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Regulatory Watch

Strengthening GMPs in India's nutra sector

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As the world shifts from cure to care, India's herbal nutraceutical industry is gathering pace. The task ahead is to evolve from age-old formulas to science-backed innovation, and drive the next big story in wellness

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Getting nutra GMP right before it's too late

India's nutraceutical players hope to make it big as nutra CDMOs, replicating its success as a global pharma CDMO force to reckon with. But India's pharma story has a sobering side to it, with gaps in GMP and warning letters from global regulators. To avoid such missteps, India's nutra CDMOs need to invest in GMP compliance from the start

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"In future, nutra will get regulated like pharma, so manufacturing should be in line with pharma standards. We are preparing for it."

This quote from Shankaranarayanan Jeyakodi, Co-founder, Zeus Hygia Lifesciences, a Hyderabad-based nutra ingredients company, in our cover story, '*India Herbal Nutra Inc: The next engine of global wellness?*', sums up the growing realisation that regulations will rule the nutraceuticals sector.

India already has a regulatory framework, with the regulator Food Safety and Standards Authority of India (FSSAI) finetuning the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022 from time to time.

But the problem is that Good Manufacturing Practices (GMP) for chemical-based medicines cannot be applied in toto for nutraceuticals. Moreover, there is no easily available data on GMP inspections conducted on nutraceutical manufacturing units.

India's nutraceutical players hope to make it big as nutra contract development and manufacturing organisations (CDMOs), replicating its success as a global pharma CDMO force to reckon with.

But India's pharma story has a sobering side to it, with gaps in GMP and warning letters from global regulators. To avoid such missteps, India's nutra CDMOs need to invest in GMP compliance from the start.

But while responsible nutra companies try to comply, nutraceuticals differ from pharmaceuticals and pose unique challenges. In the story, '*Strengthening GMPs in India's nutra sector*', Dr Pirthi Pal Singh, President & Group R&D Head, Tirupati Group, makes that point that the sector needs clearer, nutra-specific GMP guidance that reflects the biological variability of natural materials while maintaining safety, consistency, and consumer trust.

The concern is that the rapid growth and competition to seize global market share will make companies cut corners on GMP and quality. Evolving regulations coupled with a resource-strapped regulator, and inspectors trained to inspect pharma manufacturing sites, creates confusion and chaos. Unfortunately, unethical companies thrive in this uncertainty, confident that their deliberate slips will not be detected.

Such rogue nutra manufacturers may survive for a few years, but the law will catch up with them. More importantly, consumers are getting more vocal and social media channels abound with examples of users calling out brands falling short of their label claims.

Unfortunately, it only takes a few such bad apples to taint the full basket. Rebuilding consumer trust will take more time, effort and capex, than winning it in the first place.

That's a lesson the pharma sector has learnt. Let's hope India's nutra sector takes cues and does not take the same missteps.

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Nutrition has to be made easy for consumers to understand, only then will it help earn their trust and confidence

Amarpreet Kaur, Co-founder of Good Monk, discusses key trends shaping India's nutraceutical market, including shifting consumer behaviour, regulatory clarity, and the growing demand for functional, evidence-based nutrition in an exclusive interview with **Neha Aathavale**

What gaps in the Indian nutrition supplement market did you identify that led to the creation of Good Monk's hassle-free daily nutrition concept?

With our fast paced lives, changing environment and lack of time tend to leave us with minimal time to focus on health and nutrition tends to take a back seat. Good Monk came to life from a very personal experience where we identified a gap that we experienced. As parents, we always go through anger and frustration of kids not eating healthy food and choosing junk or unhealthy foods. As a parent you are often caught in between getting their tummies full with what they want or battling with them to feed them healthy, nutritious food. We realised that it is a battle that every parent has to fight daily at home with their kids. All we needed was a partner in this journey, which can make it a bit easy for us – a magic potion, which can help us get them to eat healthy, help solve the nutrition gap in the modern families today. Solve the glaring deficiencies of micro-nutrients which over 80 per cent of Indians suffer from, which is creating havoc in terms of families health and immunity.

There was a need for something that made nutrition easy and solved the nutritional requirement in a hasslefree manner.

How do you approach product formulation to ensure a scientifically-backed nutrient mix while keeping it convenient and palatable for consumers?

As Indians we all love our meal time. Meals are more of an emotion for us as opposed to a means of nutrition, and one of the biggest challenges facing us was how to add nutrition without ruining the experience. One of the foremost steps to which was building the formulation with no taste maskers, added salt, sugar or preservatives. Good Monk offers the right blend of nutrients and to deliver that, it requires a very rigorous R&D approach.

We have a very strong team of nutritionists, R&D team which work under the guidance of an extremely seasoned Scientific Council to work rigorously to identify ingredients and create formulations that align with our goal of making nutrition easy, clean and effective. We work with some of the country's best ingredient suppliers and work with best in class nutra manufacturers that uphold highest quality standards in manufacturing of both ingredients and the finished product.

In a competitive market with multiple supplements, what strategies have helped Good Monk differentiate itself and gain traction?

Our product offering is fairly differentiated from the current nutrition supplement landscape. We are focusing on making products that don't seem like an additional step to your already stretched lifestyle. We want to smuggle nutrition seamlessly into your daily meals without altering the taste or texture or experience of your meals. This has been our key USP and consumers are choosing us for convenience. While innovating, our goal it to create options that provide the necessary micro-nutrients to our consumers. One of our best-sellers, Healthy 50+ was launched when we realised that this age bracket has a higher need of a certain micro-nutrient profile due to poor nutrition absorption and dietary defi-

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ciencies. At an early stage of our journey, we invested in clinical testing for some of our products and have seen very successful results from the same, strengthening our belief that our nutrient combination and application approach promises a superior product solution to consumer needs.

What trends in consumer behaviour and nutrition habits in India have influenced your product development and market strategy?

While wellness is a mainstream term, most consumers are still apprehensive about ways in which they need to integrate the wellness products in their lives. It is no longer about popping multiple supplements, it is about ingredients, nutrition, efficacy, absorption and a lot more. Consumers are way more aware of their body requirements and they prefer clear messaging on what the product does. As brands, we have the responsibility to understand our context and change our approach based on the altered consumer profile across different platforms. For e.g. A Tier 1 town consumer who is entering the category has very different questions vs somebody in a metro, who's been having supplements for many years. We do believe that nutrition, wellness information and science has to be made easy for consumers to understand - only then will it help to earn their trust and confidence. We also try to study our consumer's media habits and affinity in terms of interests etc so as to customise communication across different platforms for higher resonance

How does the current regulatory environment for nutraceuticals in India impact your product offerings and growth plans?

India's regulatory and policy environment is extremely stringent about its guidelines, thereby keeping consumer interest at the top. They are very supportive and encouraging of the needs of young start-ups that are trying to solve a consumer problem. The system provides clear guidelines in most areas - it provides fair clarity on what we can/cannot do. As brands, we need to ensure that consumer welfare is primary and as long as we work within the guidelines and abide by policies, the system facilitates brands.

The future is preventive nutrition with functional solutions. Consumers' demand for clean, easy to use and effective nutrient solutions is going to explode across multiple areas and not only restrict to a few generic areas

The future is preventive nutrition with functional solutions. Consumers demand for clean, easy to use and effective nutrient solutions is going to explode across multiple areas and not only restrict to a few generic areas. Evidence based claims along with some level of personalisation and customisation will drive higher affinity and stickiness with brands. Brands that are able to integrate tech solutions that help consumers identify their challenges and solve them, will stay ahead of competition. Consumers demand for effectiveness over natural or any other trend/fad will clearly help differentiate between winners.

Which areas of the Indian nutra market does Good Monk see as opportunities for innovation, and how do you plan to expand your product portfolio in the coming years?

Wellness as a segment is seeing a lot of consumer traction and the kind of choices being made are extremely varied. We are able to bring people into the category through our unique formats and offerings. One of the biggest advantages of being a D2C brand is that we are connected directly with consumers and hence have first hand feedback on what the consumer wants and requires. Consumer feedback has been the backbone of our innovation strategy and we have found great success listening to our consumers on what are their pain points and unmet needs.

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India is currently facing a silent epidemic of Vitamin D deficiency, impacting one in five people

Aakash Healthcare and Indian Council for Research on International Economic Relations (ICRIER) recently launched a report on the roadmap to address vitamin D deficiency in India. **Dr Aashish Chaudhry,** MD and Head – Orthopaedics & Joint Replacement, Aakash Healthcare, and **Dr Arpita Mukherjee,** Professor, ICRIER, in an interaction with **Kalyani Sharma** highlight that India is currently facing a silent epidemic of Vitamin D deficiency and share why a national *'Vitamin D Kuposhan Mukt Bharat'* campaign is urgently needed

The report notes that despite abundant sunlight, nearly one in five Indians are Vitamin D deficient. From a healthcare practitioner's perspective, what makes this 'silent epidemic' so difficult to diagnose and address in India?

Dr Aashish Chaudhry: India is currently facing a silent epidemic of Vitamin D deficiency, impacting one in five people, across all demographics. This has deep implications for national health outcomes, in addition to putting an economic burden on our healthcare system.

