GMP Compliance in Nutraceuticals

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The nutraceuticals market is predicted to develop at a high compound annual growth rate (CAGR) of 9.0 percent through 2030, with a share of 44.89 percent in 2021. India's nutraceuticals market is one of the fastest expanding in the Asia-Pacific region. The nutraceuticals market in India is predicted to increase to $18 billion in 2025, according to Invest India, as demand for dietary supplements from the upper and middle classes develops.

Consumers' growing interest in health and nutrition can be related to the industry's popularity and expansion along with the interest in products for boosting energy and improving their physical endurance and mental alertness. The habits of Indians have changed dramatically over the last decade. Fast food and packaged food consumption, as well as a sedentary lifestyle, have contributed to an increase in the incidence of lifestyle diseases such as diabetes, cardiovascular disease, and obesity. As a result, Indian customers, particularly those from the upper socioeconomic and middle classes, see nutraceuticals as viable alternatives to prescription medications/ allopathic medicines.

Chemical or bioactive substances known as nutraceuticals are prized for their beneficial biological functions and health-improving benefits. The substances included are natural like ginseng, garlic and some herbal substances like phytochemicals which are plant derivatives along with vitamins, soluble and insoluble fibers. The nutraceutical hasn't always fulfilled the criteria to serve a therapeutic function. As a result, the delivery methods for them must be planned to result in goods with constant quality characteristics. The creation of materials customized to a particular application that can trigger incredibly precise reactions with proteins and cells is thought to be the core emphasis of "biomaterials research." The focus of the most thorough inquiry is on the synthesis, characterization, testing, and optimization of biomaterials as well as the biology of host-material interactions. Toxicology, biocompatibility, functional tissue structure, pathobiology, mechanical and performance requirements, healing, industrial involvement, regulation, etc. are just a few of the characteristics that the biomaterial must meet.

The nutraceutical industry required the knowledge about GMP compliances and non-clarity of regulations along with longer timelines for approvals are the biggest challenges being faced. Good manufacturing practices need to be strengthened. Also, there are safety issues which exists such as adulteration and contamination, especially with specific product types and safety pertaining to cases of forgery. Thus, a need remains for continued efforts and improved techniques along with training which is necessary to assess the quality of nutraceuticals and national well-being also. CGMP prevents incidences of product mix-ups,

contamination, deviations, failures, and errors which in turn assures that nutraceutical products meet the required quality standards. Nutraceuticals are considered as foods by the FSS Act, 2006, Rules and Regulations, 2011. In FSSA in India (FSSAI) has defined regulatory guidelines for approval of nutraceuticals in the Indian market. This Act talks about nutraceuticals, dietary supplements and various functional foods.

All these advancements are in relation to rules and regulations which go hand in hand with Good Manufacturing Practices (GMP) as standards are must to ensure safety and high-quality products for delivery to the consumers. Regulations for any commodity includes general regulations covering all items and specific regulations for specific nutraceutical categories. GMP is a system to guarantee the products are consistently produced and controlled in accordance with quality standards. It's intended to reduce any dangers associated with nutraceutical production that can't be eliminated by testing the finished product. It also complies with safety and sanitary norms. GMP is first and foremost a management framework, requiring full and detailed specification of the product, and everything that goes into making, storing, and distributing it, as well as management of the materials, resources, measures, and precautions vital to maintain the standard requirements.

Government of India (GOI) has taken several initiatives with respect to GMP guidelines in nutraceuticals. A new ministry was established under the name of ministry of AYUSH to promote traditional healthcare practices in the country with the goal of reviving and popularizing India’s alternative medicine system thus introducing nutraceuticals. The Health Supplements and Nutritionals Compliance Guidance Document have been prepared to address new regulations for the industry. It covered product’s definition, labelling requirements, ingredients and rules on licensing and importation. Therefore, the document helps India’s nutraceutical industry to grow globally. It focuses on procedures for ensuring high standards of safety, hygiene, quality and traceability in compliance with GMP. FSSAI in partnership provides foundation level requirements for the manufacture of health supplements within India’s food safety system to develop companies to its best. A Memorandum of Understanding (MoU) has also been signed between FSSAI, Confederation of Indian Industry (CII) and International Alliance of Dietary/Food Supplement Associations (IADSA) to give full support to Resource Centre for Health Supplements and Nutraceuticals (ReCHAN) in strengthening India’s health supplements sector. Covid situation have led changes in policy shifts which was accomplished by Prime Minister’s Atmanirbhar Bharat programme which was a boon for the nutraceutical market as it received the opportunity to be self- reliance and self- sufficient to grab the growing market.

The collaboration between ASSOCHAM and MRSS India aims to help the Nutraceuticals market flourish holistically. The partnership hopes to attract investments from Indian and multinational companies with or without prior Food & Beverage or Pharmaceutical experience, with a strategic intent to benefit investors, a ready market for rapid growth, a value-added

character reinforced by consumers' and stakeholders' perceptions, and lower healthcare costs/insurance liabilities. For the combination or single use of vitamins and minerals at levels equivalent to a maximum of one (01) Recommended Dietary Allowances (RDA), the regulations on Nutraceuticals do not apply to newborns up to the age of 24 months, dosage formats such as tablets, capsules, and syrups are included.

The manufacturing activities themselves, and a quality control/quality assurance system that can go by various names but it is evident that there are two complementing and interacting components of GMP. Both of these elements need to be well-designed and implemented. The different managements of these two roles must have the same complementary nature and interaction, with each function's authority and responsibilities clearly defined, agreed upon, and mutually accepted. The manufacturing function's management also encompasses the significant other key functions that provide direct services or advice to the manufacturing function.