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Spinco Biotech CuttingEdge



India's Vibrant Market : Expert Insights from Visionary Indian Leaders on Pharma, Chemicals, Food, Nutraceuticals, and Beyond 77

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Customerization......Since 1981

Deep Dive

Innovation is the Key

- preventive care through nutraceuticals



hank you very much for sparing your valuable time for our readers of CuttingEdge. May I request you to share your key milestones for shaping Indian nutraceutical industry and promoting preventive care worldwide throughout your journey of success.

Sami-Sabinsa Group, today the largest exporter of natural nutraceutical ingredients in India, is celebrating its 35th anniversary, and all along we have remained committed to our fundamental principles of innovating, delivering uncompromised quality, and bringing customer delight.

Referring to your topic, there are three crucial decisions that I would attribute towards establishing Sami-Sabinsa as a global health-science company, as outlined below:

A. In 1975, when I immigrated to the United States, a revolutionary thought propelled my entrepreneurial journey and turned the concept of 'Natural Nutraceuticals' into a global phenomenon. My entrepreneurial aspirations led me to start Sabinsa Corporation and I decided to pitch Ayurveda as a system of medicine in the U.S. But soon I realized that the Americans were particular about clinical evidence and weren't convinced with our natural system of medicine. Using technology, I decided to transform medicinal herbs into a modern drug form and make them available as 'Natural Nutraceuticals'. By approaching American institutions and various pharma groups in America, I popularized this plant-based nutraceutical, which gained acceptance gradually. This breakthrough concept and my perseverance in accomplishing it helped me craft the success journey of Sami-Sabinsa Group.

- B. I am determined that innovation is the key for a business to attain trajectory growth. India is a depository for medicinal plants, and there is much that can be uncovered about them and bring their benefits to the people. Hence, I launched Sami Labs Ltd., in 1991 in India to research and manufacture standardized extracts from medicinal plants. Through research, Sami Labs launched its first commercial product, Citrin[®], a weight management supplement from the extract of Garcinia cambogia. This product gained worldwide acclaim upon its launch. At Sami-Sabinsa Group, innovation has always been a tradition that has helped us establish a leadership position for our products in many competitive markets. Today, Sami-Sabinsa Group has launched over one hundred products through research, and our innovations have garnered worldwide acclaim. Recently, we have been honoured with the prestigious American Botanical Council (ABC) Award in the USA, recognizing our commitment to delivering innovative, high-quality and research-based natural products. We are the first Indian Company to receive this award. The 'SFE - Herbal Industry Leader Award - 2023' presented by the International Bioresources Conclave and Ethnopharmacology Congress (ISE SFEC-2023) is an acknowledgement of our outstanding work in the field of herbal products. The '2023 Technology Innovation Award' for our product LactoSpore®, which we received in Nanjing, China, and the Thomas Alva Edison Awards which we have received three times previously are a testament to our research success in the industry.
- C. Our **culture of Patenting** our innovations has protected our business and prevented our customers from procuring under-quality products that may not yield the desired efficacy. Today Sami-Sabinsa Group has reached the Intellectual Property Milestone of over 427 Granted Patents, which has helped us to protect and scale our business globally.

Couple of years back, on a pleasant evening, I received a 'surprise' email. It was all about a challenging HPLC method for a nutraceutical product. It was from none other than the 'Father of Indian Nutraceuticals Industry'. Dr. Muhammed Majeed, Founder & Managing Director of Sami-Sabinsa Group, who asked for a simple analytical method for a complex molecule. I still reminisce his discussions and emails that always illuminate us for newer innovations. Probably, these kind of discussions and breakthrough concepts that he has crafted is the backbone of the success journey of Sami-Sabinsa Group over more than three decades.

Dr. Majeed owns several awards for his exemplary services in the nutraceutical and cosmeceutical industries. Recently, in 2022, he has been named the 'Legend of the Millennium in Nutraceutical Industry' by the Associated Chambers of Commerce and Industry of India (ASSOCHAM). In 2023, he has been honoured with the Life Time Achievement Award at the 1st Kerala Pharmaceutical Congress. The award is in recognition of his contributions towards shaping the Indian Nutraceuticals industry and promoting preventive healthcare. He always emphasizes that innovation is the key to business success. Today, Sami-Sabinsa Group has launched over one hundred products through research, and their innovations have garnered worldwide acclaim.

Here are his comments and experiences that inspire us to do innovations today for tomorrow's success.

