Seeking High-quality Products: Whose Definition Should We Believe? (Part I)

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Summary

I write this 2-part column from my experience as a quality control/quality assurance director, which comes from comprehensively testing several thousand raw materials and finished products for the past 9 years. I expand upon previous articles to make the case that a high level of quality control is the only way to produce consistent high-quality products. We all want these high-quality natural products, but to make sure you actually get them takes some work. Each clinician must do the homework to find out how good the products you buy really are.

***Editor's note**: This is the first of a 2-part article.*

A clinician member of a functional medicine chat group asked a professional products company (Company Y) to complete *IMCJ*'s Manufacturer Quality Assurance Self-Audit Form (found at www.imjournal.com) and provide documentation and evidence of quality control practices. What he got back was an emailed note from Dr X, the chief science officer of Company Y. In this article, I compare and contrast the responses given to what should have been given.

In this comparison, I do my best to educate and distinguish between very general statements about quality assurance versus detailed and specific quality testing and quality practices. I ask that you keep in mind that this was written in the spirit of bringing detailed awareness to comprehensive quality control practices and *not* to bash another (albeit unnamed) company. Company Y's response is merely the platform used to detail such an awareness. My main motivation for using this particular response is that on the surface the answer sounds sincere—as it may be—and even, to the untrained ear, sufficient. I write to educate beyond such an appraisal. After finishing this, I hope you, the reader, will understand why, just because something sounds good, it may not be good at all. Thus, if you get back a reply such as this, you will be equipped to respond and ask for more.

A Starting Point

Here is a reprint of the e-mail sent to the chat group member, with identifying information deleted:

> Hello Doctor,
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> We at Company Y share your belief that nutritional supplement raw materials be of the highest quality and purity, free from contaminants. For this reason, Company Y never buys on the spot market and does not buy from brokers. We purchase raw materials from highly reputable companies that we have screened and qualified. Regarding solvents, all of our botanical raw material suppliers do their own extractions. The vast majority of botanicals we use are either aqueous or ethanol extractions. Residual solvent levels comply with European and United States Pharmacopeia National Formulary (USP-NF) standards at less than 0.5% for all products extracted with alcohol or water. For all products extracted with other solvents such as acetone or ethyl acetate, residual content complies with European and USP-NSF standards. Residual levels are tested by gas chromatography.
>
> We do not routinely test every batch of botanical raw materials independently. . . . It is simply not financially feasible to do this. Solvent testing at the most competitive laboratory we have found starts at $150 for the first solvent and costs $100 per additional solvent. There are at least 50 different solvents from which to choose. A full panel of all these would cost in excess of $5000. Routine testing would significantly increase the cost of goods sold. It is financially impossible for any company that markets competitively priced products to test every raw material batch. Any company claiming this type of testing should provide proof of testing for multiple botanicals and multiple batches of each botanical.
>
> We have a high degree of confidence in the ethics and quality control procedures of our vendors. It is unfortunate that other companies appear not to be able to trust their suppliers. All of our botanical raw materials are produced, extracted and tested by the vendors to European and United States Pharmacopoeia standards. We have every batch of our fish oil independently tested and we independently test each batch of probiotics.
>
> I hope I have addressed your concerns. If you have additional concerns or questions, please contact me directly.
>
> Sincerely,
>
> Dr X
>
> Chief Science Officer

What I find most interesting about the comments from Dr X is that they are extremely general and not specific whatsoever. We are not told exactly and specifically what Company Y does or does not do regarding testing quality nor are we told with what frequency they do their testing. This leaves buyers in a quandary. How are we to evaluate if the company is deficient or adequate in quality verification? Ideally, clinicians should be able to determine this by a thorough evaluation of detailed information and the evidence presented by the company—hence the *IMCJ* self-audit form is comprehensive and geared toward providing those answers.

The website dictionary.com (http://dictionary.reference.com) gave the following definition for *verify*: "to prove the truth of, as by *evidence*," to "confirm," "substantiate," "authenticate," "validate" (italics in the definition are mine).

