Quality Control and cGMP Assessment

The focus of this assessment is to assist us in providing the best quality supplements and medicines for our patients. It is our belief that creating and maintaining a quality assurance (QA) program is our responsibility because, without it, we have no way to discern which manufacturers are in alignment with our commitment to quality, safety and excellence. The FDA announcement of the final rule establishing cGMPs presents an opportunity to update our QA program records. We want to thank you in advance for completing this questionnaire and working with us to provide safe, high quality, clinically-effective interventions for our patients.

Please return this quality control (QC) assessment to:

Alpine Valley Wellness Center, PC
ATTN: Gary Piscopo, ND, LAc
430 Elva Way
East Wenatchee, WA 98802
Office: (509) 886-9355

Company Information
Date:
Company Name:
Business Contact information (address, fax, telephone number, website)
Contact Person (i.e. person completing this form) Name: _____ Phone number: _____ Email: _____
Contact personnel: Plant Manager: _____ e-mail: _____ Head Purchasing Agent: _____ e-mail: _____
How many employees on staff for the following: **QC/QA** **Production** Full-time _____ _____ Part-time _____ _____ Temporary _____ _____ Contract _____ _____
Name and title of person in charge of QC/QA:_____ E-mail: _____
List the industry trade groups to which your company belongs (for example – NNFA, AHPA)

Type of on-site laboratory: □ Analytical/Chemistry □ Microbiology □ None

cGMP and Quality Control Measures	Yes	No	N/A
1. Does your company have a Quality Control (QC) unit?			
2. Does the QC unit report to upper management?			
3. Do written procedures exist to define the responsibilities and authorities of the quality control unit? If yes, please attach the procedures.			
4. Do you have a cGMP system in place?			
If yes to the above, which cGMPs is the facility guided by? (check one) □ Food □ Dietary Supplements □ Pharmaceutical			
5. Is the facility registered/inspected to any regulatory standards? If so, which? □ ISO □ FDA □ HPB □ TGA □ Other (specify)_____			
6. Is there a plant-wide internal cGMP audit program? If yes, please attach a copy of your internal audit form and answer the following: a. How often do you audit? (Please circle answer.) Yearly Every 2 yrs Every 5 yrs Other: b. Who is responsible for conducting the audits? _____			
7. Has your company been audited by an independent auditor to assure compliance with cGMPs? If yes, please provide a copy of the most recent audit. If no independent certification exists and you follow cGMPs, please provide a detailed explanation of how you assure compliance with cGMPs.			
8. Are written procedures available for a plant-wide internal GMP inspection program? If yes, please attach procedure.			
9. Is your company registered with the FDA?			
10. Has your facility ever been inspected by FDA? If yes, please provide a copy of the most recent audit.			
11. Has your facility ever been inspected by the state department of health or state department of agriculture? If yes, please provide a copy of the most recent audit.			
12. ***Does your company carry liability insurance?*** If yes, please provide a letter verifying that we are protected by the policy if there is a claim made naming your product. If no, please provide a letter outlining what steps will be taken by the company to protect us if a claim is made naming your product.			
13. What methods are used to protect personnel and materials from adulteration? Please provide on a separate sheet of paper.			
14. Does a written GMP training program exist for employees? If yes, please attach an example.			
15. How do you ensure all employees are qualified to perform their jobs? Please provide on a separate sheet of paper.			
16. In areas where it is necessary to prevent contamination, adulteration and/or product degradation, what measures does the plant implement? (circle all that apply) a. Ventilation b. Air filtration c. Humidity-control d. Temperature-control (range maintained:_____)			
17. Is there a pest control program in use for your facility/facilities?			

