Development of Contract Supplier QA Agreement

The QA Agreement is negotiated and signed at the same time as the Contract Supplier Business Agreement. Initial conversations outlined here will identify barriers to obtaining a satisfactory QA Agreement. You are simply gathering information to determine the level of understanding & mutual support you have with a potential Supplier, and learning what remaining work will be necessary to comply with the FDA regulations (DSHEA).

Discussion with Suppliers - Preliminary Questions

1. FDA Final Rule June 2007, enforcement begins June 2009.
2. Discover any areas of different understanding & resolve differences through discussion & expert advice.
3. Are Management & QA from [COMPANY] and Contractor (supplier/manufacturer) all on the same page, trained in the new requirements?
    a. Offer links to current webinars, and workshops.
4. Does Contractor consider themselves compliant with FDA regulations?
    a. On what basis?
5. Does Contractor support coming into compliance with FDA?
    a. By what date?
6. Critical priority to reach full compliance before any costly FDA enforcement.
7. Has Contractor been inspected for compliance with FDA DSHEA regs?
    a. Who performed inspection?
8. Does Contractor already have a standard template that [COMPANY] can review:
    a. for the QA Agreement?
    b. for the Manufacturing Agreement?

NOTES:

Aspects of Supplier QA Agreement

1. Establish an outline of cooperation and actions that will deliver us to mutual compliance ASAP.
    a. Discuss, implement, and report progress weekly/monthly/periodically.
    b. Establish how inter-company communication will function.
2. **Tasks for [COMPANY]:**
    a. Review finished product specs, & rewrite for FDA compliance if needed.
        i. Solicit spec suggestions from Contractor.
        ii. Provide clear written explanation of all documentation required for each item and lot.
        iii. Use lab consultant to establish analytical testing requirements:
            1. for each finished product formulation.
            2. for each active raw ingredient.
            3. for each non-active component.
    b. Review internal procedures & write SOPs for FDA compliance.
3. **Tasks for Contract Supplier :**
    a. Review adequacy of raw ingredient testing program per current FDA regs.
        i. Provide raw ingredient specs to [COMPANY], including definition of Identity, Purity, Strength, Composition and Limits on Contaminants.
    b. Review adequacy of Master Manufacturer Records for each product formulation:
        i. Make any necessary edits, and
        ii. Provide all Item MMRs to [COMPANY] according to FDA regs.
    c. Review adequacy of Batch Records to prove compliance with [COMPANY] spec, label, and MMR.
        i. Make any procedural changes or BR format edits, and
        ii. Provide all Batch Records to [COMPANY] for each Lot produced, prior to delivery.

Points to be included in Supplier QA Agreement to ensure compliance with FDA regulations.

1. Contract manufacturer must operate in compliance with current FDA regulations, and supply [COMPANY] with all manufacturing documentation necessary for [COMPANY] to demonstrate compliance to FDA according to DSHEA regulations.
2. All required documentation must be provided for each lot prior to delivery. Payment terms on delivered product will be dated from delivery of product AND receipt, by [COMPANY] QA, of all required documentation.
3. FDA-compliant analytical testing (Identity, Purity, Strength, Composition, Limits on Contaminants):
    a. Is conducted on all lots of raw ingredients and components.
    b. Is conducted on all lots of finished products.
4. A current, complete, & accurate Master Manufacturing Record (MMR) must be provided to [COMPANY] QA for each finished product item under contract:
    a. The MMR must be sufficient to comply with the [COMPANY] finished product specification and [COMPANY] label.
5. A complete Batch Record must be provided for each lot delivered that documents and proves compliance:
    a. With the item MMR,
    b. With the [COMPANY] label,
    c. And with the [COMPANY] finished product specification.
6. Finished product may not be shipped by the contractor prior to completion of all required testing.
7. Contractor must report all manufacturing or specification deviations to [COMPANY] QA without delay.
    a. These may include, but are not limited to, errors in label copy, specs, exceptions or deviations from MMR or Batch Records procedure, exceptions or deviations from analytical testing procedure.
8. Contractor must report all FDA visits & inquiries to [COMPANY] within 24 hours. Regardless of whether [COMPANY]-labeled product is directly involved.
9. Contractor must provide a copy of annual 3rd party audit and inspection that confirms compliance with all Federal, state, and local regulations, including FDA DSHEA and Bio-Terrorism regulations.
10. To comply with FDA DSHEA traceability regulations each lot of ingredients or raw materials (including packaging) must be traceable <u>forward</u> to all finished product lots in which it may have been used. In addition each lot of finished product must be traceable <u>backwards</u> to every raw ingredient or material lot that may have been used in its manufacture.

11. Contractor will allow [COMPANY] access during normal business hours to inspect manufacturer's facilities and operations, and review all operational and QA records that pertain to [COMPANY] products, or raw ingredients or components that may pertain to [COMPANY] products. Inspections may be conducted by [COMPANY] staff or by firms or individuals under contract with [COMPANY].
12. Contractor must maintain SOP and other documentation that complies with FDA regulations, including proper documentation of SOP modification, revision, and authorized approval.
13. [COMPANY] written finished product specifications may not be altered verbally. Authorized changes to [COMPANY] specs will only be provided in written form.
14. Only the signatures of company officers are acceptable and legally binding on this agreement.

COMPLIANCE WITH THESE CONTRACT REQUIREMENTS IS NECESSARY TO MEET EXISTING FDA DSHEA REGULATIONS, 21 CFR PART 111.

PRODUCTION LOTS THAT DO NOT COMPLY WITH THESE CONTRACT REQUIREMENTS ARE SUBJECT TO REJECTION BY [COMPANY].

[Company] Representative _____ Date _____

[Supplier] Representative _____ Date _____