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Contract labs

Choosing and auditing a third-party lab to ensure products are properly tested

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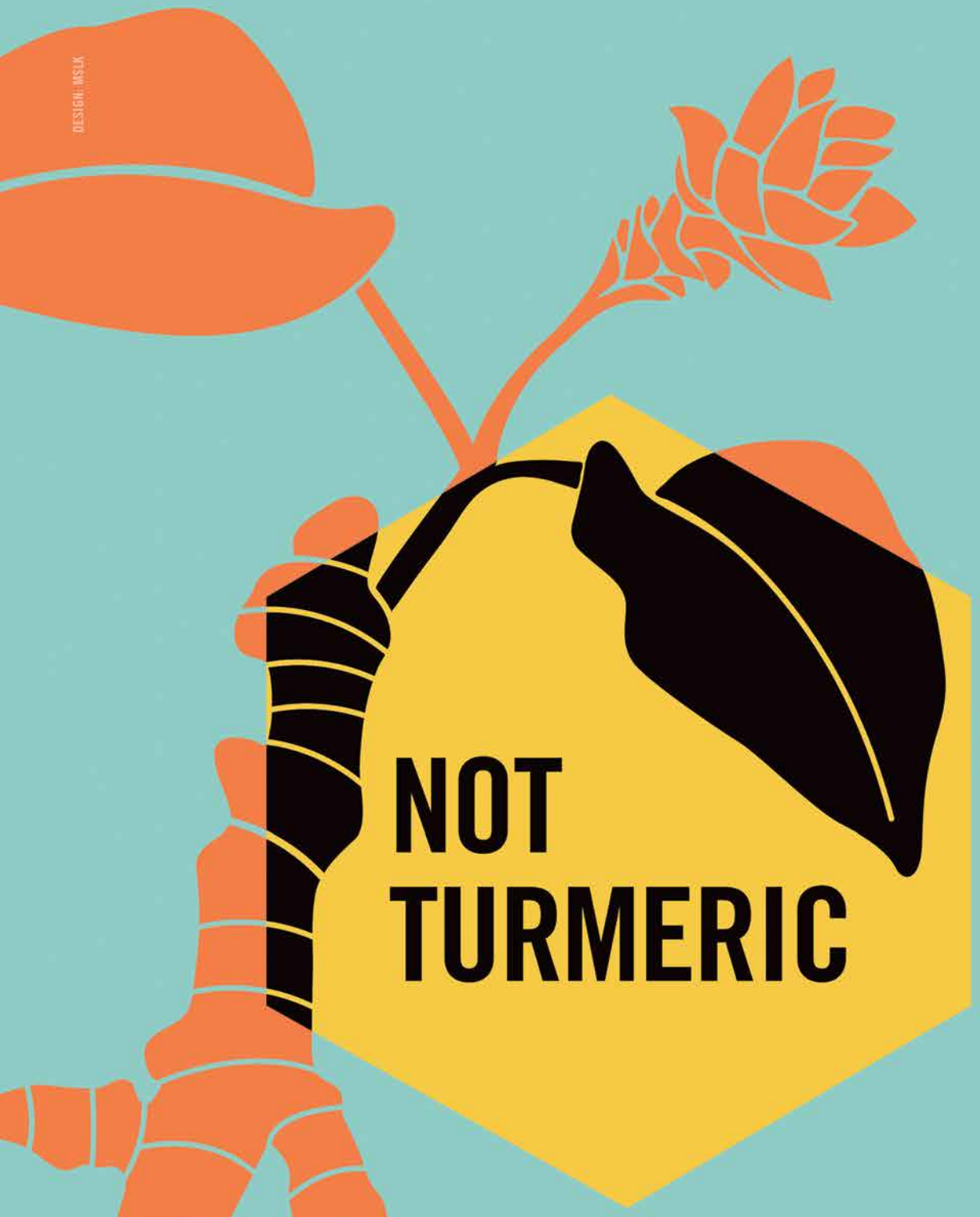

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Think inside the box

"Think outside the box," they say.

"Think bigger!" they shout.

"BE INNOVATIVE!" they scream.

The long-asked and never-answered question of "who are 'they,' and why should I listen to what 'they' have to say" is ongoing and, unfortunately, won't be answered today.

Instead, I'd like to introduce a new "they," who urge you to:

- Think inside the box
- Think smaller
- Think simpler

Now, before you whip out your pitchfork and demand new "they" take a hike, let me explain: When it comes to quality of supplements and foods, brands should pay close attention to what's *inside the box*, making sure the *small* bits (ingredients) are what they should be (and not what they should not be), and put as much effort—or more—into the basics (like regulatory compliance, safety and efficacy) as they do the exciting, forward-thinking stuff.

Paramount to achieving these parameters, they say, is laboratory testing. And, in this case, I can tell you exactly who "they" is: the industry experts sharing their thoughts, advice and experiences in the articles of this digital magazine.

Every brand owner must ensure its products meet FDA requirements for safety, identity, purity, strength and composition. To help brands who lack the resources or expertise to conduct adequate testing to ensure those regulations are met are contract laboratories. And to help brand owners allocate the right contract lab partners, develop and maintain effective partnerships and ensure testing methodologies are effective is this digital magazine. We also cover special considerations for food products on page 5 and explore a new American national standard for pesticide testing on page 21.

For those who want to bring exciting, forward-thinking concepts into their testing strategy, the article on page 25 presents how testing will be the "next generation of transparency."

What's more, we're diving deep into contract labs at SupplySide West in Las Vegas during the "SupplySide West Workshop: Trust in Testing: Contract Labs for Safe, Compliant Supplements" workshop on Thursday, Oct. 17, 2019 at 2 p.m.

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Considerations for testing of food products

by Alex Smolokoff

INSIDER's Take

- Before a food product reaches a consumer, it must meet rigorous standards and regulations.
- These standards are set not only as recommendations by third parties, but also as U.S. law.
- Contract laboratories and third-party consultants can assist brands to ensure their products are up to standards.