If yes, please attach an example of pest control SOP and/or recent inspection record.			
18. Who is responsible for the overall sanitation program at the facility?			
Raw Materials	**Yes**	**No**	**N/A**
1. Are written specifications available for raw materials? If yes, please attach an example.			
2. Are written procedures available for defining the sample sources and which test parameters are analyzed? If yes, please attach a copy of the SOP table of contents.			
3. Do you have written procedures for the receipt, identification, examination, handling, sampling, testing, and approval or rejection of raw materials and components? If yes, please attach SOP table of contents or summary for each.			
4. Do you have written specifications for your raw materials, packaging materials, and labeling materials? If yes, please attach an example.			
5. Are identity tests and quantity tests performed on each lot of raw material?			
6. For quality assurance verification of raw materials and finished products, which do you use? (circle one) In-house laboratory Contract laboratories Both No laboratory verification testing is performed			
7. If you have an in-house lab: Who is responsible for supervision of the lab? _____ How many analysts by level of education are available in the lab? GED ____ BS ____ MS ____ PhD ____			
8. If you use contract laboratories, do written procedures exist for their selection and monitoring? If yes, please attach an example			
9. Which of the following are tested for in raw materials (circle all that apply) Microbiological contaminants (bacteria, molds, etc.) Heavy metal contamination? Pesticide contamination? Potency Chemical solvent residue Other _____ None			
10. Which of the following are tested for in herbal materials (circle all that apply) Authenticate proper botanical genus and species Microbiological contaminants (bacteria, molds, etc.) Heavy metal contamination? Pesticide contamination? Potency Chemical solvent residue Other _____ None			
11. For the testing of raw materials, which is true (circle one): Each batch is tested Skip lot testing (how often _____) Other: _____			
12. For the testing of herbal materials, which is true (circle one):			

Each batch is tested Skip lot testing (how often _____) Other: _____			
13. Are herbs sustainably harvested?			
14. Are any herbs you use threatened or on the endangered species list? If yes, which ones and what are your sources for these herbs?			
15. What percentage of the herbs you use are certified organic, and by what standard?			
16. Are any of the herbs used genetically modified?			
17. Are any of the herbs used irradiated? If yes, are they labeled to indicate this in the final product?			
18. Are any additives and/or fillers used in your products? If yes, please indicate what kinds.			
19. Are your quality requirements communicated in writing to your suppliers?			
20. Are your raw material suppliers audited by (circle one) Company personnel A third party Not audited			
21. If your raw material suppliers are audited, how often? (circle one): Yearly Every 2 years Every 5 years Other:			
22. Do you track supplier performance? If yes, how often (circle one): Quarterly Semi-annually Yearly Every 2 years Every 5 years Other			
23. Do you have a written raw-material-supplier certification program? If yes, please attach the program or table of contents is program is more than 5 pages			
24. Are Certificates of Analysis accepted in lieu of testing (other than identification)? If yes, please provide a detailed written explanation for how you assure quality of raw materials at time of receipt.			
25. Do you conduct periodic re-testing on stored, raw materials that have gone through a QC release process?			
26. Are retained samples maintained for all raw materials and finished goods?			
Finished Products	**Yes**	**No**	**N/A**
1. Are there written specifications available for tests to be conducted to assure the purity, quality and composition of finished product? If yes, please attach a copy of the SOP table of contents or summary.			
2. Do you have written specifications for finished products? If yes, please provide an example.			
3. Are your finished products tested for label-claim potency prior to distribution? If yes, please provide test data for 1 product. If no, please provide a detailed explanation of the methods used to validate potency claims.			
4. Do you perform potency testing to verify that the product meets label claim throughout the expiration-dating period? If yes, please provide stability potency assays on 1 product batch that was tested to verify the expiration date claim. If no, please provide a detailed explanation of the methods used to validate potency claims throughout the expiration-dating period.			
5. Are identity tests and quantity tests performed on each lot of finished product?			
6. Is each lot of finished product tested for heavy metal contamination?			
7. Is each lot of finished product tested for pesticide contamination?			
8. Is each lot of finished product tested for microbiological contamination?			
9. Do all products have expiration dates or “use by” dates on your labels?			
10. Are written procedures available for how expiration dates are derived? If yes, please attach an example.			

