Ensuring high-quality dietary supplements with 'quality-by-design'

October 3 2012

If applied to the $5-billion-per-year dietary supplement industry, "quality by design" (QbD)—a mindset that helped revolutionize the manufacture of cars and hundreds of other products—could ease concerns about the safety and integrity of the herbal products used by 80 percent of the world's population. That's the conclusion of an article in ACS' *Journal of Natural Products*.

Ikhlas Khan and Troy Smillie explain that the U.S. Food and Drug Administration (FDA) regulates dietary supplements as a category of foods, rather than drugs. Manufacturers are responsible for the safety of their products. However, they need not obtain FDA approval to market supplements that contain ingredients generally regarded as safe. While

manufacturers, packagers and distributors are required to follow good manufacturing practices, variations in growing, processing and even naming the plants used to make supplements opens the door to problems and introduces challenges with reproducibility. As a result, "the consumer must take it on faith that the supplement they are ingesting is an accurate representation of what is listed on the label, and that it contains the purportedly 'active' constituents they seek," Khan and Smillie note. The authors looked for solutions in a review of more than 100 studies on the topic.

They concluded that a QbD approach—ensuring the quality of a product from its very inception—is the best strategy. One key step in applying QbD to dietary supplements, for instance, would involve verifying the identities of the raw materials—the plants—used to make supplements. "It is clear that only a systematic designed approach can provide the required solution for complete botanical characterization, authentication and safety evaluation," they say.

More information: "Implementing a 'Quality by Design' Approach to Assure the Safety and Integrity of Botanical Dietary Supplements" *J. Nat. Prod.*, 2012, 75 (9), pp 1665–1673. DOI: 10.1021/np300434j

Abstract
Natural products have provided a basis for health care and medicine to humankind since the beginning of civilization. According to the World Health Organization (WHO), approximately 80% of the world population still relies on herbal medicines for health-related benefits. In the United States, over 42% of the population claimed to have used botanical dietary supplements to either augment their current diet or to "treat" or "prevent" a particular health-related issue. This has led to the development of a burgeoning industry in the U.S. ($4.8 billion per year in 2008) to supply dietary supplements to the consumer. However, many commercial botanical products are poorly defined scientifically, and the

consumer must take it on faith that the supplement they are ingesting is an accurate representation of what is listed on the label, and that it contains the purportedly "active" constituents they seek. Many dietary supplement manufacturers, academic research groups, and governmental organizations are progressively attempting to construct a better scientific understanding of natural products, herbals, and botanical dietary supplements that have co-evolved with Western-style pharmaceutical medicines. However, a deficiency of knowledge is still evident, and this issue needs to be addressed in order to achieve a significant level of safety, efficacy, and quality for commercial natural products. The authors contend that a "quality by design" approach for botanical dietary supplements should be implemented in order to ensure the safety and integrity of these products. Initiating this approach with the authentication of the starting plant material is an essential first step, and in this review several techniques that can aid in this endeavor are outlined.

Provided by American Chemical Society