

# Chapter 49

## New Product Development and Regulatory Challenges in Nutraceutical Industry

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### ABSTRACT

*Functional food ingredients and dietary supplements are essential for health promotion and disease risk reduction. The demand for various food products is increasing day by day due to ever increasing population. Different multinational companies have invested to meet the demands of the people all over the world. However, some miscreants have adulterated different food products that caused various concerns to the people and the government. Hence, different laws in different countries have been regulated to maintain the quality of food. However, there is major legislation and product approval challenges which should be aligned by global common regulations to move forward by reducing the scope for conflict between our regulatory approaches and by forging closer cooperation that can only be addressed by appropriate and accurate ingredients understanding, safety legislation, clinical studies benefits, advanced food processing technologies and various analytical studies. The nutraceutical revolution will direct us into a new era of medicine and health, in which the food industry will become a research oriented, analogous to the pharmaceutical industry. The present review article discusses the recent status of nutraceuticals and their importance to prevent various diseases.*

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## **INTRODUCTION**

Nutraceuticals is a broad umbrella term that is used to describe every product derived from food sources with extra health benefits in addition to the basic nutritional value found in foods. Nutraceuticals is a combination of nutrition and pharmaceuticals. Nutraceuticals are a diverse product category with various synonyms used internationally. The term “nutraceutical” was coined by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine. This term has been part of the industry lexicon for almost a decade. Unfortunately, it still seems to be apprehended up in a scrambled web of complementary definitions, regulatory watchdogs and consumer confusion. “Functional foods,” “nutraceuticals,” “pharmaconutrients,” and “dietary integrators” are all terms used incorrectly and indiscriminately for nutrients or nutrient-enriched foods that can prevent or treat diseases (Hardy, 2000). The idea of nutraceutical was started from the survey in U.K, Germany and France which concluded that diet is rated more highly by consumers than exercise or hereditary factors for achieving good health (Keller, 2006). The natural bioactive chemical compounds that promote health, prevent from diseases or provide medicinal properties are known as nutraceuticals that provide physiological advantage that will ultimately delay the process of increase life expectancy, ageing or support the structure or function of the body (Zhao, 2007). Vitamins, minerals, herbal supplements and certain animal products are integrated in this category or functional foods (Menrad, 2003). The discovery and production of nutraceuticals over pharmaceuticals is well seen in pharmaceutical and biotechnology companies.

United States represents the largest customer base for food sales with 37% of overall demand in terms of geographic sales distribution followed by Europe with 33% and the rest is contributed by the developing economies. Israel and Germany have come forward as the key innovation hubs of the nutraceutical industry and the developing nations like Brazil, China and India have huge potential for the nutraceuticals market. India may put an example for production of nutraceuticals but requirements a concrete and solid foundation and well developed regulatory mechanisms (Zhao, 2007). This will solve the food problems of India and will provide food security for long term to the developing nations. Further, the burden of diseases arising due to malnutrition can be eliminated if sufficient funds would be relocated in this direction. The term nutraceuticals is not well accepted on global, regulatory systems and has no regulatory definition while the dietary supplements are considered to be more prominent (Ross, 2000). Presently, over 470 nutraceuticals and functional food products are available with documented health benefits. The nutraceutical industry is a dynamic, evolving industry that offers exciting opportunities to fuse scientific discovery with growing consumer notice in health-enhancing foods (Hobbs, 2001). The approach to regulating and marketing nutraceuticals is notably heterogeneous on the global level. This is largely due to challenges in classifying these products, absence of a appropriate regulatory category for these hybrid products, and varying views on what is considered adequate scientific substantiation to conclude their functionality.

The nutraceutical industry that encompasses three main segments which consist of functional foods, dietary supplements, and herbal/natural products is a self-motivated, developing entity that offers novel opportunities to merge scientific discovery with growing consumer concern in health-enhancing foods (Ross, 2000). Dietary supplements refer to the preparations intended to compensate for the nutrients that otherwise might not be sufficiently present in the diet. Dietary supplements are categorized as food in some countries, while in other countries they are considered as drugs or natural health products. On the other hand, the term functional foods refers to supplements that have new or more ingredients added, resulting in improved function and improvement of health.

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