CHOOSING AN

ANALYTICAL TESTING LAB

Choosing a testing lab has enormous ramifications for brands, manufacturers, and suppliers, directly impacting regulatory compliance, product quality, and consumer trust. It's critical to choose a contract lab with the expertise that fits your products and that can function as a true extension of your quality systems. We offer this guidance to help the industry navigate lab qualification and choose wisely, whichever lab you ultimately decide upon.

Key Topics

(Click to access or continue scrolling)

Testing requirements

Legal obligation to test
by Rend Al-Mondhiry

What to look for in a lab

Qualification questions

Developing a partnership

Risks of subpar labs

Contract manufacturing
by Len Monheit

FROM ALKEMIST LABS

TESTING REQUIREMENTS

FDA REQUIREMENTS

The Dietary Supplement Current Good Manufacturing Practice (cGMP) rule details several requirements for testing and documenting manufacturing quality process controls. While the regulations are prescriptive, the agency does not specify the analytical techniques, test methods to use, or exact parameters to be measured. Just because the regulations are somewhat vague about testing doesn't mean you can afford to be.

Many brands and manufacturers utilize third-party testing laboratories to comply with cGMP requirements whether they manufacture their products in house or rely on contract manufacturers. Brands also use contract labs to monitor and confirm the testing that their contract manufacturers are completing. Because labs play such an important role in ensuring not only regulatory compliance but product quality and safety as a whole, it is vitally important that companies have a thorough program to qualify and select testing labs with demonstrated expertise that pertains to your products.

It is important to understand cGMP requirements.

Code of Federal Regulations (CFR) PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

Key sections regarding laboratory testing include:

Subpart E – Requirement to Establish a Production and Process Control System § 111.70 through § 111.76

Subpart J – Production and Process Control System: Requirements for Laboratory Operations § 111.303 through § 111.325

Never forget: as far as the regulations are concerned, your contract testing lab is an extension of your own facility, and you are ultimately responsible.

LEGAL RESPONSIBILITY TO TEST AND RAMIFICATIONS IF YOU DON'T TAKE THIS SERIOUSLY

Rend Al-Mondhiry, Partner, Amin Wasserman Gurnani, LLP

Beyond cGMP compliance, ingredient testing serves another important purpose. If a product is labeled as having an ingredient – whether the product is a supplement, food, or cosmetic – consumers expect the product contains that ingredient. And not a substance that looks like that ingredient, but the actual ingredient. When an efficacy or health-related claim is made for the ingredient, the stakes are even higher.

Take *Sambucus nigra* (elderberry) for example, which is well-known for its immune system-enhancing and antioxidant properties, and consumers rely on it to deliver on these benefits. With adulteration of this valuable botanical still an issue, lack of ingredient testing poses tangible risks. Not only loss of consumer trust and reputational risk, but also legal consequences.

The Federal Trade Commission's (FTC) truth-in-advertising laws require marketing to be truthful, non-misleading, and substantiated, including when products are advertised as containing specific (and especially sought-after) ingredients. If adulteration is a concern, asserting compliance with cGMPs simply isn't enough. Competent and reliable testing demonstrating the ingredient's identity is essential, and working with a qualified lab – one that understands any challenges surrounding the ingredient – is a necessary component. For botanicals in particular, the lab should be familiar with the appropriate methodologies and reference standards.

It's not only FTC that companies need to think about. Competitors can bring challenges before the BBB National Programs' National Advertising Division (NAD), and one such case involving elderberry products addressed in detail the importance of reliable ingredient testing. After determining the company did not have a reasonable basis for claims that its dietary supplements contained elderberry, NAD recommended that the advertiser discontinue all challenged claims related to the presence and quantity of elderberry in its products.

In addition, products that lack a labeled ingredient, or that don't contain the labeled amount, poses class action risk. Multiple complaints have been filed against brands in cases where products allegedly failed to contain enough of the ingredients or lacked the ingredient altogether. Partnering with a qualified lab through the supply chain can help prevent these challenges from occurring, while also maintaining consumer trust and product integrity.

COSTLY CONSEQUENCES

Unfortunately, some manufacturers and brands skirt their due diligence in performing required tests—but they do so at considerable risk to their reputations, their bottom lines, the safety of consumers, and their very ability to operate. In fact, FDA has filed multiple consent decrees and injunctions against manufacturers when there are documented and repeated failures to comply with the law.