Manufacturers, suppliers and CPG companies in the food space must ensure their products and ingredients check several boxes for consumers: Does the product taste good? Does it have a stable shelf life? Is it priced appropriately? Is it healthy? How does it compare to similar products manufactured by competitors?

Above all those considerations, however, food products and ingredients must be safe.

Considerations such as flavor, texture, affordability and healthiness can be weighed differently by different CPG brands and for different products. But safety cannot be overlooked nor ignored, no matter the product. A consumer must be able to trust that a food product is both safe and contains what—and only what—the label claims it does. Failure to ensure the safety of a product doesn't just mean losing business; it could result in legal action.

A food product must comply with several standards and regulations before it can hit the market; a CPG brand must also ensure any and all future batches of that product meet those same standards, without fail.

On a federal level, the Food Safety Modernization Act (FSMA), signed into law in January 2011, gave FDA new authority to regulate the growing, harvesting and processing of food products. These guidelines are necessary to combat adverse food reactions and sicknesses, which remain a problem in the U.S. According to FDA, nearly 50 million people in the U.S. get sick from foodborne illness each year, of which about 128,000 are hospitalized and 3,000 die. FSMA has, in the words of FDA, sought to change the focus from combatting these foodborne illnesses to preventing them.

The provisions of FSMA are myriad, but all relate to the assurance that food products are safe for consumption. Some of the many areas FDA was granted oversight of include:

- Mandatory preventive controls for food facilities, which involves evaluating hazards that could affect food safety, specifying preventive and corrective steps and controls are in place, and maintaining records of such;

- Mandatory produce safety standards, including established science-based standards for the safe production and harvesting of fruits and vegetables;
- The authority to prevent intentional adulteration of foods, "including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points."

Additionally, FSMA granted FDA authority to regularly conduct inspections to ensure compliance.

FSMA isn't the only set of regulations CPG brands should seek to follow, though. The International Organization for Standardization (ISO) also, as its name implies, sets standards for, among many other industries, food products. ISO is a network of members—the National Standards Bodies, one per country. In the U.S., that member is the American National Standards Institute (ANSI).

ISO 22000 lays out many of the network's food safety-related standards and "defines the steps an organization must take to demonstrate its ability to control food safety hazards and ensure that food is safe for human consumption." Key benefits of following this standard include, in ISO's own words:

- The ability to consistently provide food-related products and services that are safe and meet regulatory requirements;
- Improved management of risks in food safety processes;
- Demonstrating strong links to the United Nations' Codex Alimentarius, which develops food safety guidelines for governments.

Unlike FSMA regulations, ISO standards are not law, but voluntary recommendations. Even still, because these standards could overlap with federal regulations, following them is a safer bet than not. ISO standards are constantly evolving and responding to needs in the industry—and open to suggestion for new standards from industry experts, which then go through the proper channels to national and, eventually, international consideration.

Partnering with third-party testing labs and outside consultants can help brands ensure they meet ISO and regulatory requirements. These labs and consulting firms have both the budgets and specialization that many CPG brands, especially smaller or startup brands, do not.

Michael Hoard, Ph.D., vice president of technical affairs, Arizona Nutritional Supplements, wrote for **INSIDER** in October 2018 of the considerations that go into whether or not to rely on outside labs. While he was specifically citing the testing of supplements rather than food, many of the same lessons apply.

"Some of the considerations used to make this determination should be frequency, turnaround, monetary cost, personnel, equipment, build-out, method development, method verification/validation [and] standards," among others, he wrote.

It is also important for CPG brands to understand that, ultimately, all responsibility falls on them to make sure their products are safe. Therefore, choosing a trustworthy consulting firm or third-party testing lab is critical. ISO, in addition to creating standards for foods, also has a set of standards for laboratories; finding a lab certified by a third-party to comply with these ISO standards is a good place to start.

"Beyond certifications," Blake Ebersole, president, NaturPro Scientific, wrote for **INSIDER** in October 2018, "verifying the lab first requires transparency on the methods and processes that affect its reliability of results."

Regular auditing of any labs one is partnering with is also crucial.

"Audits are integral to the partnership, not a 'value added' portion of the business," Jim Lassiter, COO, REJIMUS, wrote for **INSIDER**. "The critical elements for successful audits include selection of the auditing party, understanding the specific operations being performed … and their specific regulatory obligations, and routine follow-up to ensure activities … are at least equal to the last successful audit."

AIBMR Life Sciences is a consulting firm that works with both ingredient suppliers and finished good companies.

Alexander G. Schauss, Ph.D., senior director of research and CEO, AIBMR, noted companies of all sizes often find struggles in the same areas of testing. With a staff that includes naturopathic physicians and a registered dietician, AIBMR can help in a wide range of testing areas.

"Manufacturing and identity continue to remain … the most complicated and difficult areas for companies large and small to get correct," Schauss said. "Manufacturing and identity includes and may not be limited to: ingredient identity (purity, strength and composition), certificates of analysis (CoAs), specification sheets, microbial testing, stability, solvent residues and pesticide residues for products of agricultural origin.

"Failure to do a good job at this has been the leading reason for so many IALs (inadequate information letters—aka 'bad day' letters) issued by the FDA," he concluded.

Schauss also explained partnering with outside consultation can save CPG brands not only the hassle and backlash of failing to adhere to standards and regulations, but also considerable money in the process. He cited one example of a company planning to spend US$350,000 to conduct several toxicology studies to support the safety of a novel ingredient they intended to add to food to obtain GRAS (generally recognized as safe) status.

"Our research determined the studies were unnecessary," Schauss said. "We provided the client documentation that showed the toxicology studies had already been published, plus the ingredient was grandfathered under DSHEA [the Dietary Supplement Health and Education Act of 1994], based on records we retain that companies long ago had thrown out."

Determining GRAS status is a highly important aspect of the natural products industry in the U.S., Schauss noted.

"Major retailers are being very careful to make sure that foods and ingredients they purchase have proper regulatory status in the U.S.," he said. "Importantly, [GRAS] status also usually affords an exemption from having to submit an NDI [new dietary ingredient] notification, which is advice that gives ingredient suppliers a financial advantage."

