

# STRATEGIC DEVELOPMENT OF NUTRACEUTICAL SECTOR – CRAMS PERSPECTIVE

**Sandeep Gupta**

Director & CEO, NUTRAWORKS, Chief Founder & Director, Expert Nutraceutical Advocacy Council (ENAC®)

In the era of unheralded biological hazards with the Pandemic and with daily stress, health is not an abstract issue at global and national levels, but a concrete reality that touches individuals, households and communities. Reducing the burden of diseases is very essential and factors like boosting immunity and a health conscious lifestyle plays a major role. The first line of defense is to adopt a healthy lifestyle. The four strong pillars - Healthy Eating, Regular Exercise, Mindfulness and Supplementation are the adaptations for upgrading our lifestyle and taking our immunity from Good, Better, Best to Robust. I concretely believe in these pillars and follow a regular regimen for adopting a healthy lifestyle.

Nutraceuticals are supplementary products for holistic approach, completing the nutritional requirements for a healthy living. These are macro and micro nutrients which includes vitamins, minerals, botanical extracts, proteins, antioxidants, etc. with an intention to supplement the normal diet of a person. Nutraceuticals not only play a large role in building and strengthening immunity but also promotes wellness from within, nourishing the cells of the body for all they need.

With growing health concerns, for a country with the population of more than 1.3 billion, the Government of India has increased its healthcare budget by 137% from the previous year by allocating INR 2.23Lakh Crores. This emphasizes on how important it is for the individuals of the nation to be proactive and take charge of healthy living.

## Evolution of the Nutraceutical Industry

Currently, more than 90% of the total global nutraceutical market is accounted by the USA, Japan and Europe. The global

market is expected to reach \$336 billion by 2023 from \$247 billion in 2019 at a Compound Annual Growth Rate (CAGR) of 8%. But with these global markets attaining maturity, the focus of nutraceutical players is now shifting towards developing economies, especially those across Asia Pacific, including India.

Indian Nutraceutical Market's estimated valuation stands at around \$5 billion as of 2019 and is expected to reach \$11 billion by 2023, increasing at a CAGR of 21%. By 2023, India is also expected to hold at least 3.5% market share of the global market.

The myopic view of the industry towards health supplements and nutraceuticals has broadened post the gazetted release of structured & well drafted, Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016. I was one of the pioneer and the strongest baton carrier in the process of releasing this regulation which helped and guided the industry to regularize on ideation, conceptualization and development of products in the interest of public health with undue safety. This also introduced globalization in the nutraceutical sector taking way forward and making the world's best qualified, clinically researched and proven for its benefits, branded ingredients available for the Indian population.

The Indian Nutraceutical industry has progressed over the years with understanding of various natural sources of the ingredients like KSM66® Ashwagandha for managing stress, providing energy and strength; super-antioxidant AstaReal® Astaxanthin for building immunity, stamina and endurance; Setria® Glutathione as a master Antioxidant, Vegan Omega3 (Megashine-O®) for healthy Heart, Joints & Respiratory health; Fenugreek fiber (Fenulike®) for healthy weight management and gut health; Highest Bioavailable Curcumin for healthy Joint & Immunity; from the waters of Irish Coast, Aquamin® Magnesium for muscle and mental health; Plant Protein that can be added to all your favourite dishes, Collagen for hair, skin and nail health, Probiotics for Gut Health, EVanolMax™ Tocotrienols for hair, skin, brain health and healthy heart.

## CRAMS (Contract Research & Manufacturing Services):

With globalization in the Nutraceutical Industry, changing dynamics adopted from the Western World, up gradation of regulatory norms, compliances and need for the best quality products introduced the model of CRAMS with the expertise of Research and Development, Manufacturing capabilities and strong regulatory self-compliances. This gives the marketeers the confidence in the quality and safety of the products which are provided to the consumers.

CRAMS is an organization built with a 'bench to bedside' approach taking care of new product ideation, conceptualization, scientific rationalization, development, regulatory compliances, testing compliances, quality assurance and commercialization of Nutraceutical and Health Supplement Products.

