic to think one person can perform all the testing needs and associated compliance activities alone. While it may be possible to fill additional laboratory assistant positions by someone without a laboratory background and provide training, the technical leads need to come with an immediately deployable knowledge base or the laboratory will struggle to bring the necessary equipment and technology online. Leadership qualities in the early hiring phases cannot be overemphasized. Any critical hire must have laboratory experience and demonstrate leadership qualities since staff throughout the organization will continually look to them for guidance. It should be generally expected that qualified technologists will require higher levels of compensation and flexibility to be recruited.

Because laboratory instrumentation requires ongoing maintenance, regular troubleshooting, and an intrinsic understanding of how it works to prevent extended downtime, independent problem solving and the authority to make critical laboratory operation decisions is an expectation for critical hires. One of the most important observations a lead technician will make is that a failed result could be the result of a process failure, rather than a sample problem. To confirm this suspicion technologists will need to be able to modify instrument settings, prepare new calibration standards, conduct additional experiments, and review and analyze data to identify possible causes. All of this is part of their scientific training; years of undergraduate and post-graduate training cannot be replaced by good intentions to learn. It should be noted that instrument manufacturers will provide technical support, but it usually comes at a significant time and financial expense. Manufacturers should not be relied upon for regular support.

Hiring clinical laboratory technologists (i.e. someone who has worked in a medical laboratory) will offer a significant advantage by bringing substantial experience working in a compliance driven environment. As previously discussed in the Accreditation & Compliance section, clinical laboratories work in highly regulated environments in which a culture of compliance is ingrained as an essential part of operations.

Additional hiring challenges

Location matters. Cannabis testing is a hands-on activity in which employees must be present in the laboratory. To reduce transport time, and therefore resulting turn-around time (TAT), many testing laboratories are built close to cultivators and manufacturers. While these locations may be financially appealing to laboratories, they are often rural and not close to academic or industrial centers.

Compensation matters. While the critical laboratory personnel need to be a major recruiting focus, general laboratory assistance including samplers, lab assistants, and administrative assistance should not be an afterthought. E4 Bioscience believes that paying someone minimum wage results in fast food restaurant level loyalty. A laboratory that wants long term commitment, adherence to compliance, and nimble action needs to pay overmarket rates, provide educational opportunities, and recognize that dedicated employees are harder to recruit than might be expected. Unlike fast food restaurants, where training is relatively quick and easy, a new hire in a cannabis laboratory must go through lengthy and rigorous security, compliance, and laboratory training.

Without any doubt, E4 Bioscience cannot over-emphasize the importance of beginning recruiting as early as possible and continuing to develop a pipeline of potential new hires that fits the culture of the company. The best-looking lab with the newest equipment cannot run a single test without competent, trained staff.

About E4 Bioscience

E4 Bioscience helps cannabis investors and laboratory teams design, build, equip, operate, market and maintain compliant cannabis laboratories. Whether a building a new lab or retrofitting an active lab, our team offers value based solutions to avoid delays, generate sustainable revenue, and maintain compliance.

Please contact us if you would like to schedule a 1-hour free discovery call or Webex.

If you found this helpful, have recommendations about how we can improve, or want to provide suggestions for topics you would like to read about in our next blue paper, we'd love to hear from you! If you found an error, outdated information, or would like to sponsor a blue paper, we'd like to know that, too.

Shaun R. Opie, PhD
CEO and Managing Partner

Dr. Opie is a cannabis ninja, science geek, and serial entrepreneur. He has co-founded and operated several laboratories in different verticals including research and development, clinical diagnostics, and cannabis safety testing. His ventures have all been privately held and performed regulated, high-complexity testing. His contribution to laboratory operations include business planning, laboratory design and construction, obtaining multiple accreditations and licenses, compliance, technology assessment and selection, assay design & validation, reimbursement strategy, staffing, and extensive content marketing.

Dr. Opie is committed to educating others and has held several adjunct faculty appointments at nationally recognized universities. He spent 2 years as an Entrepreneurship Expert at the W.P. Carey School of Business at Arizona State University to advise student and faculty entrepreneurs about business planning, financial modeling, pre-revenue venture funding, venture development and growth strategies. He is currently a participating member of the AOAC International - Cannabis Analytical Science Program, and a lecturer on cannabis laboratory compliance. He is an invited editor for a textbook being printed and distributed by the global publisher Springer Nature in Q4 2020 titled, "Cannabis Laboratory Planning, Design, and Operations".

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