The passing of FSMA in 2011 forever changed the way foods are grown, harvested and processed. All food product manufacturers and CPG brands not only have strict and extensive regulations and standards to meet, but face considerable penalties for failure to do so. Third-party labs and consulting firms can help companies of all sizes meet and maintain these various standards and regulations.

Utilizing a **contract lab** for your next product innovation?

Check out these can't-miss sessions at **SupplySide West & Food ingredients North America**

Trust in Testing: Contract Labs for Safe, Compliant Supplements
Thursday, October 17, 2019 | 2–4pm

Co-Packers: Helping Navigate the Food and Beverage Landscape
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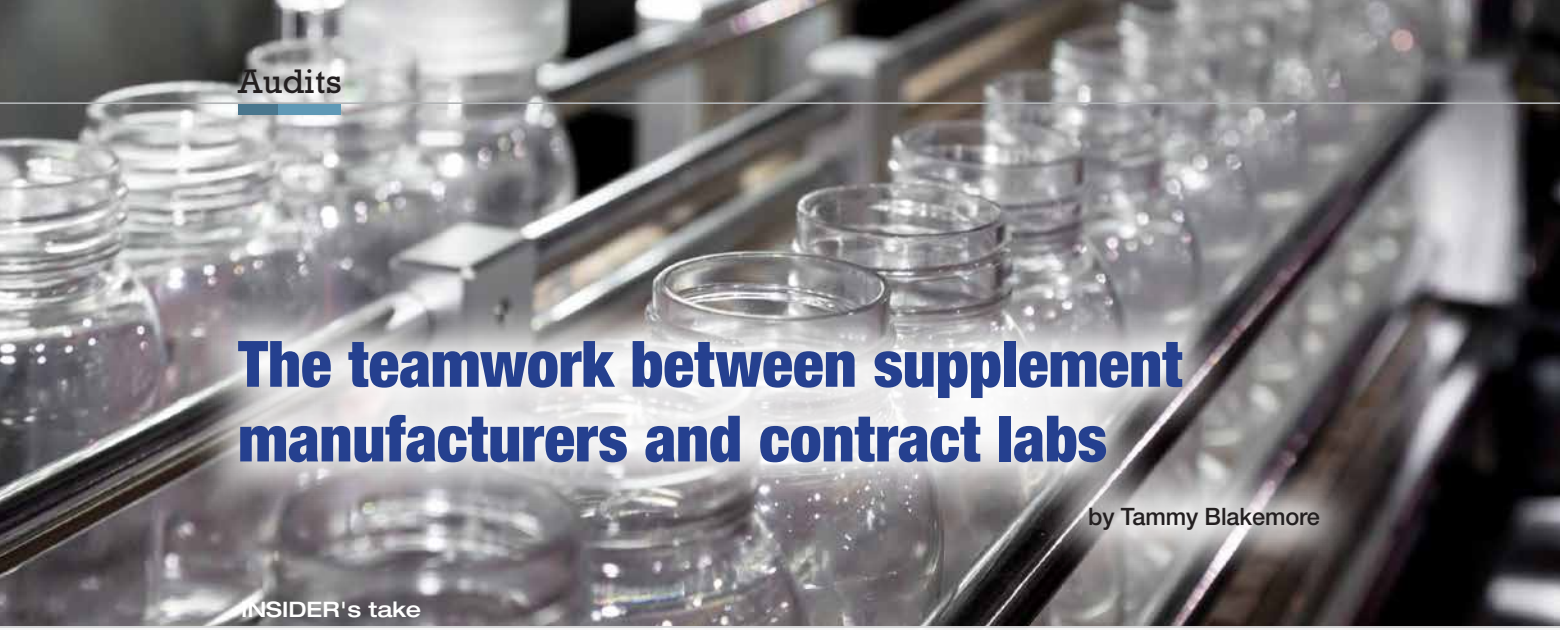

The teamwork between supplement manufacturers and contract labs

by Tammy Blakemore

INSIDER's take

- Supplement brands should vet potential contract labs to ensure the labs are experts in the required testing methods for the types of products.
- Contract labs that are certified to ISO specifications or are endorsed by other third parties can help a brand understand the labs' capabilities.
- An onsite visit can help a supplement brand better understand how a lab operates, addresses unexpected results and trains employees.

People often ask about the role of contract labs and why supplement manufacturers would need to use them. The answer is straightforward: Contract labs play a vital role in testing and independent verification activities. Many kinds of contract labs have expertise with various test methods and offer a variety of services, so it's important for supplement brands to find a lab that specializes in the types of products they manufacture.

Each lab specializes in and is proficient with certain methods, so the goal is to find a lab that is familiar with the specific materials/ingredients, and has experience running the method required for them. This is an important first step in finding a compatible testing partner. For example, if a brand plans to test an enzyme blend, working with a lab that has experience with enzymes or other specialty ingredients will help ensure a smooth product launch. In addition to understanding and being able to test for quality, the specialty contract lab should have knowledge of any testing challenges that can occur with blended enzyme products, helping to guide the brand if results are unexpected. A skilled contract lab's knowledge is invaluable, from understanding possible testing interferences during product development to helping create a testing plan for finished products. Specialty contract labs can save valuable time getting the product to market, and saving time equates to saving money.

It shouldn't be a challenge to discover if the lab has the skills to run the needed methods. A brand should communicate openly about its requirements—asking the lab about its testing focus will help determine if it is a good fit for analyzing the products. Also, if the lab is ISO/IEC 17025:2017 accredited, requesting its scope of accreditation will give a list of methods it is proficient with. The International Organization for Standardization (ISO) offers specific standards for many industries, including laboratories. One of ISO's goals is to ensure labs are run at high standards of quality and have the proficiency test data to prove their testing abilities. Having ISO 17025 accreditation

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signifies the laboratory has been audited and meets the general competency and proficiency requirements for the methods included on its scope. These standards are lengthy, and the requirements are stringent, so looking for this accreditation in a specialty contract lab should give reassurance of a wise choice.