Failure to ensure quality through rigorous testing can have more than regulatory consequences. It also impacts consumer safety and trust. Consumer trust and loyalty that took years to build can be lost overnight when a significant quality failure emerges. The resulting consequences cost far more than the upfront investment of proper quality testing.

The lesson: There's no substitute for thorough, fit-for-purpose testing conducted by a responsible and well-qualified testing lab. In fact, it's your regulatory responsibility.

> The upfront cost of quality testing is far less than the consequences of not testing.

WHAT TO LOOK FOR IN A LAB?

START WITH EXPERTISE AND ENGAGEMENT

There are many contract labs to consider as you start your search. Some large conglomerate labs have a huge variety of testing capabilities spanning a range of industries. No matter the size of the lab, you are best served to focus on labs that specialize in the type of testing you require and are true subject matter experts. Equally important is choosing a lab actively engaged with the broader industry and scientific community. Labs that are immersed in the dietary supplements industry have access to crucial information that will benefit you, such as emerging adulteration concerns for specific materials and advances in analytical techniques.

ACCREDITATION, CERTIFICATIONS, AND OTHER GOOD SIGNS

Whenever possible, look for testing labs with ISO 17025 accreditation. ISO 17025 is the International Standard Organization requirements for the competence of testing and calibration laboratories which among other things guarantees overall quality management structures are in place. Ask for the lab's ISO 17025 certificate as well as their scope of accreditation which will reveal which of their testing services are covered. Review it, check that it is current, and make sure it covers your testing needs.

Another good sign that a lab is serious about testing is participation in the National Institute of Standards and Technology's (NIST) interlaboratory studies program or other such proficiency testing programs. In this voluntary program, NIST sends participating labs blinded samples for specified testing. After analysis, the labs then return their results to NIST, which summarizes them and ranks their accuracy relative to other—anonymized—labs in a comparison report. Participation in such proficiency testing programs is a useful way for labs to monitor their own performance.

As for leaning on a lab's FDA registration number as a gauge of its credibility, don't. That number merely signifies FDA's awareness of the lab's existence and says nothing about qualifications, audit history, or performance. Fortunately, FDA does offer two very useful tools to research inspection and citation history of laboratories and manufacturers – its data dashboard and warning letter database.

FDA Data Dashboard and Warning Letter Database

The FDA offers two very useful tools that provide history and citation information for manufacturers and laboratories that they have inspected.

https://datadashboard.fda.gov/ora/index.htm

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

QUALIFICATION CHECKLIST

There is a wide variety of information you will gather as you begin vetting potential testing labs including capabilities, track record, location, billing terms, submission process, etc. We have developed a check list of the key technical and quality related questions we believe you should be asking when qualifying your lab.

REGULATORY HISTORY

- How long have they been in operation and have they had previous names/aliases?
- Do they have concerning citations in the FDA data dashboard or warning letter database under their current or any prior names?
- Are they ISO/IEC-17025 accredited or hold other industry certifications?
- What analytical techniques are covered under their scope of accreditation?
- Will they allow onsite facility audits?

TEST METHODS AND OPERATIONS

- How do they document testing standard procedures?
- How do they verify test methods and results are fit for purpose and scientifically valid?
- What are their quality control acceptance criteria for each experiment?
- Do they participate in NIST or other proficiency testing schemes?
- Do they outsource to other labs? If so, which one(s) and how are clients notified?

TRANSPARENCY & TECHNICAL SUPPORT

- How transparent are their test reports?
- Do they disclose full method details and raw data upon request?
- Do you have a key contact who can arrange technical support?
- Are their scientists available for collaborative calls with your team?
- Will they help you explain their results to your vendor or client upon request?

INDUSTRY & SCIENTIFIC ENGAGEMENT

- Do they participate in trade associations and working groups?
- Are they involved in scientific organizations such as USP & AOAC?
- Do they contribute towards scientific papers, poster presentations, and webinars?
- Are they viewed as experts in the analytical techniques they perform?

DEVELOPING A PARTNERSHIP

LEAN ON YOUR LAB

At its best, your outside contract lab should feel like a trusted inside lab. The communication and collaboration between you and your partner lab should be so strong that they feel like an extension of your own team and a key quality partner.