> Dr. Venkat Manohar Director Indian Institute of Chromatography & Mass Spectrometry (IICMS), Chennai venkat.manohar@iicms.in

Innovation is the Key

May we know your suggestions / comments on how we can move forward to practice ayurveda similar to allopathic drugs.

In order to promote ayurveda and strengthen the entire AYUSH system, the Government of India has taken a number of steps and implemented many initiatives. To advance the Ayush Sector, The Ministry of Ayush has established Central Research Councils, Medicinal Plant Boards, Pharmacopoeia Laboratories, and the Pharmacopoeia Commission that sets the standards for ayurveda and other Indian medicines.

From the Industry side, nutraceutical and ayurvedic product manufacturers should invest in research to discover more innovative applications for our traditional herbs. Understanding the great opportunity for ayurvedic products, Sami-Sabinsa Group has set up independent research divisions in areas includina Natural Drugs, Phytochemistry, Synthetic Chemistry, Tissue Culture, Biotechnology, Analytical R&D, Biological Research, Microbiology, Formulation R&D. and In addition to lab facilities, our R&D infrastructure encompasses open fields for trials and greenhouses. As a result of our efforts, Sami-Sabinsa has been a pioneer in launching many ingredients in the market, such as ForsLean® (Coleus forskohlii extract) for weight management, BioPerine[®] (black pepper extract) for bioavailability enhancement, Curcumin C³ Complex (Curcuma longa extract) for antioxidant support, Sabroxy[®] (from Oroxylum indicum herb) for brain health, Gugulipid (Commiphora mukul extract) for cardiovascular support, etc.

Today our plant-based nutraceutical products are being used in dietary supplements, food and beverage, cosmetics, and other industries in various formats such as tablets, capsules, drinks, cookies, gummies, bread, chewable tablets, stick jelly, freeze-dried blocks etc. Our in-house R&D Centre is also responsible for constant improvement in productivity, cost savings, and quality enhancements that have made our nutraceutical products globally competitive.

Standardizing the ingredient is another important aspect that ensures the quality of the ingredient is maintained throughout its shelf life and in subsequent batches, providing the desired positive health benefits.

The nutraceutical industry continues to expand through research, IPR, value addition, and exporting high quality products that reflects Prime Minister Narendra Modi's objective of adding value to products and creating natural demand on a worldwide scale.

All of Sami-Sabinsa's products are standardized, making us a more reliable ingredient partner for numerous international brands in a range of applications. The trust we have built with our customers by providing efficacious, safe, and quality products has helped us spread globally to 17 Countries.

Clinical evidence is another important parameter that customers are particular about and is instrumental in boosting the use of ayurvedic products. For instance, Sami-Sabinsa's flagship ingredient, Curcumin C³ Complex[®], which has immune-supporting, antioxidant, anti-inflammatory, and detoxification properties, has undergone over 98 clinical studies and is currently the most clinically researched product in the marketplace. It has won six international awards, including the 'Scientific Achievement Award' from the National Business Journal in 2007.

Please highlight how your organization has overcome the challenges on availability of herbs of same quality.

Before starting the regular supply of raw materials, our vendor partners are extensively evaluated. To determine the quality of raw material, several tests, including the right biomarker concentration, yield percentage, microbiological count, adulteration, etc., are carried out. Vendors are authorized for further supplies only if they meet the Company's quality standards. Sami-Sabinsa Group works only with select partners who can deliver raw materials to prescribed standards in sustainable quantities.

Further, at our manufacturing facilities, all raw materials received for production undergo thorough screening to authenticate that they are free from any adulteration. Raw material characterization is carried out to ensure purity and the desired level of active content in the raw material. Through advanced testing equipment, the quality of ingredients is monitored throughout the production process and on finished goods to assure optimum quality.

Ensuring 'Quality Consistency' through Cultivation:

Sami-Sabinsa Group also cultivates a variety of medicinal plants through various farmer groups to ensure consistent raw material quality. The Company is a pioneer in contract farming of medicinal plants and is engaged in the commercial

cultivation of medicinal crops including Coleus forskohlii, Curcuma longa, etc., Through the tissue culture technique, elite genotypes of rooted cuttings that have a higher percentage of survival and desired quality traits are developed and given to farmers for cultivation. Sami-Sabinsa currently has about 2,500 acres of land under the contract farming model in the Indian states of Tamil Nadu and Karnataka. Through our agricultural officers, regular examination of the field and growing practices is done. Our farmers are trained to follow Good Agricultural and Collection Practices (GACP) to ensure the quality of produce. The program todav has created alternate avenues of livelihood for about 2,000 farmers, who are also assured of a guaranteed buyback by the company.