Just like a brand would carefully qualify an ingredient supplier or other partner, labs need to be qualified as well. If the lab has ISO/IEC 17025:2017 accreditation, it is already ahead of the game, but other qualifications must be considered. Make sure the lab is using scientifically valid methods, which are appropriate for their intended use. These qualifications and all aspects of their quality management system can be addressed in the interview process before choosing a testing partner. This can be accomplished with a vendor qualification questionnaire, an onsite audit/visit and ongoing communication with the lab.

Being in the lab helps create a better understanding of its sample flow, security, equipment, team members and quality systems, which gives confidence in the results it provides.

An onsite visit builds strong relationships and develops a better understanding of how the lab operates. Being in the lab helps create a better understanding of its sample flow, security, equipment, team members and quality systems, which gives confidence in the results it provides. Without seeing how it operates, it will be difficult to fully understand how it keep samples organized or how it avoids cross-contamination of the micro lab when plating both probiotic and bacteria-free samples. Ideally, a tour will include a look at the sample entry area, and how the lab organizes orders and uniquely labels samples. This ensures the lab has adequate controls in place to keep sample integrity. A brand can see how the microbiology lab is designed, and how a probiotic testing lab will have a separate plating area with filtered air handling and cleaning procedures for this high-plate-count testing. This visit should also allow a brand to review lab procedures and look at proficiency testing data.

Proficiency testing can be conducted in a variety of ways. Certain programs, available for purchase, show scores from test results that are the culmination of many labs running the same sample. However, labs that provide specialty testing and use less common methods may have smaller-scale proficiency testing with fewer labs participating. Sometimes, the ingredient manufacturer and the lab will conduct a study to compare results for several lots of a specific raw material. This shows that the method can be run outside the manufacturer's lab and has transferred well to the contract lab. Many labs

also conduct studies between analysts to show staff qualification for a specific method. Labs should go above and beyond to verify the results will be consistent no matter which analyst performs the testing. These proficiency testing procedures can provide peace of mind in the decision to use the contract lab, and all the data can be discussed during the onsite visit.

Reviewing team member training, out-of-specification (OOS) practices, calibration records and a host of other procedures can be completed during the audit. Being confident in the test results, and knowing the products are safe for consumers, makes the contract lab relationship an important one to invest in.

Even manufacturers with in-house labs often need to use a contract lab because their in-house labs cannot perform all the test methods needed for the wide range of products produced. Often, the method development costs do not warrant an in-house method for nonroutine work. It makes more sense to use a contract lab that has years of experience and proficiency test data for the methods the in-house lab has not developed. Also, taking the time to qualify other labs with similar capabilities provides the brand with valuable backup resources or a trusted partner for OOS verification. Quality is a big job, and no single lab can manage it alone, so building a team that includes outside partners is critical to success.

Tammy Blakemore is general manager at SORA Labs, a third-party dietary supplement testing lab that specializes in enzyme activity testing and probiotic enumeration.

Precision decision: Choosing the best independent supplement testing labs

by Lisa Schofield

INSIDER's take

- Supplement brands should test raw materials, in-process formulations and finished goods, so products are reviewed several times during production.
- Transparent, regular and truthful communication with third-party testing labs is necessary to ensure products are tested using appropriate methods.
- Contract labs should be vetted using a careful lab qualification procedure that includes onsite and paper audits, method validation and personnel review.

A supplement brand conducts research to show the ingredients in a product are efficacious. Once that's supported, the brand is anxious to go to market. But a crucial step necessary to protect the brand and consumers is testing. And often, brands use independent supplement testing labs to achieve the best results.

"A strong testing program is key to ensuring products that are delivered to the consumer meet the 21 CFR 111 [Title 21 of the Code of Federal Regulations, Part 111] requirements for safety, identity, purity, strength and composition," emphasized Brea Viratos, vice president of quality and regulatory, Columbia Nutritional.

According to Tara Couch, Ph.D., senior director of dietary supplement services of EAS Consulting Group, 21 CFR 111—cGMP (current good manufacturing practice) in manufacturing, packaging, labeling or holding operations for dietary supplements—doesn't require brands to conduct process validation on new dietary supplement products. "That said, it is always beneficial to perform trial runs on new products—and this should typically be done during the R&D [research and development] stage," she said, adding that this not only allows for assessment of the manufacturing process, but also provides a finished product sample that can be tested in the lab.

When to test

Despite being knee-deep in R&D and engaging sales and marketing to gear up for launch, testing needs to be done at specific stages in the development process. Labs have certain protocols when working with products.

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At the source, however, is the ingredient supplier. Some suppliers have in-house testing, which helps support quality and safety standards. For example, Steve Smith, quality control (QC) manager at BI Nutraceuticals, shared the following protocol for raw materials: Every lot is sampled based on the number of containers received. BI uses the square root of N plus 1 to determine the number. All the samples are checked for insects, excreta and visible mold. If clean and uniform, they are composited and tested for identity by multiple methods, as well as for pesticides and irradiation. Other testing is conducted at this point which varies according to the product, usually including ash and acid-insolvable ash. Anything confirmed out of spec may cause BI to return the product to the supplier.

Next is in-process testing. After steam-treating the material, during milling, multiple samples are pulled from every pallet. This is done, Smith explained, to check each sample for color, particle size and magnetic metal. Many products also require density and moisture confirmation at this stage. They are composited if all the samples are uniform.

"As lots are completed, the sample composites are made," he said. "A final test of all the above in-process testing is run in addition to heavy metals," he said. "Some of our products also require assay. Full micro is tested on every lot at this stage, which depending on customer requirements, could include a suite of 11 different test methods."

Materials in their most raw form (plants) can be reviewed by organoleptic tests right from the field, according to Elan Sudberg, CEO, Alkemist Labs. "This is a suitable test method as long as training records are up to date and documentation is good. However, this industry rarely trades in whole raw materials, but rather fine powders that mostly require some chemical test to confirm identity and potency," he commented.