CRAMS focuses on the following parameters to deliver the best quality supplements which are safe to consume:



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Chief Founder & Director, Expert Nutraceutical Advocacy Council (ENAC®)

Sandeep Gupta's leadership dynamism is over 25 years of extensive experience with Pharmaceuticals & Nutraceuticals in Multihued functions like Strategy, Marketing, Legal, Regulatory and Government relations. He has launched 400+ Products and has evaluated 1000+ ingredients. He is the Strategist, mentoring National Wellness Project, along with Bollywood Celebrities and sports clout with integrated due diligence with Strict compliance of Clean, Safe & Qualified Nutrition. He is also spearheading International Alliances to bring World class Nutritional products to India. He is the Chief Founder & Director of the First and the only Nutraceutical Council, Expert Nutraceutical Advocacy Council (ENAC®) leading with 150+ experts. He is also the Chairman - Standard Review Group, Nutraceuticals, FSSAI, Agile Global Spokesperson for Healthcare & Food Industry Globally. His recent achievements being the First & the only Indian on Executive Advisory Board at Informa Exhibitions (Vitafoods & Supply Side), Panelist Judge for Nutraceutical Ingredients Asia Awards since 2018 and has recently appeared in the list of 100 top Achievers - leading with excellence globally.



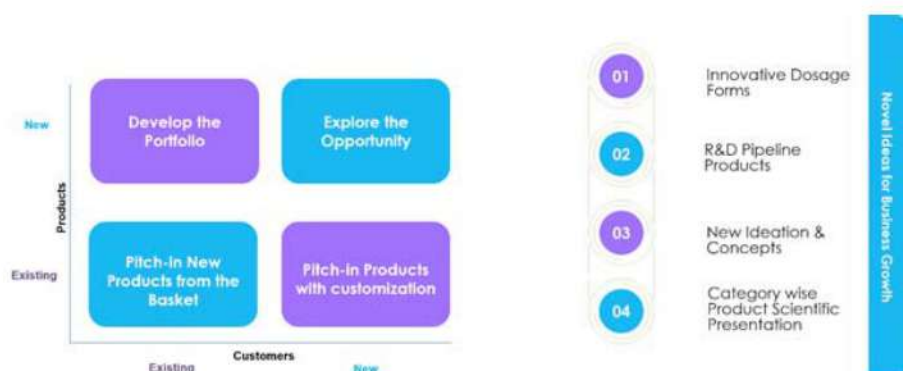
### 1. Market Intelligence

This involves understanding the health condition demographics, unherald biological emerges, trends in the market, seasonal and lifestyle variations affecting the health of the population. Based on these factors, nutraceutical products can be ideated and formulated to cater to the consumers. Catering to the needs of the market by analyzing the gaps for betterment of the health of population.

### 2. New Product Development Perspective

Developing new products with value addition for the betterment of health of the consumers can be driven by CRAMS. Every Company has a strength in particular health segment and always tries to cater to the arising needs of the population. CRAMS can play a crucial role by introducing new products with innovative dosage forms, branded ingredients from across the Globe for the Indian Customers.

Below is one such module which CRAMS can follow while ideating new products for their customers:



Adaptation of ANSOFF Matrix for Nutraceuticals, Health & Dietary Supplements by NISA (Nutraworks@Intelligence Strategic Alliance)

### 3. Ingredient Identification & Sourcing

New Product Development should be based on the principle of identifying the right ingredient, set at the right dose for its effectivity and within the safety limits and delivered in the right dosage format for maximum absorption. Sourcing the ingredients that are clean, safe, qualified and proven for its benefits backed with clinical studies gives an edge over the generic products. CRAMS should identify the branded ingredients which provides complete transparency from the extraction to the production processes.