Pradesh, In Madhya the Sami-Sabinsa Group is working on a reforestation programme where high-value, 50,000 vulnerable trees, Pterocarpus medicinal marsupium, have been planted to date. In 2018, this programme won the NutraIngredients - USA Editor's Award for the best industry initiative. Similarly, Sami-Sabinsa has been working on the large-scale cultivation of an endangered medicinal species called Picrorhiza *kurroa* in the higher reaches of the Jammu & Kashmir region in India.

Our efforts of contract farming and conservation of medicinal plants enable us to obtain the desired quality raw material and also enhance the sustainable livelihoods of marginalised communities in different Indian States.

What are the intricacies in successfully developing nutraceutical products and sustaining them in the competitive world? The nutraceutical industry is fortunate that the Government of India has made concerted efforts for the market to flourish. As per the online data, the Indian nutraceuticals market stands at a market value of US\$ 10.1 billion in 2022, and its exports are worth US\$ 1.3 billion. This innovation-driven sector continues to expand through research, IPR, value addition and exporting qualitatively competitive products that are in accord with Prime Minister Narendra Modi's objective of adding value to products and creating natural demand for them on a worldwide scale. However, some impediments are creating hurdles for the industry to fully contribute to the sector's growth and exports. One of the key concerns relates to the Biological Diversity Act (BD Act) 2002 which Sami-Sabinsa Group is addressing in various forums.

Some of the industries' key concerns in the Biological Diversity Act include:

- (a) Recognising the value-added products and including the oleoresins, extracts, and isolated phytochemicals in Section 2(p) of the act pertaining to the definition of value-added products.
- (b) The definition of the non-Indian entity in Section 3(2) of the Bill is still not in harmony with Section 2(42) of the Companies Act 2013. There is the inclusion of the term 'foreigner' in the amendment, which has caused uncertainty for the industry. Hence the Act needs to be harmonized with the Companies Act.
- (c) Due to the requirement that importers of bioresources must approach the National Biodiversity Authority for clearance of each consignment, the manufacturing activity

is getting affected. But as per the UN Rio Declaration of 1992, each nation has sovereign rights over its own bioresources, and another nation cannot control them. Hence, the imported raw materials must be brought out of the purview of the act.

- (d) The absolute powers vested to raid the business premises by authorities must be limited to certain situations only, which need to be defined in the act.
- (e) The Biological Diversity Act advocates that industries accessing bioresources need to share the benefits with the local community, who are custodians of the resources. The industry is prepared to distribute the 'access benefit share' for sourced wild plants, especially rare and endangered species, and intends to pay the 'benefit share' directly to the custodians through the Biodiversity Management Committees set across the country.

By addressing these critical concerns, the Act can motivate nutraceutical manufacturers to further focus on research and make manufacturing globally competitive. Secondly, manufacturers can reduce their reliance on imports and collaborate with local cultivators for their raw material needs. This would support the livelihood of the cultivators and conserve the rare medicinal plants in the country, thereby leading to sustainable management of biodiversity.

What measures do you suggest for taking the herbal preparations on a mass scale?

Clinical trials are an important tool to gain customer trust and

launch nutraceuticals and herbal preparations on a mass scale. During the pandemic, our research team developed a herbo-mineral formulation, ImmuActive[®], to effectively manage COVID-19 symptoms as an adjunct therapy. Before launching the product, clinical trials were conducted to ascertain its efficacy and safety.

randomized, double-blind, Α placebo-controlled studv was conducted on 100 COVID-19 patients with ImmuActive® as an adjunct treatment for COVID-19. The study suggested that the supplementation significantly lowered the ordinal scale in COVID-19 patients, reduced the number of days of hospitalization, and lowered the time required to turn viral negative by RT-PCR test. The study also showed that the supplement has no adverse events and is a safe adjunct treatment for effectively managing COVID-19. Based on the study, the product ImmuActive[®] was launched on a large scale in the Indian market.

How do you overcome the challenges on retaining talent and what are your tips for the younger generation and start-ups?

Sami-Sabinsa strongly believes, that the passionate and motivated youth of India, has the larger responsibility to take forward and examine our traditional practices as ayurveda in the context of new knowledge and sophisticated technologies available to them.

