

A Quality Dietary Supplement: Before You Start and After It's Marketed – A Conference Report

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European Journal of Nutrition: Volume 54, Issue 1 (2015), Page 1-8

Abstract

Consumers worldwide are turning to dietary supplements as one part of their personal goal to lead healthier and more active lives. In truth, the quality of life now supersedes the length of life as no one would trade living to one hundred (the last forty with compromised physical abilities and decreased mental acuity) for 80 years of travel, time with family, and intellectual pursuits. If there is the possibility of preventing a disease or debilitating condition through efficient lifestyle changes (additions, subtractions, modifications) and to also avoid the costly and escalating medical and pharmaceutical treatments that accompany having the disease/condition, then a sensible individual would focus on their overall health and wellness...proactively, instead of reactively. However, an important caveat is that over-regulation or inappropriate application of current regulations can increase the price of dietary supplements and nutritional products and thus cause underutilization of the potentially beneficial physiological attributes of these products. Conversely, strict adherence to regulatory guidelines could result in safer dietary supplements and fewer adverse reactions requiring medical attention. If new regulations or stricter interpretation/application of existing regulations result in certain dietary supplements being taken off the market, will continued demand create a completely unregulated, underground economy that will create unforeseen problems? More research should be supported by government agencies to determine the effectiveness of dietary supplements, nutritional products and complementary medicine in reducing personal and societal medical costs and further contribution to the overall health of the population.

Since the completion of the good manufacturing practices (GMPs) regulations in the USA in 2007, the dietary supplements industry has continued to experience solid growth, thanks in part to a regulatory structure that allows new products a quick time-to-market. In turn, consumers have benefitted from the wide range and availability of dietary supplements that help support a healthy lifestyle. However, with this opportunity and ease of the open market comes a great deal of responsibility to ensure that dietary supplements are safe and meet the quality standards that consumers, and regulators, expect. The industry that is engaged in producing dietary supplements and ancillary nutritional products, (sometimes termed differently in other regions of the world) now more than ever need to strengthen their quality control systems to prevent adulterated goods from entering commerce. To achieve that end, industry also needs to work collaboratively with national and regional regulators. These steps would serve to create early warning systems to identify raw materials moving through the supply chain that are at risk for contamination, adulteration or poor quality. Further, when excessive demand, rising prices and limited availability surround key ingredients or materials of sudden interest, then substandard quality though accident or intentionality become more common and harder to detect. Responsible manufacturers at both the initial “dietary ingredient” and final dosage form “dietary supplement” experience a number of anomalous findings in expected parameters for quality

through the rigorous application of in-house hazard analysis and critical control point (HACCP) and GMP systems of incoming raw material qualification and compliance.

Post-manufacturing issues related to quality include aspects of stability and shelf life over the course of the expected consumer availability of each formula and lot number. Post-market adverse event data are a critical component of the product safety assessment process and allows for ethical and responsive stewardship by the manufacturer for each and every item placed on the market. It is important to understand how this information may be utilized to establish best practices for post-market data collection, documentation and communication.