



## 12 Questions to Ask Supplement Manufacturers BEFORE You Hire Them

Entering the dietary supplement marketplace can be daunting, especially when you're brand new to the game.

You put a lot of thought into figuring out what supplement you want to make. You should put just as much consideration into who's going to make the product for you. Choosing the right contract manufacturer can mean the difference between a top-seller and an average product, or between success and failure.

How do you go about picking the right contract manufacturer for your needs? Do a little research, but do yourself a favor and ask any manufacturer the following questions BEFORE you hire them.

### 1) What industry certifications does your manufacturing facility have?

The most respected industry certification that you want in a supplement manufacturer is GMP (Good Manufacturing Practice).

GMP is the highly regarded system for ensuring that products are routinely produced and controlled according to quality standards. The US Food and Drug Administration enforces GMP, so you best be sure that a GMP certified facility makes your products.

Don't just ask a contract manufacturer if they are certified – see the current certification yourself. Make sure you work with a facility certified under FDA code 21 CFR111.75 (for manufacturing, packaging, labeling or holding operations for dietary supplements). And don't fall for made-up GMP icons on a company website or marketing material. Anyone with access to a mediocre graphics program can design their own GMP logo, or they can be obtained cheaply from the internet, but this doesn't guarantee compliance with GMP protocols.

GMP certification is available through different independent agencies, including Underwriters Laboratories (UL) and NSF International. Search their databases yourself to verify if your potential contact manufacturer is certified.

Verify certification with UL [HERE](#).

Verify certification with NSF [HERE](#).

This is how Amazon qualifies your products for sale on its marketplace. Amazon requires GMP certification from your contract manufacturer.

**The PureNSM Promise:** When you partner with PureNSM, you get the peace of mind in knowing that your supplements are manufactured in a triple-certified GMP facility – by UL, NSF, and Natural Products Association (NPA).



You can verify our UL certification [HERE](#).

Search for us under *Nutritional Supplement Manufacturers* or *PureNSM*.

You can verify our NSF certification [HERE](#).

Search for us under Manufacturer Name *Nutritional Supplement Manufacturers*.

You can verify our NPA certification [HERE](#).

Search for us under *Nutritional Supplement Manufacturers* or *PureNSM*.

## **2) Does your company follow FDA manufacturing procedures?**

The rumors that supplements are unregulated are FALSE. The FDA regulates the supplement industry, and it's important to work with a contract manufacturer that strictly adheres to the FDA's standard operating procedures (SOPs) to ensure the quality and safety of your products.

How do you know if a contract manufacturer has SOPs that meet or exceed the standards set by the FDA? Take a tour of their facility. Ask to see how raw materials are stored and look for labels indicating quarantine, testing, and release dates. Ask to see examples of their completed production records.

All this is possible without revealing proprietary information. So if you're not allowed to see the facility in action, take it as a sign that the company is not fully transparent about its operations. Would you trust them with your brand's reputation?

**The PureNSM Promise:** We're more than happy to show you our production facility at work. Come see our production, lab, and warehouse staff in action. We'll walk you through the entire production process from the delivery of raw materials to finished product status. We'll even show you examples of production records and raw material test records in line with FDA requirements.

PureNSM operates an FDA-registered production facility under 21 CFR, part 111 of the Federal Code of Regulations (21 CFR111.75). We will gladly furnish proof of our current FDA registration upon request.

## **3) Can you help me avoid product recalls and financial losses resulting from Proposition 65 non-compliance?**

If your products are sold or consumed in the state of California, regardless of your physical location, you need to comply with Proposition 65 (Prop 65).

In 1986, California adopted a stringent law that requires businesses to warn consumers about exposure to various chemicals known to cause cancer, birth defects or other reproductive harm. That list of potentially harmful chemicals is now close to 900 strong.

While good, in theory, to protect consumers from various toxins, Prop 65 does not distinguish between added chemicals and naturally occurring chemicals absorbed from the environment (i.e. lead from a man-made chemical in a pesticide and lead absorbed by a carrot grown in soil get the same treatment under Prop 65).

Additionally, many substances require the Prop 65 warning at levels far lower than the limits set at the federal level.

Prop 65's limits put supplements at risk, especially if they contain raw, unrefined botanical ingredients.

If your product does not have the Prop 65 warning and contains higher levels than the allowable maximum of any of those 900 or so chemicals, you could face a product recall, costly fines and legal fees, as well as a damaged reputation.