Many people do not realise they are deficient because Vitamin D shortage often shows up slowly, with vague symptoms like tiredness, muscle weakness which in many cases are dismissed for stress or symptoms or ageing. Also, testing is expensive so lots of people don't get it done.

There is abundant sunlight, but in big cities, people are working indoors most week during the day time. In cultures, where people, especially women wear clothes that cover most skin, they may not get enough sunlight and in turn, vitamin D.

Dr Aashish Chaudhry

Dr Arpita Mukherjee

The study highlights the rising burden of rickets in children and osteoporosis among the elderly. What are the long-term healthcare and economic implications if Vitamin D deficiency remains unaddressed?

Dr Chaudhry: If nothing is done, children with rickets are likely to develop bone deformities. This can result in stunted growth, and even disabilities. Elderly people develop more chances of getting fractures. Also, due to weak bones, there is greater risk of falls and hip breaks. If the issue remains unaddressed, it is likely to drive up healthcare costs over a period of time.

Given the high cost of testing and supplementation, what measures do you think are urgently required to make Vitamin D detection and treatment more affordable and accessible to all sections of society?

Dr Chaudhry: We need a national "Vitamin D Kuposhan Mukt Bharat" campaign, modeled on the success of Anaemia Mukt Bharat, to raise public awareness, align stakeholders, and mobilise CSR and international support for it.

Our policy brief proposes setting uniform national guidelines for Vitamin D testing and treatment, integration of Vitamin D testing into existing health programmes, multi-stakeholder partnerships for implementation, including NGOs, think tanks, and international organisations, and promotion of R&D for low-cost testing kits and making fortified foods available at lower costs.

India is a country blessed with sunlight, yet Vitamin D deficiency has reached epidemic proportions. Why is this paradox happening, and what surprised you most during the research for this report?

Dr Chaudhry: It is not enough to have sunlight. The sunlight should also reach the skin, unblocked, without pollution. Many people stay indoors during working hours, live in high-rise buildings, wear clothing that covers most of the body, or use strong sunscreens. Air pollution also blocks UVB rays which are needed to make vitamin D.

Many of us associate Vitamin D only with bone health, but your report points to much

wider consequences. Could you explain how this deficiency impacts not just health, but also productivity and national development?

Dr Chaudhry: In addition to strengthening the bones, Vitamin D also plays an important role in immune system. Without enough vitamin D, people get more infections and recovery from illness is slower. Low vitamin D is linked with fatigue, low mood, even depression. Studies have shown that also worsens risks of diabetes, heart disease, and possibly certain cancers. On a national level, if we try to analyse its impact, the workforce becomes less robust, the health system gets strained, and government budgets have to spend more on treatment instead of investing in growth, education or infrastructure. In short, we can say that vitamin D deficiency weakens both people and the nation's ability to progress.

The report calls for a comprehensive "Vitamin D Kuposhan Mukt Bharat" roadmap. Could you share the key pillars of this roadmap and how inter-ministerial collaboration can make it successful?

Dr Arpita Mukherjee: The key pillar of this roadmap includes:

a. The Ministry of Health and Family Welfare should take the leadership role and set up an inter-ministerial committee of all relevant ministries and departments like Ministry of AYUSH, Ministry of Food Processing Industries to identify what each government agencies can do to address the deficiency. Then exactly like Anaemia Mukt Bharat, all of them can work together to address the deficiency. It is important to get funding under Union Budget for this cause.

b. Set measurable targets for each government department, identify the high-risk population, and lay down a package of practice

c. Launch mass campaign on benefits of sun exposure, right diet, how to identify the deficiency, etc.

Our policy brief proposes setting uniform national guidelines for Vitamin D testing and treatment, integration of Vitamin D testing into existing health programmes, multi-stakeholder partnerships for implementation, including NGOs, think tanks, and international organisations, and promotion of R&D for low-cost testing kits and making fortified foods available at lower costs

d. There is need capacity building of health workers like ASHA workers to identify and address he deficiency.

e. Expand food fortification beyond milk and oil.

f. Add Vitamin D testing in existing government programmes to reduce cost of testing.

g. Have R&D on Vitamin D fortification.

h. Partner with industry, international organisation, other stakeholders like state governments to scale-up the efforts.

Food fortification and supplementation are seen as critical interventions. What lessons can India draw from global best practices to scale up fortification and targeted supplementation?

Dr Mukherjee: The report gave examples of many countries (both developed and developing) which have adopted food fortification and supplementation. Important lessons are mandatory fortification has better results than voluntary fortification. Staples/cereal fortification helps the fortification to reach low-income groups. Supplements should be low costs and made easily accessible to most vulnerable groups. Periodic surveys should be done to identify the vulnerable groups and pilots should be done to check the impact of supplementation.

Awareness remains a major gap in tackling Vitamin D deficiency. What role can mass campaigns, schools, and community initiatives play in changing behaviour and ensuring preventive action across age groups?

Dr Mukherjee: Mass campaigns can help in the following:

(a) Individuals to identify the deficiency at an early stage

(b) Provide easy remedies like sun exposure and right diet

(c) Encourage outdoor activities and help individuals to take preventive action.

However, the campaign must be customised to target different population groups and stakeholders. For example, awareness is needed not only among teachers in school but children and their parents. Community level camps can help to raise awareness.

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For decades, India exported quintals of botanicals; with Quantum Ayurveda, we export intelligence

Shafiulla Nuruddin Hirehal, Director, Greenspace Herbs explains how his Quantum Ayurveda platform uses acoustic and electromagnetic tuning to make botanicals more consistent and effective at lower doses. He explains how this upgrade can shift India from a bulk herb supplier to a global hub for IP-led, clinically validated nutraceutical innovation, in an interview with **Lakshmipriya Nair**

If you had to describe Quantum Ayurveda in one sentence to investors, what would you say?

Quantum Ayurveda is our proprietary, physics-driven (frequency- guided) platform that tunes botanicals with acoustic energy to imprint measurable signatures; aiming to deliver faster, lower-dose efficacy and a clear path to modern, data-driven validation.

What sparked the idea to bring quantum science into Ayurveda? You've called this the Tesla moment for supplements, what do you mean by that? What gap in the nutra industry are you addressing with Quantum Ayurveda?

Two long-standing frustrations pushed me there: first, the 'milligram arms race' in supplements—people taking multiple capsules of the same herb to feel something; second, batch-to-batch variability even when the HPLC looked identical. Ayurveda has always been about restoring vibrational harmony; modern physics gives us instruments to measure and steer that harmony. So, we began asking: instead of only optimising how much chemistry we deliver, what if we also tune how that chemistry behaves, its energy signature and microstructure, so the body recognises and responds more consistently? That thinking became Quantum Ayurveda, our physics-first, frequency-guided approach to botanicals.

Tesla didn't invent electricity; he reimagined how to control and deliver it, so it did useful work, reliably, at scale. In the same spirit, we're not inventing new plants; we're reimagining how their energy is prepared and delivered. Using controlled acoustic and electromagnetic exposures during processing, we imprint a reproducible energetic 'fingerprint'

on familiar botanicals without altering their chemical identity, and we verify that with mainstream spectroscopy and dissolution readouts. Think of it as shifting from a dose-first model to an energy-and-dose model that's measurable, transferable, and built for quality systems.

What gap in nutraceuticals are you addressing with Quantum Ayurveda?

◆ **Reproducibility beyond chemistry:** Today's QC largely stops at molecules; we add energy signatures and solid-state attributes you can see on the instruments you already trust.

◆ **Dose efficiency and consumer experience:** Instead of 'more milligrams', our goal is faster onset and comparable outcomes at lower doses, cleaner labels and better compliance.

◆ **Evidence that speaks regulatory language:** We're packaging the physics with conventional substantiation—dissolution curves, permeability models, and clinical outcomes; so brands and HCPs can communicate confidently.

◆ **A shared vocabulary for East and West:** Quantum Ayurveda translates concepts like *doshas* and *Ojas* into measurable bioenergetics and materials science, giving Ayurveda a modern, testable framework.

◆ **Internally, we call the resulting materials Energised Active Supplement Ingredients (EASI) because the aim is simple:** Familiar herbs, prepared with better physics, measured with better tools, and experienced by consumers in a way they can actually feel.

How are you validating this science, through clinicals, biomarkers, or pilot studies? Are Indian regulators or AYUSH bodies open to recognising such new tech-driven standards?

1) Physics and chemistry first—prove the material is different. Before a single human takes a capsule, we run a preclinical QC stack to verify that our 'frequency-guided' processing actually changes the material in ways regulators already understand. That means orthogonal readouts (e.g., FTIR/Raman, XRD/DSC for solid-state attributes; particle size/zeta potential; dissolution and permeability assays such as PAMPA/Caco-2) and a pharmacopeial baseline (ID, purity, contaminants, HPTLC fingerprints) anchored to the Ayurvedic Pharmacopoeia/PCIM&H framework. This keeps the 'quantum' story grounded in standard, auditable tests used for ASU drugs today

2) Bench biology—link the physics to function. We then test whether those material differences matter biologically: cytokine panels in LPS-stimulated macrophages (IL-6, TNF-a), Nrf2/ARE antioxidant activity, mitochondrial

stress tests, permeability/uptake in relevant cell lines, and (where applicable) receptor or enzyme assays. Positive signals here don't equal clinical efficacy, but they help us pre-specify mechanisms and biomarkers to carry into human studies.

