RETAILER PRODUCT TESTING GUIDE

ALKEMIST LABS

With dietary supplement testing so much in the news this year, consumers are asking more questions about how the products our industry sells are tested, and they are looking for real answers. Since testing is a complicated business, how can you know what to ask to ensure the products on your shelves are getting the right testing?

As a testing lab that focuses exclusively on natural products, Alkemist Labs believes that true transparency in testing is crucial for giving customers peace of mind, so we've developed tools to help you make sure that you've done your homework and the products you offer for sale contain what they are supposed to contain, and nothing else.

Retailer testing guide: This is a checklist you can use when speaking with supplement company reps about the quality and testing rigor that goes into the brand's products. Use it to do your part in ensuring testing transparency from ingredient source to retail shelf.

ACCREDITATIONS AND GMP'S

1. **Do you follow the cGMP's for dietary supplements?**
   All dietary supplements sold in the United States must be manufactured under the cGMP's. Anything short of an unequivocal "Yes!" should give you pause.

2. **What accreditations do you hold?**
   There are a number of accreditation bodies which will provide an International Organization for Standardization (ISO) accreditation as well as organizations such as: NSF Certified, USP Verified & UL Stamp of Approval are all trusted names in the industry.

3. **Have you been audited by the FDA? What were their findings?**
   Having an FDA audit is an excellent bellwether. They should be willing to provide an audit report, which will give you a glimpse into their organization. Minor findings by the auditor are expected but numerous major issues may require additional follow-up to ensure that they've been addressed.

4. **Have you ever been issued a warning letter?**
   A warning letter is a letter issued by the FDA for misconduct such as making an unsubstantiated health claim or not following cGMPs. These are publicly accessible documents so the manufacturer should have no reservations discussing these with you. You can search for warning letters by company at this link: http://www.accessdata.fda.gov/scripts/warningletters/wlFilterByCompany.cfm

ENSURING IDENTITY, STRENGTH AND PURITY

No two answers in this section will be the same as they are variable depending on the manufacturer and the component in question. So look for general answers in the positive.

1. **What criteria do you use when selecting a raw material vendor?**
   The correct answer should be that they do have criteria that their vendors must adhere to.

2. **What is your procedure to ensure your raw materials are identified correctly?**
   The correct answer is that they analyze every shipment for identity.

3. **What do you do to ensure your raw materials strength?**
   An acceptable answer would be that they have validated their supplier and verify strength routinely. It is not required to be done on every lot for verified suppliers, however a manufacturer with a robust quality assurance program may actually test every lot.

4. **What analyses do you utilize to ensure your product is free of impurities and contaminants?**
   A correct answer would be we perform one or more the following.
   i. Pesticides screen
   ii. heavy metals
   iii. residual solvents
   iv. microbial contamination
   v. an assay specific to the component, such as dioxins in fish oil.

5. **What procedure do you follow to ensure your finished product's potency?**
   An acceptable answer would be that they have validated their manufacturing process and perform routine confirmation testing every specific number of lots. A higher-quality manufacturer may verify potency with every manufactured lot for simple products; however, this is very cost prohibitive on a multivitamin or complex formula, so it is not common.

6. **How have you established the shelf life?**
   The correct answer would be with a shelf-life study on the finished product formulation and packaging. It is not acceptable to guess or use the raw material's shelf-life data.

7. **What overages do you put in the product?**
   The correct answer would be that they use a specific overage percentage to account for production variability and shelf-life. The incorrect answer is that they do not put in an overage as that answer demonstrates they have little understanding of their product or the GMP requirements.

FAILED PRODUCT PROCEDURES

1. **What is your procedure after you've identified a failed component identification assay?**
   Quarantine and conduct additional investigation would be the bare minimum. Some will say they return the shipment. An excellent answer is that they destroy it so that a failing product is not simply recycled into another less-careful company's product.

2. **What is your procedure after you've identified a failed product potency or contamination analysis?**
   Quarantine and additional investigation, and even a recall, if warranted, would be the bare minimum. Review and upgrade their cGMP procedures is the best answer.

3. **Do you investigate all client complaints and adverse events?**
   An affirmative answer is the hallmark of a company that cares about its brand. They are required by law to report serious adverse events.