Guest Editorial

Are you concerned about the practice called “dry labbing” (i.e., fabricating or faking laboratory quality assurance test results) in the dietary supplement (DS) industry? You should be, as there are probably more than a handful of laboratories that may be operating under these types of practices. Not all dry labs will be operating as blatantly as the lab that was identified in the recent Dateline NBC segment covering that topic. Some labs may in fact be performing selective dry labbing, which means they will do testing on some samples, and not on others, which would make it much more difficult to prove.

Here are a few useful tips for companies using 3rd party contract analytical laboratories.

1. When sending samples to independent laboratories, do not tell them exactly what specifications you are expecting for the sample. Bear in mind that you must tell the lab something, as it would make it very difficult for the lab to perform proper analytical testing without having some idea what the concentration range of the analyte (compound of interest) actually is. For example, if you were sending the lab a product which contains 75 mg of caffeine per capsule, you would not want to tell the lab that you expected 75 mg per capsule. It would be better to tell the lab that you were expecting somewhere between 25 mg and 150 mg per capsule. By not providing the laboratory with the exact specification, it makes it very difficult for them to fabricate an expected value.

2. Send challenge samples to all of the contract laboratories you use. Challenge samples are also known as “dummy” samples, and are an intentional effort to misrepresent what you are telling them. For example, send your laboratory a sample of vitamin C capsules, and tell them you would like them to test for caffeine. If the laboratory reports that there was no caffeine, then you are in good shape. The practice of sending challenge samples to your laboratories is something that should be done with some regularity. Challenge samples can also be used to perform a routine checkup on the proficiency of your laboratories. For example, certified reference materials (CRMs) could be purchased from NIST (National Institute of Standards and Technology), where they have very precisely measured and reported the values for various analytes in a botanical matrix sample, such as spinach. By sending your labs such proficiency samples you can find out how accurate their results are as compared to well-established values in CRM materials.

3. Visit, audit, and inspect your contract laboratories. Contract laboratories performing analytical testing services for dietary supplement manufacturers are in fact a part of the good manufacturing practice (GMP) process, which makes them fully accountable for being GMP. Since contract laboratories are accountable for GMPs, companies using the services of contract laboratories should visit, audit, and inspect their labs in order to be GMP compliant themselves.

4. Qualify the contract laboratories your company uses before sending samples and relying on the results they provide. As a matter of fact, it would probably be a good idea to have a standard operating procedure (SOP) for “Qualifying Independent Contract Testing Laboratories,” in which the DS company would provide a checklist for performing due diligence on a laboratory before they were “qualified” for use.

If companies in the DS industry who are utilizing contract testing labs were to follow these four basic rules, it would be very difficult to operate a dry lab without getting caught.

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