3) Human clinical trials using Gold standards.

India has been known mainly as a raw material supplier. How does this move change that? How can this help Indian suppliers move up the value chain, from farm to formula? What changes with this move?

For decades, India exported quintals of botanicals; with Quantum Ayurveda, we export intelligence—IP-backed, clinically instrumented ingredients and turnkey formulas. That flips our role from raw-material vendor to innovation partner."

1. From commodities to IP- rich actives. Our platform turns classical Ayurvedic plants into EASI branded actives created with frequency mapping, energy loading, and stabilisation, so the ingredient is delivered 'pre-tuned' rather than sold as a generic extract. That is defensible IP, not bulk powder.

2. Proof over claims. Instead of relying only on assays and per cent-standardisation, we log instrument data, Raman/NMR signatures, electron microscopy of micro-structure, dissolution curves, and pair that with pilot clinicals and biomarker endpoints. It's the kind of dossier global brands and regulators expect.

3. A proprietary process that stays inside India. Our resonance-guided processing (energy 'loading' and locking into a metastable lattice) is a materials-science step we run in-house. It measurably changes dispersion and dissolution value that sits with the Indian manufacturer rather than the overseas brand owner.

4. Global commercialisation, India -rooted supply. We develop and make in Karnataka/India with a US commercialisation bridge (Piscataway, NJ) and launch at global B2B stages (e.g., SupplySide Global 2025). That lets Indian science travel with Indian supply.

How Indian suppliers move up the value chain 'from farm to formula':

◆ **Differentiate at the farm-lot level.** We fingerprint lots with vibrational/chemical signatures (Raman/NMR) and match them to targeted use-cases and organ systems. Farmers who grow the right chemotype/quality can contract into higher-value grades instead of commodity pools.

◆ **Own data, not just acreage.** Our lab is building a database of energy signatures (25,000+ bioactives recorded so far), which will become a digital 'passport' for Indian botanicals that travel with the ingredient and command a premium.

◆ **License and co-brand.** Indian suppliers can supply EASI grades under license and appear on finished-product panels globally ('ingredient-inside' strategy), capturing recurring revenue and brand equity rather than a one-time raw-material margin.

This is how India stops being the world's herb farm and becomes the world's botanical R&D and deeptech hub: We keep cultivation here, layer on physics-first process control, generate clinical-grade data, and ship finished ingredients and formulas, not just sacks of powder. That's better margins for growers and manufacturers, greater trust for regulators and brands, and a clearer India-origin story for consumers.

Do you see Quantum Ayurveda helping Indian brands compete globally? Are global nutraceutical companies showing interest in this technology?

Yes. Quantum Ayurveda (QA) can be a force-multiplier for Indian brands abroad because it translates Ayurveda into export-grade high-tech ingredients and dossiers that fit how the US, EU, Australia and Canada already evaluate supplements: evidence, quality, and compliance. And yes, there's growing inbound interest: trade coverage and industry reports note that QA is being evaluated by major US and European supplement manufacturers. Greenspace Herbs is showing the platform at global industry venues, usually where supply agreements begin.

Yes, global companies are interested. There are two types of proof:

1. Market behaviour: For a decade, global brands have adopted technology-upgraded botanicals (e.g., curcumin phytosome, solid-lipid, or dispersion-based curcumin) precisely because they offer measurable bioavailability/efficacy gains. QA sits in that same adoption corridor: clear analytical differentiation + human outcomes.

2. Direct evaluation + visibility: Industry coverage reports that major manufacturers in the US and EU are already evaluating the QA platform, and we're presenting at global B2B shows where procurement and R&D teams place bets on following-gen ingredients.

Quantum Ayurveda gives Indian brands something global buyers recognise and reward: repeatable performance proven on standard instruments and human endpoints, wrapped in dossiers that map to US/EU/AU/CA rules. That's how you turn India's Ayurveda heritage into durable shelf space worldwide, and the early signs from trade interest and evaluations suggest the market is ready.

What's your vision for Green Space in the next five years?

In five years, I want Greenspace to make 'Quantum Ayurveda' the default way the world designs, measures, and commercialises Ayurvedic botanicals—so India isn't just the farm, it's the R&D and IP engine behind finished, globally -compliant ingredients.

Science you can measure.

We'll keep building a physics-first platform—mapping vibrational/structural 'signatures' of herbs, instrumenting our process (Raman/NMR/EM), and pairing it with AI formulation tools like NutrifyGenie—so our claims sit on data packages brands and regulators recognise. Our goal is to make our energised actives and polyherbs reproducible, dossier-ready, and easy to slot into substantiation workflows.

We're scaling in India with WHO-GMP/GMP practices, traceable sourcing to farm/region, and 'green chemistry' extraction. We then protect the energised micro-structure through packaging and tech-transfer SOPs. The aim is consistent performance, batch after batch, across geographies.

We'll continue taking Quantum Ayurveda to international stages (e.g., Supply Side Global 2025 showcase) while keeping formulation science and core manufacturing anchored in Karnataka so that India captures more value from farm to formula.

By 2030, 'Quantum Ayurveda' should mean three things to the industry: measurable performance, regulatory-ready documentation, and India-led innovation. If we do our job, you'll see Greenspace- engineered actives inside leading formulas worldwide and a stronger India presence on the label and in the patents, not only in the supply chain.

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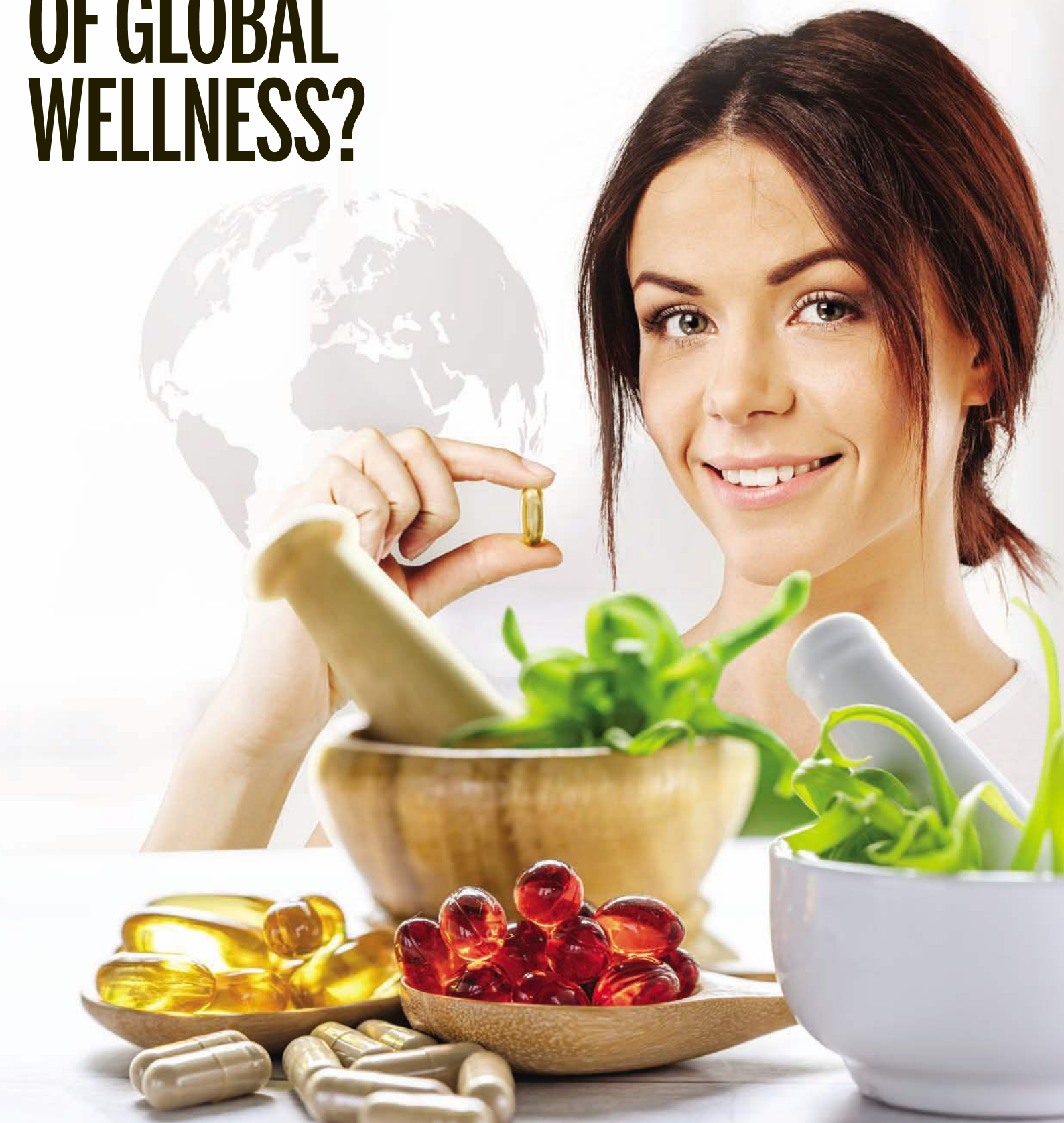
INDIA HERBAL NUTRA INC

THE NEXT ENGINE OF GLOBAL WELLNESS?