According to the answer given, Company Y is saying that it trusts its suppliers to provide raw materials that are high quality, claimed potency, pure, and free from contamination each and every time. Dr X says, "It is unfortunate that other companies appear not to be able to trust their suppliers." This is an extremely optimistic and impractical statement that, I am very sorry to have to say, is not based in reality. We have seen over and over again published reports of inauthentic, poor-quality, low-potency, contaminated materials as determined by ConsumerLab.com, the US Food and Drug Administration (FDA), and many, many other sources. It is likely the providers of those flagged low-quality products were also "trusting" their suppliers.

Just remember, trust is nice, but verification, evidence, and proof are essential. I have reviewed thousands and thousands of raw material, finished product, and stability tests our independent labs have performed. I can say with certainty that this is not an industry in which trust should be the cornerstone of quality control. I have seen too many failures even from the best and most reputable raw materials suppliers.

High Quality, Purity, and Maximum Freedom From Contamination

Company Y Statement: "We at Company Y share your belief that nutritional supplement raw materials be of the highest quality and purity, free from contaminants."

Response: Belief . . . unfortunately, in today's world (perhaps in all worlds), to believe in a principle is not enough. There must be actions behind the belief. Quality, purity, and contaminant levels have to be verified by quality testing. As he continues in his letter, Dr X tries to make the case that Company Y routinely provides such testing, but he declines to offer specific details and evidence as to how, exactly, this is done.

In fact, it is often impossible to have products free from contaminants. Even making that statement shows some level of naiveté. It would be much more accurate to say "maximum freedom from contamination." The reason is that many materials are just inherently contaminated, and there is no getting around that fact.

Botanical raw materials usually have some level of microbial content and some level of heavy metal content (both could be small and acceptable levels) because they were grown in the ground. The vast majority of botanicals have 1 or both of these contaminants—thus, most of the time, botanicals are not free of contaminants. Does Company Y routinely test for either microbes or heavy metals? Dr X does not say. If not, the company should. If its goal is to provide contaminant-free product, how do they accomplish that? Dr X does not say.

In addition, unless a product is certified US Department of Agriculture (USDA) Organic, the botanical was grown with some application of herbicides and pesticides. How would you know how much may still be in the product without residue testing? And if there is residue, the question stands whether it is USDA or FDA approved for that crop. And is it at a level that is acceptable? The answer could be *yes* on both counts, and that would be perfectly fine. However, it is not "free of contaminants."

Another contamination problem is fungus. If a botanical is stored in such a way as to promote fungal growth that produces aflatoxins, how would you know without testing that the aflatoxin level is below the FDA limit of 20 parts per billion (ppb)? What if it had 4 ppb of aflatoxin in it? In that case it would be suitable for use but not "free of contaminants."

I found a high level of aflatoxin in a batch of milk thistle (*Silybum marianum*) extract from one of the highest-quality botanical suppliers in the world. When asked how this tainted batch got through their quality control procedures, the company told me they do skip lot testing. If I had "trusted" the supplier, my patients would have consumed liver-toxic aflatoxins. By the way, an aflatoxin specification or limit wasn't on the certificate of analysis. Years of experience show they are a possible contaminant. Would Company Y have tested? The letter does not say, so we do not know.

As another eye-opening piece, it is possible that nonbotanical raw materials *will* be free of contamination because many nonbotanical raw materials don't support microbial growth and shouldn't have heavy metal contamination because they don't come from the ground. But. Often in the manufacturing process, solvents are used, and some of the solvents may leave a residue. In fact, I routinely find chemical solvent residue in nonbotanical raw materials and, frustratingly, this is true of materials from even the most reputable of suppliers. I'll address the solvent residue issue in the next issue of the journal.

So the basic problem with Dr X saying he *wants* nutritional supplement raw materials to "be of the highest quality and purity, free from contaminants" is that he does not given details as to what Company Y means by this statement and how it is assured from batch to batch. How can we clinicians evaluate quality practices without specific details?

To ensure the highest quality and purity, any manufacturing company would have to test botanical raw materials routinely for authenticity; stated potency; heavy metal content; aflatoxin content; herbicide and pesticide content; solvent residue; and bacteria, yeast, and mold content. Nonbotanical raw materials would be routinely tested for authenticity; stated potency; solvent residue; and bacteria, yeast, and mold content.