11. Are written records and data used to support product expiration dates maintained? If yes, please attach an example.			
12. Is finished product identified with lot numbers that permit determination of the history of the manufacture of the batch?			
13. Do you audit your finished product suppliers? If yes, how often (circle one): Yearly Every 2 years Every 5 years Other			
14. Do you have a finished product supplier certification program?			
15. Is the production for any finished goods subcontracted?			
16. If you use subcontractors, are they audited by: (Please circle answer.) Company personnel A third party Not audited			
17. If audited, how often? (Please circle answer.) Yearly Every 2 yrs Every 5 yrs Other _____			
18. Do written procedures exist for handling and storing retained samples? If yes, please attach example.			
19. Are any major food allergens (eg, milk, eggs, fish, shellfish, tree nuts, wheat, peanuts, and soybeans) produced, handled, or stored at or near this facility? If yes, what precautions are taken to avoid cross-contamination? Please provide on a separate sheet of paper. If yes, what cautionary language is placed on product or material labels to warn of the potential presence of allergens? Please provide on a separate sheet of paper.			
Product and Process Controls	**Yes**	**No**	**N/A**
1. Is a Master Production and Control Record available for the manufacture of each product?			
2. Who does the formulating of your products? Email_____			
3. Where required, what agents are used in your extraction process?			
4. Are effective measures in place for the identification storage and disposal of rejected or adulterated products? If yes, please provide example.			
5. Do systems exist to track lot, batch and shipping? If yes, please provide explanation.			
6. Do you rely on published clinical studies for the efficacy of your products? If yes, please provide 3 examples.			
7. Are written procedures available for the reprocessing of batches that do not conform to specifications? If yes, please provide explanation.			
8. Are written procedures available for packaging and labeling product? If yes, please attach a copy of the SOP table of contents or summary.			
9. Are written procedures available for the receipt, examination and storage of incoming labels, labeling materials and packaging materials? If yes, please attach a copy of the SOP table of contents or summary.			
10. Are written procedures available describing the precautions taken to ensure accurate labels and the handling of obsolete and deleted labels? If yes, please provide example.			
Warehouse, Distribution, and Post-Distribution Procedures	**Yes**	**No**	**N/A**
1. Do you maintain a warehouse? If not, please provide a detail description of your storage procedures and how quality/purity/potency are maintained.			
2. Are written procedures available for handling and storage of product in the warehouse? If yes, please attach a copy of the SOP table of contents or summary.			
3. Is the warehouse clean, well maintained, and separate from other processing areas?			
4. Is storage and transportation of finished product conducted under conditions that			

protect product from adverse environmental conditions and deterioration of product and container?			
5. Are distribution records available that will facilitate an effective product recall? If yes, please attach an example			
6. Are written procedures available for handling and storage of finished product reserve samples? If yes, please attach a copy of the SOP table of contents.			
7. Are reserve samples stored in the same (or similar) container/closure system in which they are marketed and under conditions consistent with product labeling for at least one year past the product expiration date?			
8. Are production, laboratory, control and distribution records for a particular batch, maintained for 1 year past the expiration date of the product?			
9. Are raw material records maintained for at least 1 year past the expiration date of the last batch of product using that material?			
10. Are written procedures available for product recall? If yes, please attach a copy of the SOP table of contents or summary.			
11. Are written procedures available for handling of returned products? If yes, please attach a copy of the SOP table of contents or summary.			
12. Are written procedures available for preventing inadvertent transfer of non-conforming product from care and control? If yes, please attach a copy of the SOP table of contents or summary.			
Customer Service	**Yes**	**No**	**N/A**
1. Are customer concerns or complaints reviewed by the QC/QA unit?			
2. Are written procedures available for handling of customer complaints? If yes, please attach procedure.			
3. Are written records available for customer complaint investigations, findings and corrective/follow-up actions? If yes, please attach an example.			

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