### 4. Regulatory Compliances

Upgradation from PFA (Prevention of Food Adulteration) Act to FSSAI (Food Safety & Standards Authority of India) has given newer opportunities to CRAMS for developing compliant products. With the implementation of FSS Act and Nutraceutical Regulation there have been set rules within which the product has to be developed. Below Image summarizes the 13.6 Category of FSS Regulation for a quick understanding

CRAMS should pursue the below regulatory compliances before the launch of any product:

- Product labelling compliances as per the FSS Packaging & Labelling Regulations
- Use of compliant ingredients and additives as per the respective Schedule of the FSS Regulation
- Food Manufacturing License under FOSCO
- Product Quality and Testing (Heavy metals, Nutritional information, etc) as per the FSS Contaminants, Toxins & Residues Regulation.

Category	Health Supplement	Nutraceuticals	FSDU	FSMP	Prebiotics & Probiotics	Ayurvedic Products
WHO	Healthy people seeking to preserve wellness	People seeking for maintenance, fitness and general well-being	People with Special Nutritional needs	People with common Health Problems	Healthy people seeking for wellness	Patients looking for specific Natural treatments
WHAT	<ul style="list-style-type: none"> <li>• Weight-loss Bars</li> <li>• Isotonic drinks</li> <li>• Vitamin &amp; Mineral supplements</li> </ul>	<ul style="list-style-type: none"> <li>• Cholesterol-lowering products</li> <li>• Products to prevent diabetes, dementia and other age related disorders</li> </ul>	<ul style="list-style-type: none"> <li>• Infant feeding formulations</li> <li>• Nutrition for Frail and Chronically ill</li> <li>• Clinical Nutrition products</li> </ul>	<ul style="list-style-type: none"> <li>• Cholesterol management</li> <li>• Heart conditioning</li> <li>• Bone &amp; Joint health</li> <li>• Urology care</li> <li>• Other medical conditions</li> </ul>	<ul style="list-style-type: none"> <li>• Immunity enhancement</li> <li>• Vaginal health</li> <li>• Gut Health</li> </ul>	<ul style="list-style-type: none"> <li>• General well being products</li> <li>• Condition specific medical extracts</li> </ul>
WHERE	<ul style="list-style-type: none"> <li>• Pharmacy stores</li> <li>• Super markets</li> <li>• Online portals</li> </ul>	<ul style="list-style-type: none"> <li>• Super markets</li> <li>• Pharmacy stores</li> <li>• Online portals</li> </ul>	<ul style="list-style-type: none"> <li>• Pharmacy stores with supervisors</li> <li>• Online portals</li> </ul>	<ul style="list-style-type: none"> <li>• Pharmacies with medical supervision</li> </ul>	<ul style="list-style-type: none"> <li>• Super markets</li> <li>• Online portals</li> </ul>	<ul style="list-style-type: none"> <li>• Special outlets providing Ayurvedic blends</li> </ul>
HOW	<ul style="list-style-type: none"> <li>• Capsules</li> <li>• Tablets</li> <li>• Pills</li> <li>• Sachets</li> <li>• Jelly- Gel</li> <li>• Powder</li> </ul>	<ul style="list-style-type: none"> <li>• Granules</li> <li>• Powder</li> <li>• Tablet</li> <li>• Capsule</li> <li>• Liquid</li> <li>• Sachets</li> <li>• Jelly- Gel</li> </ul>	<ul style="list-style-type: none"> <li>• Granules</li> <li>• Powder</li> <li>• Tablet</li> <li>• Capsule</li> <li>• Semi solids</li> <li>• Sachets</li> <li>• Jelly- Gel</li> </ul>	<ul style="list-style-type: none"> <li>• In a format suitable for oral feeding through enteral tubes</li> </ul>	<ul style="list-style-type: none"> <li>• Sachets</li> <li>• Liquids</li> <li>• Powder</li> <li>• Capsules</li> <li>• Tablets</li> </ul>	<ul style="list-style-type: none"> <li>• Liquid</li> <li>• Suspension</li> <li>• Powder</li> <li>• Granules</li> <li>• Capsules</li> </ul>

Summary of categories under FSSR by Expert Nutraceutical Advocacy Council (ENAC®)



- Comprehensive Technical and Scientific Dossier

## 5. Manufacturing Protocol

The manufacturing protocol for nutraceutical products are on the similar lines as that of pharmaceutical ones but with stringent norms in compliance with the FSS Act.