It's one thing to test a sample from a vendor, he added; however, what is shipped to be manufactured into finished products matters most, so brands should test that, too. "I am not a fan of trusting that the end product is what you hope it is without confirmation. No one should be," he stated.

Alkemist Labs generally requests 10 g of material and can deliver results for a simple identity test in four business days, according to Sudberg. "That's only 10 g out of the potential thousands of pounds you will soon receive in your warehouse," he stated. "It makes sense to test at each inflection point or change of hands for a material because these are the points at which there is a potential divergence from quality. Divergence from quality can cause major disruption down the line."

The raw material supplier must be qualified for its material, Couch emphasized, and this must be done through several avenues, notably confirmation testing results labeled on the certificate of analysis (CoA). Generally, she related, FDA's expectation is at least three rounds of confirmation testing will be done on incoming raw material by the supplier. This is coupled with a qualification of the supplier itself, done through a questionnaire completed by the supplier that discusses the quality systems it has; this is followed by an onsite audit.

At her company, Viratos explained, all materials are tested on the inbound, at minimum for identity. Other tests are conducted based upon the risk associated with the component, which include contaminant testing, such a microbiological screening, a heavy metal panel and allergen screening. Every batch of finished goods is tested for potency, via a macronutrient and micronutrient listed on the label, on a rotational basis. Additionally, Columbia Nutritional conducts a microbiological and heavy metal panel, at minimum, to check for contaminants on every finished good batch.

To control and ensure the supply chain in manufacturing and final product quality, Jiayuan Liu, lab director, Intertek Champaign Labs, recommended to test:

- Raw materials of each supply origin
- Blend mixes (at different positions of the blend containers)
- Final products before and after packaging
- Every batch or lot of products released

In addition, she advised retaining products of each lot for stability monitoring and future reference when needed.

Testing protocols designed to ensure scientific validity can vary, depending on numerous circumstances, according to Blake Ebersole, president, NaturPro Scientific. Often, each analyte on the specification for a product or ingredient requires a unique testing plan. The typical rule Ebersole's firm recommends is that "every batch must be tested until the time that there is a strong scientific rationale why less frequent testing is needed," he said.

One example he offered is when a new ingredient, such as a new variety or species (or a new manufacturing process for a currently marketed species), is developed. Often in such cases, new specifications are based on limited history, and the listed methods have not been validated or published for analyzing the new composition.

"This leads to suppliers and labs having to make educated guesses on what methods and reference standards to use, without full confidence of the performance of these methods and standards," Ebersole said.

Nebulous and nonexisting methodologies for materials and blends pose serious challenges for botanical and other natural formulas, according to Sudberg, who declared, "Somehow FDA has said, 'Well, no methods exist, so I suppose we can just trust and hope the documents showing an employee added the right amount of material are accurate.' I am not comfortable with that, and nor should you be. Methods don't exist because this industry tends to not want to pay for their development unless they are forced to do so, and that's a serious shortcoming to be explored as we grow beyond DSHEA [the Dietary Supplement Health and Education Act of 1994] and cGMPS."

Other testing challenges

Several challenges revolve around misunderstandings of brand marketers. For example, Ebersole related, one significant challenge is in communicating that the up-front costs are necessary to validate the analytical method, which often requires many hours of time on the equipment. "Often, clients are not willing to pay for the validation of methods needed to meet this critical requirement under GMP."

Another situation that frustrates labs is described by Sudberg: "We recently received a microencapsulated ingredient to test and only found out about the microencapsulation after the material failed identity testing. The supplier then told us what material we were working with, and it's been weeks of work to develop a suitable method to extract the ingredient and properly test it. Meanwhile, the ingredient is being sold and used without testing to verify the identity that is on the label, which is required by law."

Another challenge he described is skip-lot testing—which creates a statistical risk as only every second or third batch is tested. Frequently used by the pharmaceutical industry on single/simple ingredients, Sudberg noted the testing method "is often used in the dietary supplement industry to save costs, but plant-based dietary supplements are too complex for that."

Other challenges are more universal, so to speak. For example, Liu pointed to an "uncontrolled" supply chain, especially in the global scope, creating variations in raw material quality, which directly impacts the quality variance in final products. "There are significant variations of country-specific regulatory definitions and requirements of medicinal and botanical nutraceutical materials, and hence testing standards," she commented.

Advancements

Despite the challenges that seem insurmountable, testing methods and protocols are advancing. For example, Viratos noted, "DNA technology has been a game changer in the dietary supplement industry. I believe it will continue to advance our ability to detect adulterated materials. With DNA testing, it has become easier to ensure botanical identity is accurate."

She added that as the probiotic market continues its rapid growth, DNA testing technology is allowing for identification of specific strains to ensure the customer is getting what is on the label.

As CBD disrupts the conventional supplement industry, Alkemist Labs recently announced a partnership with Nutrasource (a Canadian contract research company) to launch the International Cannabinoid Analysis Program (ICAP), a comprehensive third-party verification program to support accurate, verifiable label claims of THC content in ingredients and finished products, according to Sudberg. ICAP, set to launch widely in September 2019, tests cannabis, hemp and their extracts or derivative products to ensure they contain less than 0.2% THC, a limit that aligns with the European regulations, the most stringent global standards. "We have adopted the EU cutoff of 0.2% THC by concentration which then also covers the U.S. market's 0.3% limit," he commented.

Speaking of limits, Ebersole explained that while low levels of contaminants are in everything people consume, often there are no "safe harbor limits published by regulators based on the safety of the contaminant. This leads to a situation where testing, product development and marketing is driven more by paranoia and public perception, than a scientific rationale."

Scoping out a lab partner

Due to the challenges the industry faces and some of the ambiguity of which methodologies are best, it is more important than ever to understand how to select the most appropriate laboratory partner.

Turnaround time and cost are always the first two factors brand marketers think of, and rightfully so. But, Liu asserted, quality is critical, and clients should review quality-related documents and capacities, such as quality certificates, self audits, OOS (out of specification) procedures, areas of expertise and technical team experience. "It is a good idea to schedule an onsite audit, where the client can see the facility and know the people, which gives the client a deeper understanding of the testing lab," she said.

