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Quality challenges with nutritional supplements

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More and more consumers are focused on disease prevention by taking nutritional supplements rather than taking prescription drugs which provide short term relief along with several serious side effects. With increase in popularity and more educated consumers (thanks to media, internet), high quality and safe nutritional products are necessary to gain consumer confidence. High quality supplements should be made with high quality and safe ingredients to provide quality health benefit to consumers. Good Manufacturing practices (GMP) and developing specifications for both raw materials and finished products are very critical. GMPs are intended to ensure safe, quality supplements are made in a consistent, reproducible, and documented manner. Several testing requirements which focus on identity, purity, strength, and composition of ingredients and finished products are a must to maintain quality controls in supplements. Companies must verify the Certificate of Analysis (C of As) on incoming ingredients by proper testing to eliminate contamination or fraud along the way. Raw material ingredient supplier qualification by auditing their facility is part of quality process. USP has published several monographs on dietary ingredient and finished products as well as reference materials for testing identity, potency, known impurities, and contaminants. Adulteration with APIs and their metabolites and contamination by heavy metals such as lead, arsenic, mercury, and cadmium, pesticides, micro organisms etc are currently critical issues in this industry. Weight loss products, sexual enhancement products and sports nutrition products are found out in recent years to be spiked with pharmaceutical active ingredients (APIs) and cheap unstudied ingredients. We should detect these adulterants (unlawful ingredients) by using scientifically valid test methods and protect consumers from any wrongful health problems. Since, the Manufacturer who sells the finished product is responsible for product quality and safety, state of testing is becoming more and more necessary. Testing complex finished products or ingredients require high-tech instrumentation, test methods, and highly qualified experts that many companies cannot afford to have in-house. Those companies seek the expertise outside, third party accredited laboratories to develop test methods and or even perform the testing of their products. Beyond testing, it is required regular maintenance and cleaning of manufacturing of equipments, personal hygiene and training, clean facilities, proper storage of the raw materials and finished products to prevent cross contamination and degradation.

Biography

Mythili Nagarajan has completed her M.S. in Biochemistry from University of Wisconsin, Green Bay, WI 54313, USA and M.Phil. in Natural Products and Medicinal Chemistry from REC, Trichy, India. She is the Vice President, Corporate Quality Control at Tishcon Corp, leading Contract Nutritional Supplement Manufacturer in USA for softgels, tablets, and capsules. She has more than 25 years of experience in the field of both Pharmaceutical and Nutritional Supplement research, testing, and manufacturing. Her mission is to use her extensive GMP knowledge and professional experience to assist both public and private enterprises with QC and regulatory compliance. She has published analytical test methods in peer reviewed AOAC (Association of Analytical Chemists) International Journal and served in AOAC Experts Panel Review Committee for the selection analytical test methods for finished product nutritional Supplements. She is an active member of ABC (American Botanical Council), USP (United States Pharmacopeia), AOCS (Association of Oil Chemists Society), and ASQ (American Society for Quality).

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