To avoid Prop 65 penalties, work with a contract manufacturer experienced at navigating the regulations.

Always ask a potential manufacturer about their knowledge of Prop 65. And because the most common contaminants in supplements are heavy metals, ask the manufacturer about their methods for heavy metal testing.

**The PureNSM Promise:** Having operated in the state of California for over 20 years, we've always got an eye on Prop 65 compliance.

As part of GMP regulations and quality assurance procedures, we test all raw materials for heavy metals with an ICP-MS in our state-of-the-art in-house laboratory.

We regularly test for the most frequent contaminants in food and supplements – lead, mercury, arsenic, and cadmium. Upon customer request and according to availability of standards, we can also quantify many other elements such as nickel, copper, chromium, cobalt, molybdenum, osmium, iridium, rhodium, and more.

As one of our clients, you also receive free label reviews from our experts to ensure that your product label is Prop 65 compliant.

#### **4) Will your company make sure my product label meets the current regulations?**

Your product label is just as important as the actual product. Your label is often the first place consumers look to answer their questions, and it could be the deciding factor in whether or not they purchase your product.

Although the ultimate responsibility of the label rests in your hands, an experienced contract manufacturer should be able to help you navigate through label compliance standards.

From structure and function claims to the supplement facts box format, your manufacturer should know what's required on the finished product label to steer you away from potential problems with the FDA and sales channels such as Amazon.

**The PureNSM Promise:** When you partner with us, we include your product label review in your service agreement. Our knowledgeable quality assurance team will make sure any structure and function claims are up to par, and they'll inform you of what documentation you'll need to have on record to substantiate your claims.

We will even help you comply with the new nutrition and supplement facts format requirements taking place between 2019 and 2021.

## 5) Do you test botanical ingredients with HPTLC?

Botanical supplements have not been represented well in the news lately. Accusations of adulterated ingredients and false label claims have landed reputable brands and retail establishments in hot water. And not always rightly so.

You may recall when New York Attorney General Eric Schneiderman called for DNA testing of several herbal supplements available nationwide. The results indicated that the actual ingredients did not match what the label claimed. Supplement skeptics had a field day when the story went public in 2015.

But what is not widely known is that standard DNA testing is NOT an accurate way to identify botanical ingredients.

When botanical ingredients are dried and pulverized into powders, the plant's DNA becomes damaged. Only fragments of DNA are left at this point, rendering DNA testing inaccurate.

The gold standard for identifying botanical ingredients is a method called high-performance thin-layer chromatography or HPTLC. HPTLC is the type of assurance brand owners need when standard identity testing isn't suitable.

HPTLC can also rule out spent herbs, essentially the leftovers from botanical ingredients that have gone through the extraction process. Unscrupulous vendors may try to pass off spent herbs as their full spectrum counterparts, leaving brand owners who don't test none the wiser.

If you find a contract manufacturer that uses HPTLC, make sure you're able to get copies of the results for your tested ingredients. This type of proof can save your brand's reputation if someone erroneously DNA tested your products, and the results did not come back in your favor.

*"DNA-based methods are not suitable for materials, such as botanical extracts, that were subjected to processes that denature, degrade and destroy DNA."*

- United States Pharmacopeial Convention: USP  
Statement on Validation of DNA Test Methods for  
Regulating the Quality of Herbal Supplements

Don't be sold on HPLC (high-performance liquid chromatography) or FTIR (Fourier-transform infrared spectroscopy) for botanical identity testing either. HPLC measures potency, not identity. And FTIR verifies the identity of amino acids and vitamins, not botanicals.

Knowing what is in your product and having the proof to back up your label claim is essential, especially when people question the regulation of dietary supplements. It is also paramount to make sure you get exactly what you paid for from your raw material suppliers. Even if they provide you with a certificate of analysis, make extra sure that your ingredients have not been adulterated in any way. Otherwise, you're unintentionally scamming your customers.

**The PureNSM Promise:** We test 100% of all incoming botanical raw materials for identity using HPTLC. After operating this advanced system for several years, we have amassed a library of over 250 botanical standards – and it's still growing.

When we first started using HPTLC, our in-house lab rejected about 30% of the raw materials brought in for identity testing. Once our suppliers caught onto the fact that we test raw materials against the vendor's certificate of analysis, they now know that only the best ingredients will pass our standards.

Although the rejection rate has declined, we still reject about 10% of herbs and botanical extracts because they fail HPTLC identity testing.