CRAMS should have in place the following certifications for safe and hygienic product manufacturing:

- FSSAI Manufacturing License
- Food Safety Management System Plan (**FSMS**)
- **WHO GMP** Certification
- **HACCP** (Hazard Analysis & Critical Control Points) Certification for Food Safety
- **WASH** (Workplace Assessment for Safety & Hygiene) Certified Manufacturing Units issued by QCI (Quality Council of India)
- **NSF** Certification
- **ISO** Certification
- Manufacturer can also obtain certain Global MOH (Ministry of Health) approvals like **TGA** (Therapeutic Goods Administration, Australia), **MHRA** (Medicines and Healthcare Product Regulatory Agency), UK and such others
- Products can also be certified with **Informed Sport Certificate** which signifies that product is free from banned substance and **Labdoor Certificate** which checks for harmful ingredients and contaminants in the products and provide ratings to the product.

## 6. Quality Assurance

The quality of nutraceuticals is of paramount importance for efficacy and safety, and it includes quality of raw materials, heavy metal testing, the absence of contaminants, water testing, pesticides testing, finished product testing with certificate of analysis for every batch. Assurance of nutraceutical quality requires a system approach commencing with the right sourcing of ingredient and its traceability as stated above till manufacturing of clean, safe qualified products making it available to the customers.

CRAMS should have **Quality Management System** in place. It is one of the important business process that enables manufacturer to evaluate all processes to improve efficiency in production processes.

## 7. Technical Dossier for Nutraceutical Products

Technical Dossier is a compilation of the key Technical Documents for any product manufactured by CRAMS. It involves following key data compilations:

- 1. Vendor Validation:** Both Raw and Packing Material Suppliers should be validated by the CRAMS. Vendor COAs should also be collated
- 2. Process Validation:** First 3 batches should be validated and data to be compiled which confirms that the process

can reliably output products of a determined standard

- 3. Testing Methods:** Any new product that is being launched should mandatorily have one batch COA from NABL Testing Labs. Now in certain cases the analysis of the active RM is difficult due to complex nature of the formulation based on which QBI (Quantity Based Input) was defined. Sandeep had made representations to FSSAI which are now well accepted as below

'The manuals of the method of analysis, as amended/ adopted by the Authority from time to time, shall be used for analysing the samples of food articles, wherever, such is quantified, excluding ingredients which are Quantified By Input (QBI). However, in case the method of analysing any parameter is not available in these manuals, a verification/ validated method of analysis prescribed by internationally recognize /analytical/ regulatory agencies / respective manufacturing method for proprietary foods shall be adopted by the Authority or if not available, the method followed by the food article producer'

- 4. Stability Testing:** Stability data for accelerated & RT (Room Temperature) conditions should be established for a defined period of time.

- 5. Finished Product Specifications:** This should be clearly defined for all product during formulation development activity.

## Quest of the Perfect Product

I believe in getting world class Nutrition for the Indian population and always strive hard to get the best of Ingredients, Technology, Innovation, Expertise that it takes to make a perfect product. I have developed a very detailed and diligent approach to ideate, conceptualize and design a product which is wholly in the interest of public health.



NCG (Nutraworks® Consultancy Group) Matrix for Product Development

The article is contributed by eminent and Global fame of Nutraceutical Sector, **Mr. Sandeep Gupta** who is the Director & CEO - **Nutraworks**, Chief Mentor, Global Influencer and Expert, Chief Founder & Director - Expert Nutraceutical Advocacy Council (ENAC®, www.enacnetwork.com), International Panelist - Vitafoods and Panelist Judge - NutraIngredients Asia, Investor Relations & Network Strategist, Advisor to Board of Directors - Various Organizations.