"It is important to understand the capabilities of the laboratory," Viratos underscored. While many labs offer one-stop-shop services, it is important to discern where their expertise lies in a specific methodology.

As a contract manufacturer focused on dietary supplement tablets, capsules and powders, Columbia Nutritional now performs most of its raw material identity testing in-house and has just added microbiological testing in June. The company purchased a BioLumex quick micro testing system and is in the final stages of qualifying and running side-by-side comparative tests. This will facilitate obtaining test results to shorten processing times at both ends of the process—incoming raw material micro testing and finished product testing.

Smith advised asking if the laboratory is ISO 17025 certified for food safety methods. The certification has been required by SQF (safe quality food) since 2018. “A thorough laboratory qualification process should be clearly defined, completely implemented and well documented. This just helps the laboratory plan for the FDA audit that is around the corner,” he commented.

Overall, Ebersole suggested brand marketers/manufacturers are best served if they have a lab qualification procedure in place—just as they have a supplier qualification procedure. The criteria for lab quality procedures should include method validation or certification under the scope of ISO 17025 audits, transparency of methods and results, and a defined process for dealing with OOS results.

When vetting labs, Sudberg advised to audit several that span numerous types of testing. Alkemist, he offered as an example, has expertise in plant identity and potency testing, “but we’re not your guy to test for heavy metals or pesticides, so take the same high standards to several labs that do the different kinds of testing you will need, and develop your testing team,” he suggested.

Whether a one-stop-shop or a team consisting of specialists from all over, testing is critical. Consumers are getting more label savvy, seeking information that reassures efficacy and safety, as well as contents and ethical practices in alignment with their own. “To be ahead of the curve in satisfying these consumers, brand marketing clients should work with labs that are transparent as can be,” Sudberg stated. “Marketing companies should be proud to share the lab results with the final customer: the people who buy and ingest the finished products.”

Lisa Schofield is a veteran writer and editor who got her start interviewing rock stars for national music magazines. She now writes and edits content for B2B media and suppliers in the natural health product industry. She has served as editor for Vitamin Retailer and Nutrition Industry Executive, and prior to that, as associate editor for Whole Foods Magazine. For fun, Schofield writes Stephen King-inspired short stories.

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TRUST IN TESTING: Contract Labs for Safe, Compliant Supplements

Thursday, October 17 | 2-4pm

Location: South Convention Center, Level 3, Mandalay Bay

Contract laboratories play a critical role in the dietary supplement industry. However, selecting the right lab and working together to deliver safe, efficacious products to market demands cooperation.

LEARN MORE

New pesticide testing requirements help address 'zero tolerance' gap in dietary supplement manufacturing

by Rebecca Adams

INSIDER's take

- The new pesticide testing standard is American, but will likely impact global agribusiness, as countries grapple with public health concerns over pesticide exposure.
- The updated standard is based on a study showing data on listed pesticides to develop reasonable maximum allowable limits (MALs) in botanical dietary ingredients.
- The evidence-driven approach minimizes reliance on zero tolerance while remaining protective of public health and safety.

NSF International and the NSF/ANSI 173 Standard Joint Committee recently updated the pesticide testing requirements in NSF/ANSI 173, the only American National Standard for dietary supplements. The impetus for the update is a recent NSF International study published in the journal *Food and Chemical Toxicology*, which established chemical-specific limits for 185 pesticides that may be present in botanical ingredients used in dietary supplements (2019;123:511-519).

While this is an American standard, the ramifications are global, with significant potential impact for the agribusiness market. For example, in terms of pesticide use, India had one of the top 10 fastest-growing crop protection market growth rates between 2012 and 2017. Considering the sheer magnitude of the Indian agribusiness market alone, that is a great deal of pesticides—worth over US$2 billion in 2017 alone.

The potential impact of pesticide regulation on the international dietary supplement ingredient sector in the vast agribusiness market is already playing out. Farmers in the Middle East and North Africa have faced challenges in exporting products to Western markets due to the presence of banned or restricted pesticides. It is reasonable to expect that those export difficulties will seep into other markets in the future. As a barometer for the importance global agribusiness places on the impact of pesticides, the February 2019 BioAg World Congress in New Delhi dedicated an entire half-day session to the developing field of biopesticides.

It is more than an economic concern. The 2017 Report of the Special Rapporteur on the Right to Food presented to the United Nations Human Rights Council stated:

"Of grave concern are the impacts of chronic exposure to hazardous pesticides. Furthermore, chronic effects of pesticides may not manifest for months or years after exposure, presenting a significant challenge for accountability and access to an effective remedy, including preventive interventions."

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The report included a section on challenges created by divergent levels of regulatory protection: “Without standardized, stringent regulations on the production, sale and acceptable levels of pesticide use, the burden of the negative effects of pesticides is felt by agricultural workers, children, the poor and other vulnerable communities, especially in countries that have weaker regulatory and enforcement systems.” In support of public health and in the face of inconsistent or unenforced regulations, dietary supplement ingredient suppliers have an obligation to self-regulate to achieve scientifically supported global standards.

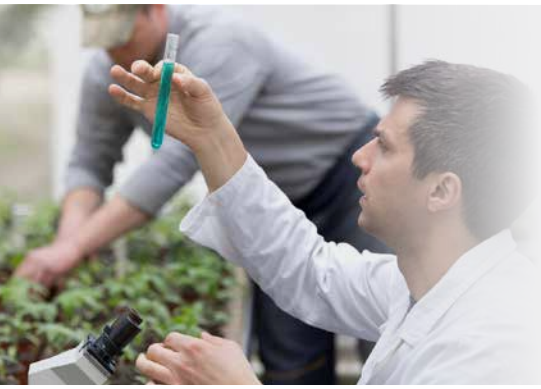
Updating pesticide standards to remain apace with both the development of new pesticides and the deepening understanding of the effects of existing pesticides is essential. The issue of pesticide regulation in agribusiness subset crops like those used in the creation of dietary supplements has been thorny for manufacturers for some time. As recently as 2017, the American Herbal Products Association (AHPA) was urging federal regulators to revamp pesticide regulations that “unfairly impact minor crops that include many botanical commodities.”