When you work with us, we're more than happy to provide you with any test results of your raw materials.

## **6) What type of testing do you perform?**

Having the appropriate tests to back up your product is critical, especially if you ever undergo a product recall.

In accordance with GMP regulations, every new batch of raw material must be tested to ensure that the finished product meets certain safety standards.

When shopping for a contract manufacturer, you'll want to know what types of tests they provide, and also the equipment used to perform the tests. And just as equally important is whether a manufacturer performs testing in-house or if they outsource. Outsourcing can be prohibitively expensive and contributes to longer lead times.

So it's a good sign when you find a contract manufacturer that has its own in-house laboratory. This is proof that they take quality control seriously.

**The PureNSM Promise:** We offer a full list of tests in accordance with GMP regulations. Before we even prepare your formula, each raw material component undergoes a series of tests.

<b>Test</b>	<b>Method</b>
Heavy Metal Analysis	Inductively coupled plasma mass spectrometer (ICP-MS)
Microbiology Analysis	Biolumix and 3M Petrifilm Plate Reader (for microbiology contamination testing)
Identity Testing	HPTLC, FTIR, DNA (depending on type of raw material)
Potency Testing	HPLC
Finished Product Testing	Microbiology, Heavy Metals, physical inspection, label review

Heavy metal testing is essential to safeguard your brand from CA Proposition 65. We've got your back when it comes to ensuring that your products are Prop 65 compliant.

We invite you to tour our state of the art in-house lab or talk with our QA and QC team to put your mind at ease. We're happy to talk you through the whole production process from when raw materials arrive at our facility to when the finished product is released from the lab and deemed ready to sell.

We're also happy to show you our meticulously-kept lab records.

We firmly believe that knowing your contract manufacturer's capabilities and seeing them in action is key to ensuring that your finished product is fully compliant with current regulations.

## **7) Is your manufacturing facility and equipment cleaned with toxic chemicals?**

Why should you care how your contract manufacturer cleans their equipment? Because as your raw materials pass through that equipment, your finished product can pick up trace amounts of the cleaning solution. For chemically sensitive people, even the smallest amount of certain chemicals can cause a negative reaction.

It's customary for manufacturers to use laundry bleach like Clorox to sanitize equipment and work surfaces. While bleach is cheap and widely available, many brands are not certified safe for food, making it easy for companies to choose this inferior bleach over NSF certified food-safe bleach.

To minimize the possibility of reactions from chemically sensitive customers, work with a manufacturer that doesn't clean their equipment with toxic chemicals and potential allergens. It's worth it to work with a manufacturer that cares to use safe and effective cleaning products that won't harm your customers.

**The PureNSM Promise:** We think purity should start at the most basic level – our manufacturing facility and equipment.

We only use edible cleaning solvents in our production facility. We use two cleaning solutions that we make ourselves.

<b>We only use edible cleaning solutions!</b>	
	<b>Black Death</b> Active Ingredients: iodine, grain alcohol
	<b>White Death</b> Active Ingredients: ammonia, grain alcohol

(Yes, consuming trace amounts of ammonia is safe. You've probably done it if you consume manufactured food products.)

## 8) Can your company make supplements without unnecessary excipients?

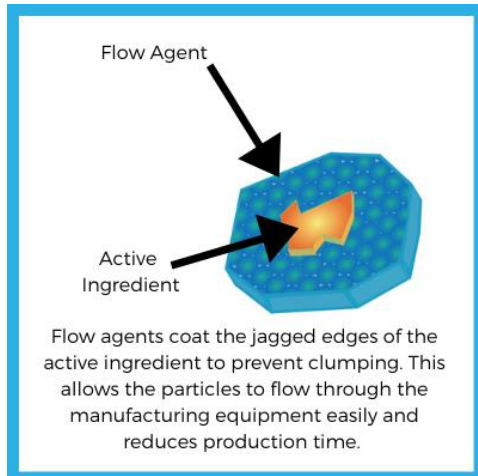
These days more and more consumers pay attention to product labels. They want formulas that are less processed, contain fewer ingredients, and have words they understand. This consumer-lead push for more transparent formulas has given rise to the clean label movement.

*"Consumers want clean labels with words they recognize."*

- Natural Foods Merchandiser

When your customers read your supplement label, what will they find lurking under **Other Ingredients**? This is where you find the manufacturing agents, or excipients, that have no nutritional or functional purpose.