At our state-of-the-art innovation centre in Bangalore, we have over 120 well-qualified and enthusiastic scientists, responsible for researching and bringing out new understandings in phytoextracts. Over 50% of this workforce are young aspirants from reputed institutes across the country who are guided and well-supported by senior professionals in handling cutting-edge technologies and upskilling their potential in the field of nutraceutical and cosmeceutical science. Our meritocratic work culture and the opportunities provided to explore and learn have made Sami-Sabinsa a preferred career destination for many young professionals. We also take pride in the fact that Sami-Sabinsa is committed to gender diversity, and we continue to strengthen the participation of women in research and business.

Startup Opportunities in the Nutraceutical Sector:

Startups have a great opportunity in the nutraceutical sector. Local cultivators who grow medicinal plants for the industry lack the expertise to execute grading and adulteration checks, leading to incorrect material supplies and production halts. This impairs the sector and impacts our global competitiveness. Setting up Quality Control labs is a great opportunity for the startups that would encourage more farmers to cultivate medicinal plants and also support the industry.

How do you envisage the applications of tools such as mass spectrometry in nutraceutical and herbal science?

Sami-Sabinsa Group operates in compliance with the highest international regulations, including those of the US FDA, the European EFSA, Australian TGA etc., and upholds strict quality control. The quality control lab at Sami-Sabinsa is equipped with cutting-edge analytical tools and qualified professionals who can run tests and check for residual contaminants in products. The analytical tool LC-MS/MS (Liquid Chromatography with Tandem Mass Spectrometry) is utilized for pesticide analysis at ppb levels. Aflatoxins and ochratoxin A analysis is also done using LC-MS/MS. Gas chromatography coupled with tandem mass spectrometry, referred to as GC-MS/MS, is used to analyze polyaromatic hydrocarbons (PAHs) and ethylene trioxide (ETO). Inductively coupled plasma optical emission spectroscopy (ICP-OES) or inductively coupled plasma mass spectrometry (ICP-MS) are employed to quantify heavy metals at ppm levels in the finished products.

Please suggest on how we can make science curriculum attractive to develop more capabilities in the coming days?

Over 7500 different species of medicinal plants exist in India, which provide a vast array of therapeutic benefits. Yet ayurveda is yet to get into the mainstream, as considerable work remains to be done to convert the science of ayurveda into a contemporary medical concept and make this gift available for widespread use. At the same time, nutraceuticals and ayurveda are also steadily gaining popularity on a global scale for their preventive aspects. This explains the immense necessity and scope for researchers, specialists and technicians to advance this field.

The industry, ayurveda / nutraceutical associations and academia must collaborate to spark interest in the young minds. Industry visits organized for high school students would make them understand the discipline, the career prospects open to them, and the significant role they can play in this stream. Another recommendation from the industry is that ayurveda and nutraceutical science be taught in the high school curriculum.

The industry is also ready to collaborate with science institutes and universities, providing young graduates with the opportunity to work on research projects and uncover the numerous medical applications of our treasured assets.

Kindly share your 'insights' and suggestions on the noble act of CSR for our young generation.

Dr. Majeed Foundation, the philanthropic arm of Sami-Sabinsa Group reflects our compassion for society. The Foundations philanthropic initiatives are wide ranging healthcare, education, women's empowerment, senior citizen and rehabilitation initiatives, among others. The COVID-19 pandemic was one of the toughest challenges that the world faced with. At such a time, Sami-Sabinsa contributed INR 10 crores towards the PM CARES Fund in India to support the less fortunate. In FY' 22–23, the foundation spent INR 6.6 crores on CSR programmes including education, women's empowerment, sanitation, rehabilitation and setting up de-addiction centers. Recently, the Foundation spent INR 50 lakh on a meal program for 1500 less fortunate children.

As India entered 'Amrit Kaal', please share your views on how organizations like Spinco can support nutraceutical companies in their growth trajectory.

For herbal extracts used in the manufacturing of nutraceutical formulations, the regulations of different countries are becoming more and more stringent and widening the spectrum of the residual contaminants. This significantly increases the time necessary to complete residual contamination analysis for each product destined for export. Furthermore, the limits for residual pollutants are getting increasingly stringent. Spinco could work to introduce more sensitive instruments as well as develop devices, technology and methodologies that will significantly shorten analysis time. This will aid in the production of high-quality, safer items for customers all over the world.

Spinco played a significant role in the beginning phase of establishing Sami-Sabinsa manufacturing units in Bangalore and Hyderabad, delivering quality instruments such as HPLCs (High-performance liquid chromatography) essential for analytical active molecule characterization in herbal extracts.