As the world shifts from cure to care, India's herbal nutraceutical industry is gathering pace. The task ahead is to evolve from age-old formulas to science-backed innovation, and drive the next big story in wellness

By **Lakshmipriya Nair**



India's herbal wisdom is being rediscovered by the world. From Chyawanprash for vitality to turmeric for healing, some of our time-tested herbs are getting a modern makeover. These traditional remedies have evolved into a vibrant herbal nutra industry, and are fuelling a global wellness wave, from kitchen shelves in Kochi to turmeric lattes in New York.

The shift for cure to care

The global wellness revolution is moving from 'cure' to 'care.' Consumers are prioritising health over healing. This shift is driving the rapid rise of herbal nutraceuticals.

As people become more aware of preventive health and clean-label living, herbal nutraceuticals are emerging as one of the most promising growth sectors. India, with its rich herbal traditions, scientific talent and expanding R&D capabilities, has a strategic advantage to lead this growth wave.

What's changed? Advances in formulation science, standardisation, and clinical validation are helping Indian manufacturers take age-old formulations to global markets with newfound credibility. Herbs once known only as home cures are now supported by research and traceable quality systems. *Ashwagandha, turmeric, amla, moringa*, and *giloy* are finding widespread adoption and being reformulated into capsules, gummies, and functional beverages for a global audience.

Stepping into the spotlight

The numbers tell the story. According to Allied Market Research, the global herbal nutraceuticals market was valued at $28,329.7 million in 2019, and is projected to reach $48,446.5 million by 2027, registering a CAGR of 7.55 per cent from 2021 to 2027.

In India, the trend is equally strong. The herbal products sector, valued at $1.87 billion in 2024, is expected to cross $2.5 billion by 2030, expanding at 5.4 per cent CAGR, as per TechSci Research estimates.

As the world looks for natural, proven ways to stay healthy, India's herbal nutra story is stepping into the spotlight.

Rooted in ancient wisdom, powered by science

India's relationship with herbs isn't new. What's new is how we're applying it. For thousands of years, be it tulsi, brahmi,

Universities like Shoolini can connect traditional wisdom with advanced research and innovation. Through validation, value addition, and start-up incubation, we can help India become a global leader in herbal nutraceuticals

DR RADHA
Assistant Professor
Shoolini University

India has a huge heritage of herbs. Only 5–10 per cent has been explored. So, the potential is huge. We need to invest in R&D to understand and leverage their potential

SHANKARANARAYANAN JEYAKODI
Co-founder, Zeus Hygia Lifesciences

The nutraceutical segment, particularly plant-based extracts, dietary supplements, functional foods, and adaptogens, has shown a sharp upward trajectory post-COVID

DR DEBJANI ROY
Executive Director
SHEFEXIL

The next generation of consumers is not only health-conscious but also value-driven and exceptionally well-informed, seeking authentic knowledge about products and their ingredients—they expect transparency, authenticity, and ecological responsibility

ABDUL MAJEED
Chairman and Trustee of Hamdard Laboratories

mulethi or neem, nature has been our first pharmacy. Today, that legacy is meeting modern science.

And, India has advantages that stand out clearly:

1. A deep herbal heritage: India's traditional systems like Ayurveda, Siddha and Unani, offer a knowledge base of more than 6,000 documented medicinal plants. Thus, India's herbal knowledge runs deep. This, in turn, gives Indian ingredients instant global familiarity and trust.

2. Manufacturing and scale: India's pharma infrastructure, certified by GMP, ISO, and WHO, provides a tested framework for high-quality, large-scale nutra production. This gives India an edge in quality and scale.

3. Cost and innovation advantage: Affordable R&D talent, strong academic research, and established supply chains position India as a hub for nutraceuticals. Companies can develop and validate new formulations faster and cheaper than their Western peers.

4. Policy support and promotion: The Ministry of Ayush, FSSAI, and Ministry of Food Processing Industries are working to streamline regulations and promote exports. Schemes under Pharma Vision 2030 and Make in India aim to position India as a global wellness leader.

5. Global consumer trust: Ingredients like curcumin and ashwagandha have become global favourites, backed by clinical research and safe-use records. They are now part of mainstream wellness routines in markets from Tokyo to Toronto.

The Indian market

Post-COVID, health has gone mainstream. Across age groups, consumers are investing in prevention of diseases. They want natural, clean-label, transparent products that fit into their daily lives, whether as gummies, teas or functional snacks.

"The nutraceutical segment, particularly plant-based extracts, dietary supplements, functional foods, and adaptogens, has shown a sharp upward trajectory post-COVID," informs Dr Debjani Roy, Executive Director, SHEFEXIL, in an earlier interview with Express Pharma.

This new audience is driving the industry to evolve faster. India's herbal nutra ecosystem is both, competitive and collaborative. Legacy players like Dabur, Hamdard Laboratories and Himalaya coexist and compete with disruptors like Patanjali, Organic India and newer entrants like Zeus Hygia, offering consumers a wide palette of herbal medicines and ingredients. Their combined efforts reinforce India's position as a global herbal nutraceutical hub, driving growth across domestic and export markets.

Affordable R&D talent, strong academic research, and established supply chains position India as a hub for nutraceuticals

Exports on the rise

India's nutra exports have shown an upward trajectory post-COVID, fuelled by global demand for plant-based wellness solutions. "Exports from SHEFEXIL's member companies have crossed Rs 9,000 crore annually across categories. Segments such as FSMP/FSDU, fermented probiotics, and Ayurveda-inspired innovations are expected to accelerate further in the next three to five years," divulges Dr Roy.

Indian companies are now key players in global supply chains, not just as exporters, but as contract manufacturers, formulation partners, and innovation collaborators for international wellness brands. Many of SHEFEXIL's member companies are leading players in the global wellness supply chain, supplying herbal extracts, functional ingredients, fermentation inputs, and finished nutraceuticals to global brands.

Science is the new currency

For decades, India has been exporting herbal ingredients and extracts. But that model is changing. Today's growth isn't just about exporting plants, it's about exporting science.

"The next decade of growth will come from credibility and innovation," opines Shankaranarayanan Jeyakodi, Co-founder, Zeus Hygia Lifesciences, a Hyderabad-based nutra ingredients company. "Ten years ago, there were fewer than 10 serious players in this space. Today, there are over 40, and the competition is only getting stronger."

Jeyakodi's company is expanding its production facilities to meet rising global demand. "We purify herbal actives, conduct toxicological studies, and provide data to branded-ingredient markets in the US, Europe, and Asia. The opportunity is huge, but credibility is the key," he asserts.

He elaborates on the rapid market transformation, "In the next five to ten years, it is going to be a huge market. Herbal supplements will be huge. More than 50 per cent consume supplements in the developed world. Companies like Zeus Hygia help to improve the quality of the product with clear data and evidence. Ten years before, there were less than 10 companies, now more 30–40 companies exist."

Today, Zeus Hygia exports to Europe, South East Asia, the US, South Korea, Brazil, Australia and New Zealand. Highlighting the evolving regulatory scenario, he says, "In future, nutra will get regulated like pharma, so manufacturing should be in line with pharma standards."

He notes the competitive pressures and untapped potential and states that US tariffs, pricing pressures, and competition from China and the US, keep Indian players alert. India has a huge heritage of herbs. Only 5–10 per cent has been explored. So, the potential is huge. We need to invest in R&D to understand and leverage their potential.

In an earlier article, published in *Express Pharma*, Abdul Majeed, Chairman and Trustee of Hamdard Laboratories, a well known Unani medicine brand, informs, "The next generation of consumers is not only health-conscious but also value-driven and exceptionally well-informed, seeking authentic knowledge about products and their ingredients—they expect transparency, authenticity, and ecological responsibility. By integrating GMP practices, digitised supply chains, and environmentally responsible cultivation, Unani medicine can demonstrate its relevance in a modern, wellness-driven world. The vision is clear: preserve its heritage while innovating boldly to create a global future for Unani."

Together, these insights underline how science and evidence need to be India's strongest exports.

Fortunately, these shifts are underway. For instance, at Shoolini University in Himachal Pradesh, Dr Radha, Assistant Professor, is leading pioneering research on Himalayan medicinal plants.

Sharing more details about her work, she adds, "I work with tribal communities of the northwestern Himalaya to scientifically validate their traditional plant knowledge. This research helps identify valuable bioactive compounds that can be developed into new herbal nutraceuticals, giving India an edge in global markets."

Her team has already filed four patents, including a nutrient-rich jam and a ready-to-drink herbal beverage made with *Bombax ceiba (Semal)*. These products retain their bioactive properties and are free of artificial preservatives, an example of how India's indigenous ingredients can be reimagined for modern wellness markets.