The new NSF/ANSI 173 testing requirements fill an important gap. Pesticides lacking residue limits are currently held to a precautionary zero tolerance which has moved closer and closer to zero over time as analytical testing methodologies have advanced. An evidence-driven approach minimizes reliance on zero tolerance, while remaining protective of public health and safety. The intent of the study was to demonstrate enough data exists on the listed pesticides to develop reasonable maximum allowable limits (MALs) on pesticides present in botanical dietary ingredients.

In the U.S., pesticide regulations are frequently centered on known risks, and designed for more traditional food crops. Moreover, the regulations are structured on a crop-by-crop basis. With the multitude of crops and pesticides, if a pesticide limit for a particular combination of crop and pesticide is unspecified, the tolerance level automatically reverts to zero. The zero-tolerance issue is exacerbated by the persistence of some pesticides over time, including ones whose use may have been discontinued for years, sometimes decades.

NSF/ANSI 173's new pesticide criteria provide a tool for industry to evaluate pesticide residues in botanical ingredients used in dietary supplements. By using U.S. Environmental Protection Agency (EPA) and international data, toxicologists have been able to develop scientifically defensible chemical-specific pesticide limits.

Unlike the food-crop focused approach, the MALs derived for pesticide residues in this new analysis are specific to dietary supplements. As a result, the MAL is the maximum estimated daily exposure level at which a chemical in dietary supplements is likely to have no appreciable risk of adverse effects if taken over an individual's lifetime. In responding to the combined lack of pesticide tolerances and action levels and the subsequent enforcement of zero tolerance by FDA on botanical dietary ingredients typically found in dietary supplements, a critical need to establish scientifically-defensible MALs based on chemical-specific human health effects criteria has been addressed.



By using EPA and international data, toxicologists have been able to develop scientifically defensible chemical-specific pesticide limits.

These testing requirement updates follow months of comprehensive research by NSF International toxicologists, who used U.S. EPA health effects criteria as well as criteria from international authorities as the basis to develop scientifically defensible chemical-specific limits for each pesticide. While this update to NSF/ANSI 173 advances the scientific basis for safer levels of pesticides in dietary supplements, it is not the final word for manufacturers seeking to import their product to the U.S. This update to NSF/ANSI 173 should not be considered a substitute for FDA pesticide residue requirements which, while written specifically for food products, remain a compliance requirement for supplement manufacturers.

Rebecca Adams, a research toxicologist at NSF International, evaluates dietary supplement and functional food product labels to the requirements of NSF/ANSI 173 and NSF certification guidelines 229 and 306, ensuring the ingredients and any potential contaminants or adulterants in the products do not present a significant public health risk or a reputational risk to consumers, athletes or the brand. She has experience in multiple disciplines including toxic tort litigation, occupational health/industrial hygiene, exposure assessment, and public health and safety. She holds a bachelor's degree with concentrations in biology and chemistry from the University of Michigan and a master's degree in toxicology from the University of Michigan.

Next generation transparency: Taking the testing lab out of the closet

by Elan Sudberg

INSIDER's take

- The next generation of transparency will be supplement brands disclosing the labs that test their products for safety, identity, purity, strength and composition.
- The cannabis/hemp industry is a good example for the herbal supplement industry to follow because of its robust testing methods and transparency marketing.
- FDA activity indicates the agency may start conducting more audits of contract labs, so brands should partner with reputable labs to avoid regulatory issues.

Transparency is on people's minds, and herb and dietary supplements brands are showing consumers more about their supply chains and practices. One of the last bastions of opacity is who conducts the testing. The answer to this question, at least for those brands using reputable testing labs, is marketing gold that companies aren't mining, but revealing a testing program and even what contract lab is used is starting to happen. Let's call it next generation transparency.

As consumers ask more questions about product quality, forward-thinking brands are increasing their transparency into sourcing, the research behind ingredients in their formulations, and their efforts to produce quality products.

In today's busy marketplace, differentiating brands can be a delicate dance for companies to perform among trending value propositions, and it's common for brands to spend a lot of marketing dollars telling that story. Concurrently, companies invest in product testing to ensure identity and strength, but the only people who know about that are the internal teams of quality assurance (QA)/quality control (QC) professionals and auditors. It's like spending US$100,000 a year on a new marketing campaign and then filing it in a cabinet. Millennials are big consumers of health and nutrition products, and they expect access to full product disclosure on their mobile phones, so this is the obvious next "best practice" companies will adopt.

The cannabis/hemp industry is driving some expectation of transparency. Even though it is operating largely in a regulatory grey area, the common practice is robust testing and flaunting it. Companies in the CBD space are revealing how they know the identity of the products they sell and how they know the THC level meets specification, and these companies are making test results available to consumers. Since the expectation is that eventually cannabis products will be treated like any other herb of commerce, it's a smart practice to go beyond the minimum required of other herbal product manufacturers. Some of these companies' level of transparency is like what Amazon is doing with remarkably in-depth information offered on its Elements line of supplements.

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Brands in the cannabis extract space often go to great lengths to demonstrate their commitment to quality, which Alkemist Labs is seeing, in partnership with Nutrasource—a Canadian contract research organization—in its new third-party verification program designed to support accurate, verifiable label claims regarding the content of THC in ingredients and finished products. These companies are eager to go beyond doing the least they can get away with.

Let's talk about the minimum requirements for a second, because this is an area of vulnerability the dietary supplements industry hasn't addressed yet. While former New York Attorney General Eric Schneiderman had it wrong to use DNA testing on herbal extracts when he accused major U.S. retailers of selling contaminated herbal supplements in 2015, the resulting brouhaha motivated large segments of the industry to step up their testing game. It's unfortunate that it takes an external force to motivate companies to improve, but it was the right response, so kudos to those businesses. The next external pressure to increase testing will come from FDA.