Supplement manufacturers use flow agents (essentially lubricants) to speed up the production time. This helps to keep production costs low, a perk that is often passed on to you, the client.

But flow agents, binders, fillers, and the like are exactly the kind of ingredients customers are moving away from, especially if these manufacturing aids are synthetically derived.

If you want your supplements made without unnecessary excipients, make sure you partner with a contract manufacturer that meets your clean label demands. Some companies may tell you that manufacturing without flow agents can't be done. Don't fall for this lie!

**The PureNSM Promise:** We've been specializing in supplement manufacturing WITHOUT flow agents and other unnecessary excipients since 1993.

Long before the clean label movement was born, we invested in learning how to encapsulate supplements without the need for flow agents such as magnesium stearate, stearic acid, and silicon dioxide. And we've had over 20 years to perfect our skills.

Manufacturing without flow agents does take more time and is more labor intensive, but we believe pure products are more effective and better for your body when they aren't laden with chemical additives.

We can help you avoid putting the following excipients on your supplement label: magnesium stearate, silicon dioxide (silica), cellulose, stearic acid, titanium dioxide, starch, maltodextrin, and more.

Even if you have a troublesome formula that sticks to the equipment, we can use a less controversial and naturally-derived alternative flow agent such as organic rice flour.

## 9) Do you actually manufacture on-site or do you outsource the labor?

This may seem like a silly question to ask a manufacturer, but ask it nonetheless.

Many of the biggest contract manufacturing companies in the US actually outsource a large fraction of their labor to other companies. This causes longer lead times and even more concerning, loss of control over how the product is made.

Doing business with a manufacturer that doesn't actually make products on-site is risky. How can you be assured of what's actually in those products?

**The PureNSM Promise:** We've been manufacturing supplements **on-site** since 1993. We maintain fastidious control over the manufacturing process because it's all done on-site: raw material purchasing, testing, formula mixing, encapsulating/tableting, botting, and labeling.

And best of all, we've specialized in manufacturing capsules without the need for flow agents and other unnecessary excipients long before it became part of the clean label trend.

## **10) Can you make my product with ingredients in their purest form?**

The clean label movement makes an appearance yet again. Not only do health-conscious consumers want formulas without manufacturing aids, but they also want active ingredients that aren't diluted with chemicals or contaminated with enhancement agents.

Diluted ingredients may cost less but consider that they may be viewed as inferior to their pure form counterparts. Take vitamin C, for example. There are several forms of vitamin C available, and some have better absorption in the body over others. A product may indicate "Vitamin C as ascorbic acid" on the label, but often times consumers aren't alerted to the purity of the raw material used. Was it made with pure ascorbic acid or a 90% ascorbic acid that has been doctored with corn starch and lactose to ease the manufacturing process?

Not all manufacturers keep your reputation in mind. They may only offer you the cheapest raw material they can get their hands on or push those that have been altered for easier production.

Be sure to verify what form of ingredients your contract manufacturer uses in your product. It's your name on the label, so make sure you're the one calling the shots when it comes to ingredients.

Here's a look at common ingredients that we use versus what you may expect from other contract manufacturers.

<b>How Nutrients are Listed on the Label</b>	<b>NSM's Preferred Raw Materials</b>	<b>Other Manufacturer's Raw Materials</b>
Vitamin C	Pure Ascorbic Acid	90% ascorbic acid with 10% corn starch and lactose
Vitamin D	Pure Vitamin D	0.1% Vitamin D dilution in a base of dicalcium phosphate, lactose, acacia, BHT, sodium benzoate and sorbic acid
Vitamin B2 (Riboflavin)	Pure Riboflavin	33% riboflavin with mono- and diglycerides for better flow, flavor and masking
Vitamin B12 (Cyanocobalamin)	Pure Vitamin B12 (Cyanocobalamin)	0.1% B12 dilution in a base of corn starch with sodium benzoate and sorbic acid
Biotin	Pure Biotin	1% biotin diluted in a base of dicalcium phosphate, lactose, sodium benzoate and sorbic acid
Pepsin	Pure, Undiluted Pepsin	Pepsin standardized with lactose
Pancreatin	Pure, Undiluted Pancreatin	Pancreatin standardized with lactose
Bromelain	Pure, Undiluted Bromelain	Bromelain standardized with lactose
Papain	Pure, Undiluted Papain	Papain standardized with lactose

We can make your vision of pure, clean label supplements a reality

## **11) How will your company communicate with me?**

Communication between businesses and customers is a given, so you want to work with a manufacturer that is honest and keeps you informed. If there's a delay in the production schedule, will your sales rep alert you as soon as possible? Will they share your formula with other clients?