Her work highlights how scientific evidence help India move from being a supplier of raw herbs to a creator of branded, evidence-backed nutraceuticals.

"We need stronger links between research institutions, industry, and policy support. With proper standardisation, licensing, and awareness about their health benefits, such products can easily reach consumers," she explains.

The challenges ahead

For all the promise, the road to growth comes with challenges, and the industry knows it. Let's examine some of the major ones:

◆ **Regulatory clarity:** Regulation remains a key factor for India's nutraceutical future. Currently, products may fall under FSSAI, AYUSH, or CDSCO, depending on formulation and claims, leading to overlap and ambiguity.

While India's regulatory ecosystem is improving, overlaps still create confusion around claims and labelling. A unified, framework would make compliance easier.

Harmonising with global standards, will help Indian exporters compete on equal terms. Likewise, greater alignment with international frameworks like European Food Safety Authority (EFSA) and USFDA would allow Indian products to access premium markets more smoothly.

Additionally, R&D incentives, export schemes, and faster IP approvals could accelerate innovation.

◆ **Threat to biodiversity:** As the market expands, sustainability and traceability are becoming non-negotiable. Overharvesting of wild herbs and unregulated sourcing practices threaten biodiversity and long-term viability.

Out of thousands of known herbs, only a small fraction have undergone human trials. Expanding peer-reviewed research is essential for global acceptance. Every herbal claim must be backed by research.

Dr Radha cautions that sustainable cultivation and community participation are the key. She suggests, "Researchers can guide cultivation methods, and businesses can ensure ethical sourcing and fair benefit-sharing with local people."

Sustainable sourcing is not just an ecological necessity, it's also emerging as a business differentiator. Global consumers increasingly value brands that can demonstrate transparency and ethical practices.

◆ **Limited clinical research:** Out of thousands of known herbs, only a small fraction have undergone human trials. Expanding peer-reviewed research is essential for global acceptance. Every herbal claim must be backed by research. Partnerships between universities, startups, and global contract research organisations (CROs) can speed up validation.

◆ **Growing competition:** Many nutra firms are small or mid-sized, lacking marketing scale and R&D depth. Industry consolidation or cluster-based models could help them grow faster. Indian exporters face stiff competition from countries like China and Japan, as well as tariffs and documentation hurdles in the US and EU. Competing on quality and traceability will be key for India.

"Universities like Shoolini can connect traditional wisdom with advanced research and innovation. Through validation, value addition, and start-up incubation, we can help India become a global leader in herbal nutraceuticals," says Dr Radha.

Opportunities for value creation

India's herbal nutra story is more than a business opportunity. If AYUSH systems was India's gift to the ancient world, herbal nutra products could be its offering to the future, powered by innovation, backed by evidence and rooted in trust.

And, its next leap will come from moving up the value chain, from raw material supplier to knowledge-driven innovator. So, how can we go about doing so?

◆ **Branded ingredients:** Develop proprietary, standardised herbal extracts with IP protection and clinical backing.

◆ **Functional foods:** Integrate Ayurvedic actives into modern consumption formats like bars, drinks, and gummies.

◆ **Contract R&D and manufacturing:** Leverage cost-effective infrastructure to become a preferred global CDMO hub.

◆ **Sustainable wellness:** Protect biodiversity through ethical sourcing, fair trade, and farmer partnerships. Build brand differentiation around traceable, ethical, and green supply chains.

◆ **Digital transformation:** Integrate AI and blockchain to monitor sourcing, quality, and compliance.

◆ **Build global-quality infrastructure:** Adopt pharma-grade GMP, automate traceability, and ensure rigorous quality assurance to meet international standards

◆ **Encourage entrepreneurship:** Support nutraceutical start-ups with funding, incubation, and market access under national wellness missions.

The decade ahead

India's herbal nutra journey is at a defining phase. India has the knowledge, resources and credibility. What we need now is convergence between research and business, tradition and technology.

The message is clear. With science-backed innovation, harmonised regulation, and sustainable ambition, India's herbal nutra products can claim their place on the global stage, as the future of modern wellness.

The foundation is ready. The market is ripe. Now, it's India's turn to lead the global wellness revolution. One herb, one idea at a time.

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From capsules to customised nutrition: The innovation wave in supplements

Dr Sanjay Agrawal, Scientific Advisor of Alkomex GBN Pharma Group US, explores the most significant innovations in nutraceutical delivery systems, their business implications, and how companies are leveraging them to engage health-conscious consumers

The nutraceutical industry has moved far beyond tablets and capsules. Today, innovation in delivery formats is reshaping how consumers experience wellness products. Driven by evolving lifestyles, personalisation, and a demand for convenience, nutraceutical brands are experimenting with novel ways to make health supplements not just functional, but enjoyable and accessible. From gummies and powders to advanced technologies like liposomal encapsulation and 3D-printed nutrition, delivery formats are becoming a differentiating factor in a competitive market.

This article explores the most significant innovations in nutraceutical delivery systems, their business implications, and how companies are leveraging them to engage health-conscious consumers.

The shift in consumer expectations

Traditionally, nutraceuticals were consumed in standardised pill or capsule form- reliable but uninspiring. However, as wellness becomes intertwined with lifestyle and identity, consumers are seeking formats that align with their routines, tastes, and preferences. According to recent market surveys, factors such as convenience, palatability, and experience often influence purchase decisions as much as efficacy.

This shift creates both opportunities and challenges for businesses. While innovation in delivery formats can command premium pricing and improve brand differentiation, it also requires significant investment in R&D, regulatory approval, and supply chain adaptation.

Key innovative delivery formats

1. Gummies and chewables

Among the most popular alternatives to pills, gummies have captured the imagination of both children and adults. The global gummy supplements market has been growing at double-digit rates, fueled by their candy-like appeal.

◆ **Business advantage:** Gummies lower the barrier to entry for first-time supplement users and appeal to younger demographics.

◆ **Challenges:** Maintaining stability of active ingredients in gummy formulations, particularly heat- and light-sensitive compounds, remains complex.

Chewable tablets, lozenges, and jelly strips also fall into this category, offering flavor-driven engagement alongside health benefits.

2. Effervescent tablets and powders

Effervescent formats dissolve in water, creating a fizzy, flavorful drink. These formats offer rapid bioavailability and allow higher doses compared to gummies.

◆ **Consumer appeal:** Convenience, hydration, and the perception of a refreshing health beverage.

◆ **Market use:** Widely used for vitamin C, electrolytes, and multivitamin blends.

◆ **Business perspective:** Effervescents open doors for nutraceutical companies to compete with functional beverage markets, blending supplement benefits with lifestyle-oriented consumption.

Stick-pack powders and single-serve sachets also appeal to on-the-go consumers who prefer flexibility over fixed-dose tablets.

3. Functional beverages

The convergence of nutraceuticals and the beverage industry is one of the strongest growth trends. Nutrient-fortified waters, herbal infusions, and ready-to-drink protein or collagen beverages embody this shift.

◆ **Consumer appeal:** Beverages are associated with everyday consumption and are easier to integrate into daily routines than supplements.

Examples: Probiotic drinks, adaptogen-infused teas, or nootropic energy shots.

◆ **Business insight:** Functional beverages often command higher margins and enjoy strong crossover potential in mainstream retail.

The challenge lies in ensuring product stability during storage, as beverages present formulation hurdles such as microbial control and ingredient solubility.

4. Liposomal encapsulation

While gummies and powders appeal to convenience, liposomal technology speaks to efficacy. Liposomes are microscopic vesicles that encapsulate active ingredients, protecting them from degradation and enhancing absorption.

◆ **Why it matters:** Many nutraceuticals- like curcumin, vitamin D, and omega-3 fatty acids- struggle with low bioavailability. Liposomes can significantly improve delivery.

◆ **Business outlook:** Premium positioning. Liposomal nutraceuticals cater to informed consumers who value advanced science in wellness products.

Though cost-intensive, liposomal delivery is expected to be a differentiator in the high-end nutraceutical segment.

5. Orally dissolving films (ODFs) and strips

Thin strips that dissolve on the tongue provide an ultra-convenient alternative to pills. They are portable, discreet, and require no water.

◆ **Consumer draw:** Perfect for travelers, children, or those with pill fatigue.

◆ **Applications:** Popular in energy boosters, vitamins, and sleep aids (such as melatonin).
◆ **Business advantage:** ODFs support microdosing formats and fast onset, enabling nutraceutical brands to tap into quick-relief categories.

6. Sprays and drops

Sublingual sprays and liquid drops enable direct absorption into the bloodstream through oral mucosa, bypassing the digestive system.
◆ **Consumer appeal:** Quick absorption, easy to use, and suitable for those with digestive issues.
◆ **Market insight:** Particularly gaining traction in categories like vitamin B12, CBD, and herbal extracts.

These products appeal to a health-savvy demographic seeking efficacy without the bulk of pills.

