

Dietary Supplement Quality Assurance Questionnaire

Name of Company:	
Mailing Address:	
Phone Number:	Fax Number:
Name of Contact:	Name of Person Completing Form:

To help us better understand your company's quality assurance and manufacturing procedures, please answer the following questions as thoroughly as possible. If a question does not pertain to the products that your company produces, write N/A after the question.

Basic Information

Number of years your company has been in business:
Does the company manufacturer its own products or do you contract out to someone else? If you contract out, who is the manufacturer?
Have clinical studies been done on any of your products? If so, which products?

Quality Assurance Issues

Do you have an in-house quality assurance/quality management program?
What is the staff size?
Does the company have a formal training program for quality assurance?
Does the company have and adhere to written standard operating procedures (SOPs) that cover manufacturing, quality control, sanitation, material procurement, etc? If yes, would you be willing to provide us with a copy of the table of contents?



Manufacturing

<p>Do you comply with GMPs?</p> <p>If yes, which ones? (USP, NFS, NNFA, FDA proposed, TGA, other)</p>
<p>Has the company been audited by an independent auditor to assure compliance with GMPs?</p> <p>If yes, who performed the audit?</p> <p>How often do GMP audits take place?</p>
<p>What additives, fillers, and excipients are used?</p>
<p>Are products produced in a facility that may cause cross-contamination with potential allergens? (gluten, corn, soy, dairy, tree nuts, peanuts, etc.)</p>

Raw Material Sourcing

<p>How many different raw material suppliers do you use?</p>
<p>Do any of your raw materials come from non-U.S. sources?</p> <p>If yes, what materials, and what countries do they come from?</p>
<p>Are all raw materials quarantined before quality assurance releases them?</p>
<p>Do you rely on the certificate of analysis provided by the supplier to verify potency and authenticity?</p> <p>If yes, what are your criteria for your supplier's verification procedures?</p> <p>If no, how do you verify potency and authenticity?</p>
<p>Do you use temperature controls while storing raw materials?</p>



Raw Material Testing

Do you do raw material testing on every lot?

If no, how often do you test raw materials?

What test do you run on raw materials?

Microbiology Testing

Are raw materials tested for bacteria, mold, and yeast?

If so, what levels are acceptable?

Is testing done on every lot?

Are raw materials tested for absence of *Salmonella* species, *Escherichia coli*, and *S. aureus*?

Rancidity Testing

Is rancidity testing done on all oil-based raw materials?

If yes, is it done on every lot?

Are oil-based raw materials tested for peroxide level?

What level is acceptable?

Are oil-based raw materials tested for anisidine levels?

What level is acceptable?

Toxin Testing

Is heavy metal testing done on every lot?



If no, how often is it done?
What heavy metals do you test for? What are acceptable levels?
Are raw materials tested for PCBs? If so, what are acceptable levels?
Do you test raw materials for any other toxins? If so, what?

Finished Product Testing

Is each lot of finished product assayed to assure it meets 100% of label claims? If not, how often do you assay?
What procedures or testing is conducted on finished product to assure purity, composition, and quality?
Are finished products tested for dissolution? If yes, do you have a time requirement for dissolution?



Expiration Date

Do your products have an expiration date?

If yes, how is it determined?

Is stability and potency testing done to verify the expiration date?

Sample Retention

Do you retain a sample of each lot of produced product?

If yes, are they stored in the same packaging as the finished goods?

How long do you keep retained samples?

Allergen Warning Label

Do you put warnings on all products that contain or may contain common allergenic substances? (gluten, dairy, soy, corn, tree nuts, peanuts, etc.)

Lot Tracking System

Is a lot number put on every bottle?

As products are sold to customers, are the lot numbers entered into a database so each product sold can be tracked by lot number?

Complaint and Return Policy

What is your return policy?

How are product complaints handled?

For Manufacturers of Herbal Products

Do you harvest any of your own herbs?



<p>If yes, which ones?</p>
<p>Do you use organic or commercially grown herbs?</p>
<p>Is plant material verified for correct genus and species?</p> <p>If yes, how is it verified?</p>
<p>Are any plants from wild-crafted sources?</p> <p>If yes, are they ethically wild-crafted?</p> <p>How do you assure this?</p>
<p>What extraction processes are used?</p> <p>If a solvent is used, what is it?</p> <p>Are the extracts tested for solvent residue?</p> <p>If yes, what is an acceptable level of solvent residue?</p>
<p>Do you test for pesticide residue?</p> <p>If yes, what type and amounts are permissible?</p>

Thank you for completing this questionnaire and helping us assure that our patients are receiving the highest-quality supplements we can offer them. Please fax completed questionnaire to _____ to the attention of _____.