A Comment on Finished Product Testing: All manufacturing companies should test finished products to independently verify that they manufactured the products correctly and have met the label claim for ingredients. If an expiration date is used on their products, they should also provide an appropriate amount of test data from several batches that proves they have met the potency

Table 1. Examples of Dietary Supplement Product Failures and Deficiencies with Country of Origin				
Material	**Problem**	**Sold By**	**Country of Origin**	**How Problem Found**
Bilberry extract 25%	Failed identity and assay	US company	Italy	Thin-layer chromatography testing and anthocyanidin potency assay
Black currant seed oil	Rancid oil	Large US company, GMP certified	United States	Peroxide and anisidine tests (rancidity markers)
Certified organic wild yam root	High aflatoxin content	US company	United States	Aflatoxinassay
Curcumin extract 90%	Contained 1,2 dichloroethane, a toxic solvent	US company	India	Solvent-residue testing
Diindolymethane	Very high benzene content	US company	China	Solvent-residue testing
Feverfew 0.5%	0.4% active marker vs 0.5%, ie, subpotent	US company	France	Potency assay
Magnesium ascorbate	Company information claims ingredient to be chelated, instead was a dry blend of magnesium oxide and vitamin C; ie, not chelated	US company	United States	I asked if the product was fully reacted. The company admitted it was not but sold it as such anyway
Potassium ascorbate	Same as magnesium ascorbate, above	US company	United States	I asked if product fully reacted; they admitted it was not but sold it as such
Milk thistle extract 80%	High aflatoxin content	US company	Italy	Aflatoxin assay
Milk thistle extract 80%	High acetone content	US company	France, Spain	Solvent-residue testing
Silybin concentrate	High acetone content	US company	Argentina	Solvent-residue testing

through the dating period. No detail is provided by Dr X as to exactly how Company Y addresses these issues.

Performing all of these quality measures specifically addresses and defines "high quality, purity, and maximum freedom from contamination." These appropriate and necessary measures are, sadly, a far cry from "we trust our supplier."

Reputation and Ethics

Company Y Statement: We purchase raw materials from highly reputable companies that we have screened and qualified.

Response: The obvious question is how were they screened and qualified? We are not told. Such a statement should never be taken at face value. Any company making that claim needs to reveal specific details as to exactly what quality control measures were performed to qualify a vendor.

The proper way to qualify an individual supplier's or a particular vendor's goods is to test the lots of received raw materials for authenticity and potency and to perform a complete contamination profile. Why did Dr X leave out those details as to how that screening and qualification is performed?

It is imperative that manufacturers independently verify raw material quality in a comprehensive manner. If they do not, they are missing problems that will get through to your patients. I and any other clinician should always ask, did the manufacturer screen and qualify the supplier of the raw materials? If so, how? Give me the details as to exactly what is done.

Company Y Statement: "We have a high degree of confidence in the ethics and quality control procedures of our vendors."

Response: That is all well and good. But you also have to consider that vendors make mistakes, they may do skip lot testing, or the vendor's suppliers make mistakes and/or cut corners. That is why routine verification testing is so important. Confidence is not enough. Any company that routinely "trusts" that quality is inherent may be missing the boat, fooling themselves, and putting consumers at risk.

Remember the definition of *verify*: "to prove the truth of, as by evidence, to confirm; substantiate, validate."

In the April/May 2008 issue of *IMCJ,* I listed numerous examples of raw materials that failed routine testing (*IMCJ* 7.2:41). These materials came from well-known reputable suppliers. If we did not submit these raw materials to rigorous quality testing, the problems would never have come to light. Above, in Table 1, are highlights of a few.

Next issue I will delve into the issue of solvent residue and finish an evaluation of Dr X's letter. I hope this makes it clearer how specific you need to be when requesting information on quality control. On the surface some answers may sound good, but you need to find out the truth behind the words.

For more information on quality assurance issues, visit the *IMCJ* website, imjournal.com, and click on "Quality Assurance" at the bottom of the left-side menu bar.

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