7. Personalised and 3D-printed nutrition

Perhaps the most futuristic format, 3D-printed nutraceuticals allow customisation of nutrient profiles, shapes, and even flavors based on individual health needs.
◆ **Consumer impact:** Aligns with the rising demand for personalized wellness.
◆ **Business model:** Subscription-based services offering tailored daily nutrition packs or 3D-printed supplements.
◆ **Challenges:** High cost of technology, regulatory hurdles, and limited scalability at present.

However, as digital health platforms and nutrigenomics gain ground, this format could redefine the nutraceutical industry's future.

Market and business implications

◆ **Rising R&D and production costs:** Innovative delivery systems require investment in new machinery, formulation expertise, and stability testing. While costs are high, early adopters can secure strong market differentiation.
◆ **Regulatory considerations:** New formats often face unclear regulatory frameworks. For instance, gummies and functional beverages may fall into overlapping categories of food and supplements, requiring careful compliance.
◆ **Branding and differentiation:** Delivery format has become a branding element in itself. A brand positioned around liposomal technology communicates science and efficacy, while one focused on gummies emphasises fun and lifestyle integration.
◆ **Consumer education:** Novel formats require education to build trust. For instance, liposomal supplements need a clear explanation of their benefits compared to standard capsules. Similarly, consumers must be reassured of the efficacy of low-dose formats like strips.

The road ahead

The future of nutraceutical delivery formats lies at the intersection of science, convenience, and personalization. We can expect three key directions:
1. Hybrid formats: Combining multiple approaches- such as effervescent gummies or beverage powders with liposomal encapsulation- for both fun and efficacy.
2. Personalisation at scale: AI-driven platforms analyzing consumer health data to recommend customised supplement packs or 3D-printed formulations.
3. Sustainability: Eco-friendly packaging and clean-label ingredients will become integral to delivery innovations.

Conclusion

For the nutraceutical industry, innovation in delivery formats is not just a technical upgrade- it is a business strategy. As consumers view wellness as part of their identity and lifestyle, companies must create products that are effective, enjoyable, and tailored. Gummies, beverages, liposomal capsules, and even 3D-printed supplements illustrate a broader shift: health is no longer about swallowing pills, but about integrating wellness seamlessly into daily life. Brands that master this balance between science and consumer experience will not only differentiate themselves but also lead the next wave of growth in the global nutra market.

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Strengthening GMPs in India's nutra sector

India is emerging as one of the fastest-growing contract manufacturing hubs for nutraceuticals, but the lack of clearer, nutra-specific GMP guidelines could prove a stumbling block, explains **Viveka Roychowdhury**

India has an enviable spot in the nutraceutical universe, with various reports predicting brisk growth. But is there sufficient regulatory oversight on the quality of nutraceuticals made in India? The recent cases of cough syrups causing the deaths of children, due to the presence of unauthorised ingredients and improper manufacturing practices, are red flags that nutraceutical manufacturers must heed.

Industry experts refer to the comprehensive regulations in place to regulate nutraceuticals. Citing the regulations, Dr Pirthi Pal Singh, President & Group R&D Head, Tirupati Group, says, "The Indian Food Safety and Standards Authority of India (FSSAI) specify that all food articles falling under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022, are specially processed or formulated for specific nutritional or dietary purpose and shall be clearly distinguishable from foods intended for normal consumption by their special composition."

Under these regulations, Dr Singh points out, "All nutraceutical manufacturers (need) to comply with the Good Manufacturing Practices (GMP) requirements as laid down under Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Business) Regulations. It generally includes: general hygiene and sanitary practices; food operations and control; management and supervision; good quality control mechanism and well established quality assurance system. FSSAI has also designed the guidance documents for an effective Food Safety Management System to implement GMP/GHP (Good Hygiene Practices) requirements in the nutraceutical industry."

The Indian nutraceutical regulatory framework is evolving toward a more balanced, fit-for-purpose model; however, it still needs clearer, nutra-specific GMP guidance that reflects the biological variability of natural materials while maintaining safety, consistency, and consumer trust

DR PIRTHI PAL SINGH
President & Group R&D Head
Tirupati Group

In reality, the pharma sector itself requires adequate resources for GMP inspections periodically at the manufacturing sites. The nutraceutical industry lacks stringent regulation compared to the pharma industry. A similar situation may be prevailing at nutraceutical manufacturing sites as well. Normally, thousands of nutraceutical samples are tested by FSSAI for quality, periodically

DR RANJIT BARSHIKAR
CEO, QbD International, and United Nations Adviser

Unlike pharmaceuticals, which consist of standardised, single-molecule active ingredients, natural nutraceuticals are complex, highly variable, and susceptible to different forms of contamination. These biological inconsistencies complicate the control and validation processes central to pharmaceutical GMPs

SHANKARANARAYANAN JEYAKODI
Co-founder, Zeus Hygia Lifesciences

GMP REQUIREMENTS FOR NUTRACEUTICALS SECTOR		
Aspect	**Requirements (as per 2022 Direction)**	**Key notes/Updates**
Licensing & Facility	All nutraceuticals, health supplements, FSDU, FSMP and Prebiotic and Probiotic Food must be manufactured in premises licensed by the Central Licensing Authority (CLA) under FSS Act, 2006	State licenses not applicable for these categories.
GMP Compliance	Manufacturing to strictly follow Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011	Covers hygiene, sanitation, equipment, quality control and personnel.
Quality Systems	Raw materials, intermediates, and finished products must meet FSSAI purity and compositional criteria	If standards not specified, adopt pharmacopoeial or Codex standards.
Documentation	Maintain Batch Manufacturing Records (BMR), stability data, in-process test results, and packaging controls	Records to be available for audit or inspection.
Tolerance Limits	-10% tolerance limit permitted for label claim until end of shelf life for active ingredients	Ensures label accuracy and stability compliance.
Prohibited Substances	No hormones, steroids, or psychotropic ingredients	Reaffirmed from earlier compendium.
(Compiled from the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022)		

Dr Ranjit Barshikar, CEO, QbD International, and United Nations Adviser, opines, "These GMP guidelines are comprehensive, focusing on ensuring the quality, safety, and hygiene of the final product. They align with the general principles outlined in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011, specifically its Schedule 4, and are often supplemented by detailed guidance documents. Compliance with these regulations is critical to ensure that the products comply with GMP quality standards. This regulatory framework not only safeguards consumer health but also enhances the credibility and competitiveness of Indian nutraceuticals in the global market. It is the manufacturer's responsibility to ensure that a nutraceutical is safe before it is marketed."

Expanding on these regulations, Shankaranarayanan Jeyakodi, Co-founder, Zeus Hygia Lifesciences informs that, "Regulations also mandate adherence to GMP, approved ingredient lists, and specific nutrient limits, with a ban on prohibited substances like hormones and steroids. Additionally, manufacturers must conduct quality and stability testing to ensure safety and meet nutritional composition requirements, along with maintaining thorough documentation for traceability."

Evolving regulations

Dr Singh points out that India's nutraceutical regulations are modern and quite advanced at certain levels. He opines that the FSSAI has taken significant steps to regulate the nutraceutical sector in the past and is also looking for further improvement to align with global practices. From 2016, when the first gazette notification for nutra regulations was released, to till date, there have been many amendments in the regulations to improve the product quality and GMP among Indian food business operators (FBOs).

He points out that FSSAI operationalised the 2022 Nutra Regulations and has issued directions (licensing, schedules of permitted ingredients, new dosage formats like mouth dissolving strips, biscuits, gummies etc., GMP, labelling/claims and approval routes). That gives regulators and industry a clear legal framework to act on. FSSAI has mandated all the nutra manufacturers to have a central FSSAI license and mandated that all the nutra manufacturers to conduct a third party audit from FSSAI recognised agencies to ensure GMP.

The ground reality

However, is there sufficient regulatory oversight on the quality of nutraceuticals made in India? Unlike the older and more established pharmaceutical sector, there is no statistical data available on the number of GMP inspections of nutraceutical manufacturing sites.

Dr Singh cautions that while India has laid a solid regulatory foundation, the effectiveness depends on consistent enforcement, industry compliance, and consumer awareness. As demand grows, we need to ramp up industry-wide voluntary standards, shared testing databases, and certified-supplier lists to raise quality bars above global standards.

As a long time GMP auditor in the pharma sector who consults on Quality by Design / CGMP in the biopharma sector, Dr Barshikar too sounds a cautionary note. He rues the fact that in reality, the pharma sector itself requires adequate resources for GMP inspections periodically, at the manufacturing sites. "The nutraceutical industry lacks stringent regulation compared to the pharmaceutical industry. A similar situation may be prevail-

ing at nutraceuticals manufacturing sites as well. Normally, thousands of nutraceuticals samples are tested by FSSAI for quality, periodically."

Tapping the opportunity

There is no doubt that the nutraceuticals sector is poised for growth, especially in countries like India. As per a Fortune Business Insights report, the global nutraceuticals market size was valued at $458.55 billion in 2024. The market is projected to grow from $500.62 billion in 2025 to $986.85 billion by 2032, exhibiting a CAGR of 10.18 per cent during the forecast period.

