

DBA

AnalyticalSM

An NSF International Company



Auditing

We have decades of auditing experience and the expertise to perform audits for any type of activity within the dietary supplement industry. Our capabilities span across processes, from marketing and labeling to contract manufacturing. Our capabilities also span across products; from dietary ingredients to dietary supplement finished products. Our highly qualified staff is comprised of former regulatory inspectors and former dietary supplement or major pharmaceutical company senior corporate compliance auditors.

For further information, call us at +1 (734) 913-5734 or email Analytical@DBA-global.com

21 CFR 111 GAP Audits

Our experienced auditors can perform consultative GAP audits at your facility against current 21 CFR 111 Dietary Supplement Good Manufacturing Practices (cGMPs). A checklist-style audit report will be provided including recommendations for the remediation of identified gaps found during the audit.

Third-Party Audits

We can assist you in the search for your ideal subcontract partner by performing a third-party audit on your behalf against cGMPs. Following the audit a detailed report is provided highlighting the potential partner's strengths, vulnerabilities, possible remedial actions and our overall recommendations on the suitability of the contractor based on your needs.

Benchmarking Audits

Our constant exposure to dietary supplement companies worldwide, both large and small, enables us to assess your facilities, procedures and practices against current industry norms and best practices. We can partner with you to assess your current position in the marketplace and provide sound advice toward your future direction.

Mock Regulatory Audits

We regularly assist clients in their preparation for an imminent regulatory inspection. Our experienced auditors will "mock" the role of regulatory inspectors by performing the inspection as would be expected from actual FDA auditors. Following the audit, you will have an in-depth and impartial assessment of your current state of compliance, a prioritized action plan for the rectification of non-compliance and vulnerability, and an understanding of the types of questions which would likely occur during the inspection with expert coaching on the most effective way to respond to the questions.

Due Diligence Audits

We regularly assist dietary supplement companies, food companies and investment banks during the due diligence process for potential acquisitions, buy-ins, joint ventures and other investment projects. We perform an in-depth assessment of the regulatory compliance status of companies and/or projects by reviewing:

- status of marketing approvals, applications, etc.
- current complaints, adverse reactions, etc. in order to assess vulnerability
- current relationships with the major regulatory authorities
- quality of staff in key technical positions
- general levels of GMP compliance
- investment required to maintain GMP compliance in the short, medium and long term