

SUPPLIER CERTIFICATION & QUALITY ASSURANCE SELF AUDIT

Your Practice Name & Address Here

FOREWORD

Our suppliers are the essence of our success. We cannot succeed without quality materials and services. We have therefore embarked on a program designed to develop working partnerships with our valued suppliers. We feel that development of an open, trusting, cooperative relationship with our suppliers is a prerequisite to a meaningful certification process.

Vendor certification is an important component of a total quality management system that assures that a supplier's product is produced, packaged, and shipped under a controlled process that results in consistent conformance to our requirements. It supports the concept of quality at the source by doing it right the first time thereby substantially reducing or eliminating the need for final quality inspections by the supplier or the customer. *The primary objective of the certification process is to assure consistent high quality* as demonstrated by predictable conformance to our requirements. The basic premise is that we want to identify suppliers that have adequate process controls in place and they provide legitimate proof that their products are consistently fit for use, authentic, meet label claim and are free from contamination or have maximum freedom from contamination.

It is our goal as a medical practice to offer products that meet or exceed all the applicable regulatory requirements, are clinically effective and safe for our patients, customers and friends. We feel very strongly about the importance and need for certification and have included it as a major cornerstone of our business philosophy. We seek to identify and do business with natural product suppliers that attain and maintain full compliance with the proposed FDA GMP guidelines for the manufacture of nutritional supplements currently published in the Federal Register.

OBJECTIVES:

We are seeking suppliers who:

- a. Are interested in making certification a standard part of doing business and we invite you to join us in our *pursuit of excellence*. Our suppliers would have in place or are willing to put in place a documented quality system.
- b. Are committed to partner with us and develop internal programs to assure consistent quality, good communication, timely delivery, and best overall cost.
- c. Have or are willing to put in place a comprehensive Quality Assurance testing program that assures raw material and finished product authenticity, label claim potency, freedom from contamination and stability over the expiration dating period.

Please answer the questions and return completed audit to: The address at the top. In an effort to protect your IP and confidentiality you may provide the first and last sheet only for SOP's, Multi-page forms, Audit Reports, etc. as proof of proper documentation.

SUPPLIER CERTIFICATION & QUALITY ASSURANCE SELF AUDIT

Please answer each question with Yes, No, N/A or provide further data.

CORPORATE AND PERSONNEL INFORMATION
1. Supplier Name:
2. Supplier address, telephone/fax number and web address:
3. Manufacturer's name, address and telephone number (including all manufacturing sites):
4. Name, address, telephone number, and contact person for any/all of your QA/QC Contract Labs:
5. Contact personnel: (Provide name and email address) Plant Manager: QA/QC Manager: Purchasing Agent:

CGMP & QUALITY OF PROCEDURES INFORMATION	Y	N	N/A
Check one column or circle one letter for each.			
6. Does the company have a Quality Control Unit?			
7. Does the quality unit have the authority to approve / reject the following: a. Procedures b. Specifications c. Test methods and results d. Raw ingredients / components e. Finished ingredients f. Packaging materials g. Labels h. Processing records i. Forms j. Instrument / control calibrations k. Reprocessing operations	a b c d e f g h i j k	a b c d e f g h i j k	a b c d e f g h i j k
8. Do you have a cGMP system in place? If so, which do you follow: a. Food cGMP's b. FDA cGMP's for Dietary Supplements	a b	a b	
9. Have you ever been independently certified for cGMP compliance? If so, by whom? a. NPA Date of Last Audit: _____ b. NSF Date of Last Audit: _____ c. USP Date of Last Audit: _____ d. TGA Date of Last Audit: _____ e. Other: _____ Date of Last Audit: _____	a b c d e	a b c d e	
10. If independently certified for cGMP's please provide proof that you successfully passed the cGMP audit. (Please attach audit report as proof)			
11. Please provide a copy of: The table of contents for your written SOP's The table of contents for your SOP forms (Please attach)			
12. Do written records exist of employee training and education? If yes, please attach an example.			
13. Does a written GMP training program exist for new and veteran employees?			

SUPPLIER CERTIFICATION & QUALITY ASSURANCE SELF AUDIT

RAW MATERIALS	Y	N	N/A
Check one column or circle one letter for each.			
14(a) If you have an in-house lab: a. Name/email of supervisor: b. How many analysts by level of education are in the lab? GED ____ BS ____ MS ____ PhD ____			
14(b) If you use contract labs are they audited by: a. Company personnel b. A third party c. Not Audited d. If audited, how often? Yearly Every 2 yrs. Every 5 yrs Other	a b c NA		
15A. When doing in-house or independent testing of "BOTANICAL" raw materials are they checked for: (Please provide 2 examples of test data for each item a-g)			
a. Identity (To authenticate material or botanical genus & species) If yes, are SOME or ALL materials tested? (circle answer) If yes, how often? (Choose one) 1. Each batch received 2. Skip lot testing (If so, how often?) _____ 3. Other _____	a	a	
b. Microbiology Profile (Bacteria, Yeast & Mold) If yes, are SOME or ALL materials tested? (circle answer) If yes, how often? (Choose one) 1. Each batch received 2. Skip lot testing (If so, how often?) _____ 3. Other _____	b	b	
c. Potency (if potency claim exists) If yes, are SOME or ALL materials tested? (circle answer) If yes, how often? (Choose one) 1. Each batch received 2. Skip lot testing (If so, how often?) _____ 3. Other _____	c	c	
d. Heavy Metals (Lead, Mercury, Cadmium, Arsenic) If yes, are SOME or ALL materials tested? (circle answer) If yes, how often? (Choose one) 1. Each batch received 2. Skip lot testing (If so, how often?) _____ 3. Other _____	d	d	
e. Chemical Solvent Residue If yes, are SOME or ALL materials tested? (circle answer) If yes, how often? (Choose one) 1. Each batch received 2. Skip lot testing (If so, how often?) _____ 3. Other _____	e	e	
f. Aflatoxins If yes, are SOME or ALL materials tested? (circle answer) If yes, how often? (Choose one) 1. Each batch received 2. Skip lot testing (If so, how often?) _____ 3. Other _____	f	f	
g. Herbicides & Pesticides Residue If yes, are SOME or ALL materials tested? (circle answer) If yes, how often? (Choose one) 1. Each batch received 2. Skip lot testing (If so, how often?) _____ 3. Other _____	g	g	
If your company does not test one or more of these items on every batch of material please provide a detailed rationale for how you prove that omitting the analysis is not missing a quality parameter.			

SUPPLIER CERTIFICATION & QUALITY ASSURANCE SELF AUDIT

FINISHED PRODUCTS Check one column or circle one letter for each.	Y	N	N/A
20. Are your finished products tested for label claim potency prior to release for sale? If yes, please provide full test data for 3 different products If not, please provide a rationale for how you prove you meet label claim.			
21. Do you put expiration dates or a use by date on your products?			
22. Do you do label claim potency testing (Stability Testing) to verify that the product meets label claim through out the expiration dating period? If yes , please provide stability potency assays on 3 different finished product batches that were tested to verify the expiration date claim. If not , please provide a detailed rationale for how you prove that you have met the label claim through the dated period.			

Thank you.