Asia Pacific dominated the nutraceuticals market with a market share of 39.84 per cent in 2024, supported by rising population, disposable income, and health awareness. Increasing consumer preference for functional foods and beverages is fueling growth across countries like China, India, and Southeast Asia.

The Fortune Business Insights report references the Government push for the sector, citing the Government's launch of eight nutraceutical products under the *Pradhan Mantri Bhartiya Janaushadhi Pariyojana* to boost immunity.

A Kearney report pegs Asia Pacific as the world's largest nutraceuticals market, growing at a CAGR of 8.8 per cent. In India, the market is valued at $8 billion and is growing at 11 per cent CAGR (2023–2027). The global nutraceuticals market is valued at more than $520 billion and is growing at 8 to 9 per cent CAGR.

The same factors that made India a pharma contract manufacturing hub hold true for nutra contract development and manufacturing organisations (CDMOs). Citing stats, Dr Singh says, "The global nutraceutical CDMO is valued at approximately $140 billion (2023) and is projected to grow at about 11 per cent CAGR through 2030. India is emerging as one of the fastest-growing contract manufacturing hubs for nutraceuticals, currently valued at about $13 billion and growing at about 14 per cent CAGR. Indian CDMOs like Tirupati Group are expanding their footprints at the global platforms and bridging domestic innovation with global outsourcing opportunities."

The good news is that CDMOs have helped democratised the nutra opportunity, proving that size is not always required to make a mark in the market. Dr Singh puts it, "One big change that India has witnessed in the last two decades, and especially post-COVID pandemic, is an increasing number of first generation entrepreneurs, start-ups, D2C brands, and SMEs who often use CDMOs and private label manufacturers for ready to launch products, thereby avoiding capex, and accelerating speed to market."

According to Dr Singh, one of the prime reasons for manufacturing of high quality nutraceutical products in India is that majority of the Indian CDMOs and manufacturers have their plants constructed based on global/WHO GMP, ensuring high-quality compliance.

The regulator FSSAI is also encouraging the Indian industries by organising events like "World Food India" and "Global Food Regulators Summit" that help nutra companies to showcase their capabilities to the world. Dr Singh narrates that regulatory bodies across the globe are now connecting directly with the Indian food regulators through such events.

But global growth comes with its own growth pains. On a cautionary note, Dr Singh alludes to the regulatory complexity and compliance burden associated with tapping international markets, as FSSAI rules require strict adherence to the law of the land, which is slightly different from the rest of the world. For example, new ingredients will need special approval before those ingredients can be sold in the Indian market.

Challenges along the way

Nutraceutical manufacturers face many challenges when complying with regulations designed for medicines. As Jeyakodi succinctly puts it, "Applying GMPs designed for synthetic pharmaceuticals to nutraceuticals, especially those of natural origin, presents unique and significant challenges. Unlike pharmaceuticals, which consist of standardised, single-molecule active ingredients, natural nutraceuticals are complex, highly variable, and susceptible to different forms of contamination. These biological inconsistencies complicate the control and validation processes central to pharmaceutical GMPs."

Jeyakodi lists challenges with raw materials, ranging from natural variability of ingredients, as the phytochemical "fingerprint" of natural ingredients can vary significantly based on factors such as plant age, time of harvest, soil, and weather conditions. This natural inconsistency makes it difficult to ensure batch-to-batch uniformity, a cornerstone of pharmaceutical GMPs.

Sourcing and supply chain complexity is another factor, as nutraceutical supply chains are often fragmented and rely on multiple suppliers from different geographical regions. This complexity makes it difficult to trace ingredients and monitor the conditions under which they were cultivated, harvested, and processed.

He also highlights the risk of adulteration and contamination, as natural materials carry inherent risks of contamination from pesticides, heavy metals, mycotoxins, or microbes. Ensuring consistent purity is a major hurdle, and adulteration with cheaper or unauthorised substances is also a risk.

On the manufacturing and quality control front Jeyakodi cites standardisation of extracts, method validation and testing, and stability testing. Regulatory and documentation challenges stem from regulatory ambiguity, as the regulatory landscape for nutraceuticals is less clearly defined and standardised compared to pharmaceuticals, and it can vary significantly by country. This creates confusion for manufacturers attempting to achieve compliance and validate product claims. Inconsistent record-keeping is another challenge, as robust documentation is a core GMP requirement. For natural ingredients with complex and fragmented supply chains, maintaining the necessary records—from initial sourcing to final product testing—can be very difficult.

Jeyakodi also lists scientific and efficacy challenges, referring to the lack of scientific evidence. He explains that while pharmaceuticals must demonstrate safety and efficacy through rigorous, randomised controlled clinical trials, many nutraceuticals lack this level of scientific evidence. This makes it difficult to substantiate product claims in a manner consistent with pharmaceutical regulations. Bioavailability issues are another challenging area, as nutraceuticals can have questionable bioavailability, meaning the body may not be able to effectively absorb or utilise the nutrients. This is a major limitation and a factor that may not be fully addressed by GMPs designed for more bioavailable synthetic compounds.

Agreeing with this sentiment, Dr Singh says, "Nutraceutical products are among the

most complex and challenging to develop due to the combination of multiple active ingredients in a single dosage form. Developing analytical methods for such complex formulations and that too at very low concentrations, remains a true scientific challenge."

In Dr Barshikar's book, the main challenges are related to quality mindset, regulatory compliance, facility and equipment, and testing from safety perspectives. Secondly, product standardisation, relating to variability in ingredient quality and effectiveness remains a concern. He also flags labeling as a challenge, with the Food Safety and Standards, Regulations, 2016, outlining essential labelling requirements for nutraceuticals. Labels must avoid claims about preventing, curing, or treating diseases and only include statements about the product's impact on structure, function, or general wellbeing if scientifically validated. Fourth on Dr Barshokar's list is the availability of experimental data.

Summing up, Singh says, "The Indian nutraceutical regulatory framework is evolving toward a more balanced, fit-for-purpose model; however, it still needs clearer, nutra-specific GMP guidance that reflects the biological variability of natural materials while maintaining safety, consistency, and consumer trust."

GMP compliance as an innovation moat

Given the complexity and challenges of adhering to GMP norms, companies will need to frame GMP compliance as an innovation moat to justify the significant capex. Jeyakodi agrees, saying that robust GMP adherence fosters an innovation moat by creating a quality-led innovation framework and enabling complex, high-value product development.

It also allows companies to secure intellectual property (IP) and proprietary processes. Perhaps most importantly, GMP adherence reduces product recalls and waste. By minimising contamination, errors, and inconsistencies, GMP lowers the risk of costly and reputation-damaging product recalls. This operational efficiency and risk reduction directly contribute to the long-term return on investment (ROI) for capex.

Taking this reasoning a step further, Jeyakodi believes that GMP adherence can also become part of a branding strategy, to position a company as a premium, trustworthy, and science-backed brand, justifying the cost of capex to consumers. In his view, this approach could build and communicate consumer trust, support premium pricing, enable brands to make robust, substantiated health claims, and facilitate global market entry. Finally, this can reinforce the brand narrative, supported by tangible certifications, and foster customer loyalty and advocacy, which are invaluable for long-term growth.

Thus, while the FSSAI evolves to more nutra-specific regulations, it will be up to nutraceutical manufacturers to keep pace and position themselves as reliable and safe brands worthy of consumer trust.

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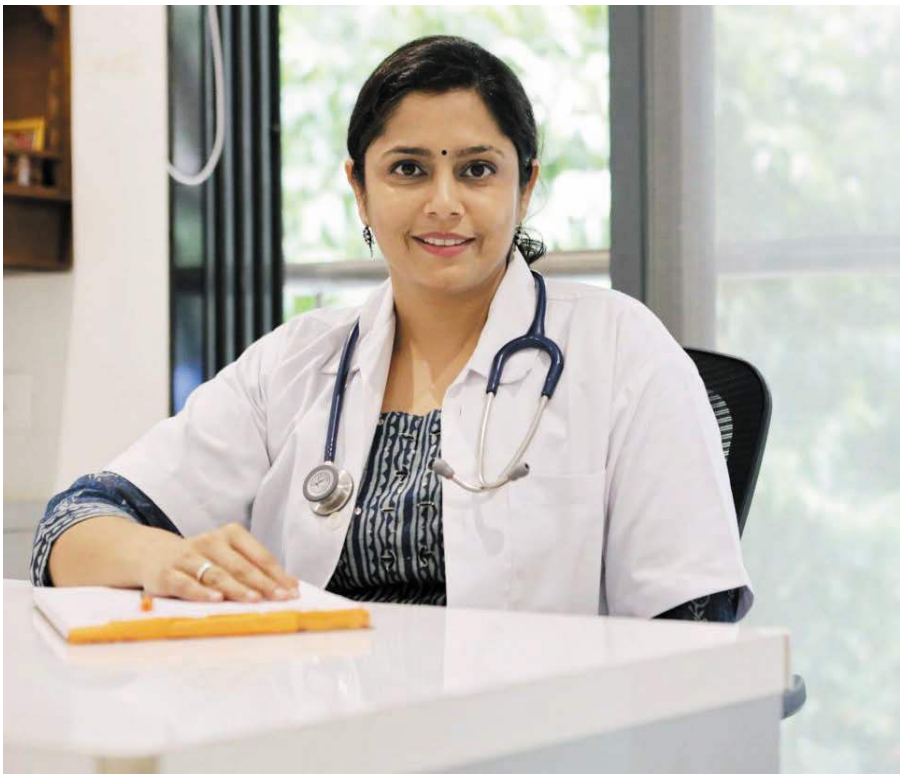
India's plant-based supplement industry needs stricter guidelines

Dr Anuja Pethe, Pediatrician, Physicians Association for Nutrition India (PAN), Director Mumbai Chapter; Consultant Pediatrician and lifestyle medicine physician highlights that 'natural' doesn't always mean 'safe'

From protein powders to herbal capsules, plant-based supplements have become a regular part of gym bags and kitchen shelves alike in the last few years in the country. The Indian plant-based protein supplements market, which was worth100 million dollars in 2023, is expected reach around 185 million dollars by 2030. It clearly shows that more Indians are turning to plant-based nutrition, believing it to be healthier, safer, and in tune with modern lifestyles.