The most important aspect of developing a full partnership with your chosen lab is having personalized service and ready access to technical support. And when qualifying labs, that should be top of mind. Will you have a key contact who can give you additional assistance in selecting appropriate test methods that fit your specifications? How easy is it to speak directly with their scientists when you receive an unexpected result? There are likely to be times when you need your contract lab to participate in conference calls with either your vendor or your customer so it is imperative to anticipate this need and choose a lab that can support you.

An expert contract lab partner can also advise clients on industry trends driving quality issues such as ingredient demand spikes that make specific products more vulnerable to adulteration and in need of closer examination. As an example, Alkemist Labs compiles and publishes a list of "Herbs and Fungi We're Watching" with trending failures for our clients to be aware of and take extra care. It's that is the sort of industry specific knowledge that is of benefit to brands and manufacturers alike.

SUBPAR LABS ARE RISKY BUSINESS

RED FLAGS AND TRUST

Not all labs are conscientious or frankly even cGMP compliant, so it is vitally important that you sniff out and avoid working with mediocre labs. If a lab's core value propositions include minimal test failures and low-low prices, they're offering you a false bargain. Conducting tests to generate accurate, quality results should always be a lab's number-one commitment.

You should question exactly what analytical techniques low-cost labs are using and probe if their methods are fit-for-purpose. FDA warning letter records show their inspectors are increasingly scrutinizing analytical methods and finding fault with substandard testing practices such as FTIR and verification "by input," which is essentially pure calculation, and not actually analytical testing at all.

One investigation that is quite useful is the submission of challenge samples to test a lab's capabilities. Challenge samples are samples submitted with intentionally incorrect information and which are intended to fail specification. For instance, the chemical potency claim is overstated or the Latin name of a botanical product is listed incorrectly. Such challenge samples can be very helpful to test a labs expertise as well as technical support processes.

NO TRANSPARENCY, NO CONFIDENCE

Labs should be open and transparent about how they operate. Why would you trust a lab that refuses to share data and methodology?

Full documentation—not just of data, but of a lab's end-to-end process—is everything when it comes to complying with FDA rules and producing a quality product. Only by maintaining and sharing that data can your testing lab act as your verification tool and post-testing support system. As the saying goes, if it isn't written down, it didn't happen. And if your testing lab doesn't reveal the test methods they used, then you can't defend it to customers or the FDA.

CONTRACT MANUFACTURING

Len Monheit, CEO, ITC Strategy

Brands using a contract manufacturer (CM) should not relinquish lab selection to the CM. In the eyes of the consumer and FDA, responsibility for quality belongs to the brand.

Under cGMPs, the brand holder, as part of its quality responsibility, has ultimate responsibility for the development of specifications and release testing to meet label claim. In fact, though, the brand is often relatively naïve regarding this responsibility, or it has evolved into a partnership with the CM wherein the CM guides using experience and its own regulatory and quality staff.

Obviously, this can lead to a very predictable conflict of interest, especially where the brand really does not have qualified individuals in place to discuss quality and testing. Often the brand is outsourcing at least some of these responsibilities, especially in startup and early-stage mode. The expertise of many of these individuals, which can be specialized, is almost always not deep enough in the nuance of analytical chemistry – especially when guiding on ingredient specific theoretic impurities.

It is also true that most contract manufacturers do not have complete in-house testing capabilities, such as sophisticated chromatography. They can perform the physical and microbial testing, but have challenges when we begin to suspect ingredient-based impurities.

Unlike third party labs, many contract manufacturers pay little attention to current issues and developments in problem products, such as adulterants. In fact, for some contract outfits, they rarely attend industry events, and the culture too is very internal, even opaque, with little sharing. Competition between contract manufacturers has led to a hesitation to free mingling for fear of poaching. The downside to this is more infrequent discussion of analytical challenges and current topics.

ALKEMIST LABS

We've drawn upon our experience to develop this document, with input from several outside experts we know to be extremely knowledgeable, with the intention to guide more suppliers and brands in choosing labs that will best support their quality and compliance. Shoddy testing is ultimately a very expensive choice to make once the inevitable consequences surface, and in the end drags down the entire industry. Insisting on a high bar in product testing protects your bottom line, and the industry's long-term success.

For more information, contact us at:
sales@alkemist.com or 714-754-4372