The cGMPs (current good manufacturing practices) leave too much room for interpretation. This regulation requires supplement brands to a "use a scientifically valid method" for testing, which is an extreme, but accurate, simplification of what is needed for safety and identity, allowing for exploitation of a gaping hole of interpretation by those who are comfortable with willful ignorance. The level of proficiency in labs varies widely, as does manufacturer commitment to testing to get the truth as opposed to testing to check off a box with accuracy being superfluous. The tip of the next iceberg started to show itself when FDA issued a warning letter in June 2019 to a contract testing lab for "failing to establish and document the accuracy, sensitivity, specificity and reproducibility of its test methods (21 CFR 211.165(e))" among other somewhat startling failings. So, brands need to ensure they are vetting their contract testing labs. Picking a good one will allow a brand to communicate with consumers about it, just like other transparent companies are doing.

To state the obvious, pulling back the curtain is an incredibly powerful thing to do if what's behind the curtain can withstand the light. Companies that make the investment to test their products with top-notch labs make powerful statements that should see the light of day. I can hear brand executives asking, "How are consumers going to understand lab test results? Have you ever seen an HPLTC lab report?" Um, yeah, I've seen a few. And they require translation, so Alkemist Labs is working on revamping its certificate of analysis (CoA) format to do just that. Good labs included test methods used for the material on their CoAs so results could be duplicated elsewhere if needed, so de-jargoning the report can come naturally to transparency-loving hearts and minds. This should—and will—become a standard industry practice.

Consumers are looking closer to see what brands are willing to tell them about the origin, sustainability, collection practices and quality of ingredients. They are not only quick to jump ship with the slightest indication of foul play or inauthenticity, but even quicker to share their experiences on social media.

The good news is that the hard work is already done if a brand is selling a quality product manufactured by a trustworthy manufacturer using good, authenticated ingredients tested by the best lab. The remaining step is to share the competitive advantage and differentiate the brand from others with next generation transparency.

Elan Sudberg is CEO of Alkemist Labs, a contract testing laboratory specializing in plant authentication, botanical ingredient identification and quantitative analytical services to the food, beverage, nutraceutical, cosmeceutical and cannabis industries. He holds a degree in chemistry from California State University Long Beach and has authored numerous journal articles on phytochemistry and analytical techniques for natural products and nutraceuticals. He is a board member of the American Herbal Products Association (AHPA), as well as AHPA's Education and Research on Botanicals Foundation.

FDA should audit supplement testing labs for GMPs – podcast

The Dietary Supplement Health and Education Act of 1994 (DSHEA) created a regulatory need for supplement safety testing, but the GMPs (good manufacturing practices), issued in 2007, set a fire in the industry to partner with supplement testing labs that meet high quality standards. Yet, without FDA audits of third-party labs for GMP compliance, labs may not be feeling the burning desire to fully comply with regulations.

Elan Sudberg, CEO of Alkemist Lab, said FDA should be conducting more audits of supplement testing labs to ensure compliance. A recent warning letter sent to ABC Testing may signal the start of this welcome trend.

Click to hear this podcast, where Sudberg discuses lab audits and other aspects of DSHEA that affect labs operations.

Takeaways: Testing 1-2-3

by Rachel Adams

Brands are responsible for ensuring their products meet regulatory requirements for safety, identity, purity, strength and composition. Testing is critical to achieving regulatory compliance and to ensuring products meet consumer expectations of quality and efficacy. Many brand owners partner with contract laboratories that have the expertise and capabilities to perform the tests necessary to ensure product quality and meet regulations. But forming the right testing lab partnerships requires careful consideration of critical category dynamics:

Testing is complex. No one-size-fits-all solution solves product or ingredient testing. Testing needs to be conducted at various stages of product development, including when ingredients are received from a supplier, during the manufacturing process, before and after a final product is packaged and every time a new batch is released. Additionally, not all testing labs specialize in every test needed for a particular product. In many cases, a product may require testing from different labs and thus, brands must put together a testing team.

Choose wisely. Lead times and costs are often top of mind for brand owners looking to partner with a contract lab. However, brands should also consider the materials that need to be tested and what methods the lab specializes in. Vetting potential testing partners is critical; key considerations when qualifying a potential testing partner include method validation or certification under the scope of ISO 17025 audits, transparency of methods and results and a defined process for dealing with out-of-specification (OOS) results. Audits are a valuable tool brands can use when qualifying a testing partner.

Foods matter, too. Safety can't be overlooked when it comes to any health product, including foods. The Food Safety Modernization Act (FSMA) provides regulatory framework for food products aimed at preventing foodborne illness. Also supporting food safety are voluntary standards set by the International Organization for Standardization (ISO) aimed to help industry ensure food safety and prevent food safety hazards. Contract labs can help brand owners meet and maintain these various standards and regulations.

In the coming year, it's possible testing could become the next wave of transparency. "One of the last bastions of opacity is who conducts the testing," wrote Elan Sudberg, CEO of Alkemist Labs. His company is working to revamp its certificate of analysis (CoA) to make it easily translatable for consumers. "This should—and will—become a standard industry practice," he wrote.

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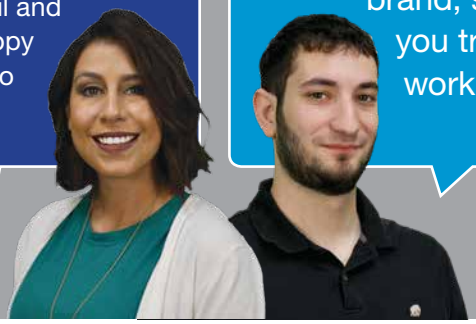
Inside INSIDER

Q. What is one key piece of advice that brands should consider when choosing a third-party contract lab?

A. During onsite audits, brand execs should talk to the contract lab employees to observe if they appear engaged, cheerful and committed. A happy workforce leads to quality work.

Sandy Almendarez
Director of content



A. Ultimately, that lab's work is a reflection on and responsibility of your brand, so make sure you trust their work completely.

Alex Smolokoff
Editorial coordinator

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