Your manufacturer should be upfront about lead times, included services, and expectations both before and after you've signed the contract to begin work.

**The PureNSM Promise:** We offer you a fully transparent experience from start to finish. We honor your trust in us by keeping you informed every step of the way. If there are any issues with raw materials, testing, formulation, production, packaging, labeling, etc., we won't hesitate to let you know. We'll work with you to find the best solutions to whatever problems arise.

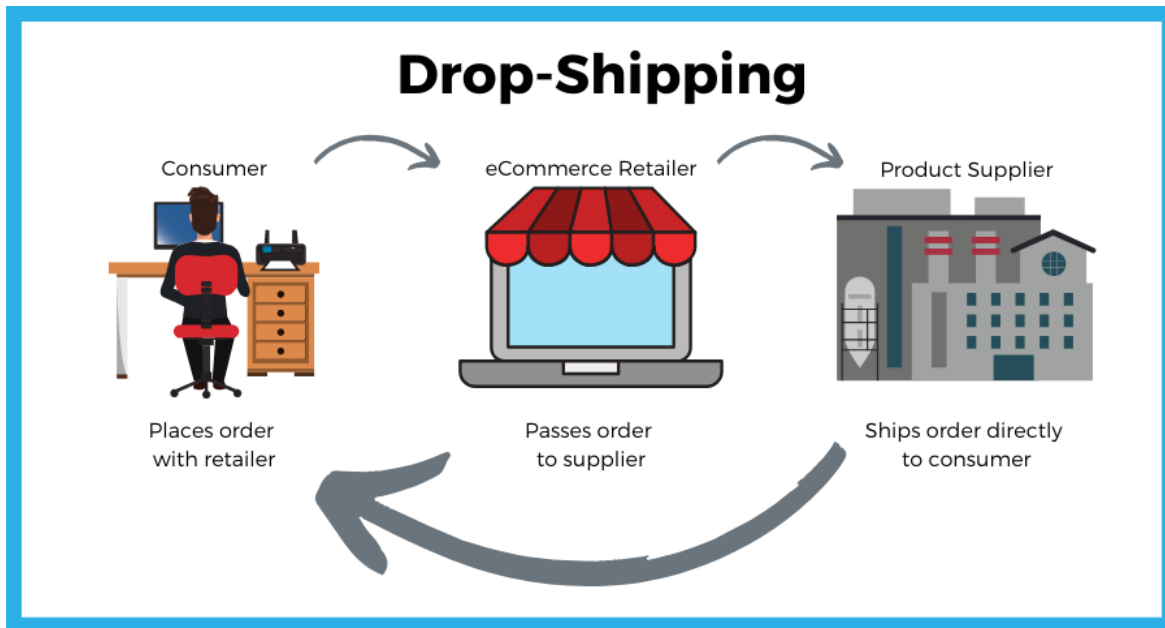
We're committed to addressing any concerns promptly before, during, and after the job is complete.

## **12) Can you drop-ship my products to my customers?**

If you plan on shipping directly to your customers, having a contract manufacturer who has drop-ship capabilities is a bonus.

If you don't have the storage space to house your product once it's manufactured (we could be talking about a few hundred or a few thousand units) or the means to handle shipments to your customers, a drop-ship service is an ideal way to go. This is an especially attractive feature if you're brand new to the supplement game and you don't have the space or the manpower to handle all your orders yet.

If you decide to work with a fulfillment company, major parcel carriers like FedEx and UPS won't give the company discounted shipping rates. But if the manufacturer who sold you the product also provides order fulfillment, the manufacturer has access to those discounted shipping rates. Over time, the savings on shipping fees add up.



**The PureNSM Promise:** Our sister company **Pick Pack America (PPA)** provides full-service warehousing and order fulfillment for several of our clients.

Since PPA is located in the same business park as us, your product goes from our production facility straight to the PPA warehouse, where your orders can be filled almost immediately. And PPA can pass along the discounted shipping rates to you.

Partner with us if you're interested in reducing the administrative and financial burdens of a brand owner. Watch your overhead costs drop when you don't have to employ your own shipping team or rent your own warehouse space.