The growing awareness about fitness, the increase in interest around plant-based diets, and the belief that "natural" automatically means "good for you" are some of the major reasons for the growth of this industry. Patients often proudly tell the doctor that they have switched to "natural" supplements. They believe that if it comes from a plant, it cannot harm them. However, this is not always true. Even a natural herb can cause side effects, interact with regular medicines, or worsen certain health conditions if taken in the wrong amount.



The plant-based supplement industry in India is growing faster than the rules that govern it. They are not drugs, yet many of them are sold with promises that sound very much like medical claims, that they can improve hormones, heal joints, or control blood sugar. A supplement that makes such claims needs scientific proof and strong regulation, but that is not always the case today.

In India, the Food Safety and Standards Authority of India (FSSAI) regulates the supplements that are considered part of the food chain. The Central Drugs Standard Control Organisation (CDSCO), regulates drugs and medicines. However, the line between the two is often blurred. A protein powder or a vitamin blend may come under FSSAI's rules, but if it contains very high doses of nutrients or uses medical claims, it can also attract CDSCO's attention. In such a scenario, many offenders may miss the radar or some cases may fall in the cracks . Thus, stronger and clear rules are urgently needed for this sector.

At present, the FSSAI does check that products contain approved ingredients and follow certain dosage limits. It also restricts the use of words like "treats" or "cures." However, many companies find ways around these restrictions by using fancy language and online marketing. The problem is further aggravated when such products are sold through social media or influencers. It becomes very difficult to regulate them.

When regulations are strict, only genuine, well-tested supplements make it to the market. This will also help build trust among consumers and healthcare professionals and push Indian brands to meet global standards and compete internationally.

India has the potential to become a world leader in the plant-based nutrition sector. However, for that to happen, safety and science must come before marketing. While some products may help, in many instances, they may have side effects.

As the Indian nutraceutical market continues to grow, there is a need for stricter guidelines and also creating awareness among the public. Consumers should learn to read labels carefully, avoid "miracle cure" claims, and consult a doctor before starting any supplement. It is equally important to educate people about the importance of well-balanced diet of whole minimally processed plant foods. It is important to use nutraceutical supplements judiciously and complement them with a healthy lifestyle.

At the policy level, it must be ensured that every product that reaches the market is safe and genuine. Plant-based nutrition can improve health and sustainability. However, it needs to be built on regulation, not hype.

Bridging the gap between clinical evidence and product efficacy in nutra

Dr Rohini Patil, Nutritionist, Founder and CEO, Nutracy Lifestyle stresses that ensuring that the claims made about nutraceuticals are scientifically substantiated is essential for consumer trust and regulatory compliance

In today's world, claiming health benefits is not enough; it also needs to be ensured that what works in clinical studies also works well for everyday users. The result of clinical research provides an authentic foundation, but it doesn't guarantee effective results in practice. Ensuring that the claims made about nutraceuticals are scientifically substantiated is essential for consumer trust and regulatory compliance.

Clinical evidence vs real-world results

Clinical studies have some differences from their real-time practices. Clinical studies measure the effectiveness of ingredients in a controlled atmosphere. Their procedure, purified forms, and measured doses are different from the real-time usage of the ingredient. Once these ingredients are used in products for people in various lifestyles and health conditions, their outcome may not be similar to the result of clinical studies. The disconnect is due to various reasons:

- **Ingredients form and dosage mismatch:** If there is a mismatch in the amount of dosage used for clinical purposes and real-time usage, it creates differences in outcome when it is consumed by people. Usage of different ingredients in the production of the product compared to the research also results in the same.
- **Validate efficacy:** Authenticate the health benefits of the product with clinical trials, ensuring the validated claims align with the verified outcome.
- **Lack of standardisation:** The inconsistent manufacturing can lead to uneven levels of ingredients in the product. The result could be harmful if a product does not meet its quality standard.

Taking measures to combat these issues is important as it affects the outcome of the product as well as the authenticity and trust of the consumer in the product.

Form insight to actions: Closing the loop

The development of nutraceutical products does not end at their launch. The process involves continuous involvement of research and development. To create clinically tested, consumer-friendly products, companies update their approach based on scientific process and observed outcomes. Several distinct factors influence the role in the evidence-efficacy gap.

Emerging clinical studies

The world of nutrition science is fast-paced. It evolves constantly; new human trials are changing the way ingredients perform under certain conditions. There is a need to actively monitor and integrate advanced research into product evolution.

Trends in user feedback

Consumers are sharing their experiences today more than ever before. Companies can gain real-time insights to monitor patterns in user outcomes of the products, both positive and negative. When it is systematically analysed and used to improve the product, it boosts the user experience as a top priority.

Expert insights from nutritionists

Data plays a key role, but human expertise is essential. Experts in nutrition and health deliver significant insights on the role of ingredients. The advice suggested by nutritionists, health professionals, and dietitians is impactful in personalised health care. Once it is combined, it provides evidence-based, consumer-focused developments in products.

Efficacy through evidence

Bridging the gap between clinical evidence and product efficacy is not just a one-time fix; it requires continuous commitment. Driven by fast-paced marketing and uncertain claims, this industry often neglects the importance of authentic nutraceutical products. The main challenge in this industry is to build trust through a transparent medium with scientific integrity.

The future of nutraceuticals relies on how closely the real-world outcome matches the evidence claimed. There is a need to set a quality standard for every product. The aim should be to deliver trust with nutraceuticals. Bridging the gap between clinical theories and product outcome is a responsibility. Nutraceuticals stand at the border of science and everyday wellness. It is essential to move beyond the claims and create credible, effective care nutraceutical products driven by science and proven by consumers.

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SGS Nutrasource awards NutraStrong™ Collagen Verified certification to Lonza Capsules & Health Ingredients

Lonza Capsules & Health Ingredients (CHI), a leading supplier in the joint health ingredient space has received NutraStrong™ Collagen Verified certification by SGS Nutrasource for its UC-II® collagen product

The NutraStrong™ Collagen Verified programme is the first independent certification system dedicated to evaluating and verifying the identity, source, safety and quality of collagen ingredients and products to ensure that consumers receive what is claimed on the label.

Kevin Yan, VP of Product Certifications at SGS Nutrasource said, "Congratulations to Lonza on its success in securing the Collagen Verified distinction. This coveted certification verifies that UC-II® collagen meets the highest standards of purity, source integrity, manufacturing excellence and claim substantiation and will help this breakthrough product stand out in an increasingly saturated market."

Multiple human clinical trials of Lonza's UC-II® undenatured type II collagen ingredient show that a small daily dose (40 mg) supports joint comfort, flexibility and mobility by working with the body's natural cartilage repair processes to promote normal cartilage building. Its low dose and versatility enable delivery in different formats, including small capsules or gummies, without compromising efficacy.

NutraStrong™ Collagen Verified programme is the first independent certification system that evaluates and verifies the identity, source, safety and quality of collagen ingredients and products. Achieving this certification for UC-II® collagen underscores Lonza's commitment to delivering clinically studied, high-quality ingredients that brand owners, and ultimately consumers, can trust

Hanna Charron, Associate Director, Global Product Management, UC-II®, Lonza CHI said, "Achieving the NutraStrong™ Collagen Verified certification for UC-II® collagen underscores our commitment to delivering clinically studied, high-quality ingredients that brand owners, and ultimately consumers, can trust. This certification is another way we demonstrate our dedication to transparency, scientific rigor and excellence from raw material sourcing through to finished product formulation."

Lonza CHI is a global leader in capsule design, manufacturing and encapsulation technology dedicated to creating customised solutions that help deliver groundbreaking health products to the market.

The programme is further endorsed by the Collagen Stewardship Alliance (CSA), reflecting growing industry alignment around the need for trusted, transparent and effective collagen solutions.

Len Monheit, Executive Director at the CSA commented, "The CSA's mission is to foster responsible growth of the global collagen category and the Collagen Verified programme plays a vital role in this effort by recognising suppliers and brands that do the right things by prioritising quality, efficacy, and transparency. This is about elevation and driving transparency in this category."

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