

### **India: Gen Next hub for Cosmeceutical Trials**

US demand for cosmeceuticals is projected to rise by 7.4% per year to \$8.2bn in 2012. A mixture of cosmetics and pharmaceuticals they provide additional health-related benefits such as skin nourishing, improving skin tone, texture, radiance and reducing wrinkles. The skin care segment will account for 63% of all cosmeceutical product demand through 2012 and is expected to grow to \$22.1bn in worldwide sales by 2013<sup>1</sup>. The healthy growth in the cosmeceutical market worldwide is attributed to the aging baby boomer generation, an increase in disposable income as well as aspirations of the younger generation to enjoy beautiful, young-looking skin while aging<sup>2</sup>.

#### **Challenges faced by cosmeceutical manufacturers**

Competition is at its peak with the emergence of several companies enticing consumers with their gamut of products. However, claims of effectiveness of some cosmeceuticals lack credible evidence, thus the industry is challenged to provide convincing evidence of the effectiveness of their products.

The consumers are becoming aware about the science behind cosmeceutical products. They are becoming more erudite; demanding innovative products with exceptional quality. They are skeptical to use any product which does not provide clinical study efficacy or safety data. They prefer to use products of companies who are known to conduct clinical studies on finished formulations tested on human faces. Proof of efficacy of ingredients is more important because consumers have wide variety of choices and will discontinue use of ineffective products.

Comprehensive animal and human clinical evaluation studies to determine safety and efficacy is therefore a prerequisite for the development of cosmeceuticals. Ethical and statistically validated clinical studies give an opportunity for companies to substantiate their claims.

#### **Assessing safety and efficacy**

The comprehensive study design including purpose, clear identifiable end points, substantial sample size appropriate statistical methods and ensuring compliance to legal and ethical standards ensures authenticity of the product. The safety of the product can be established by simple test like open or occluded patch test or complex tests like repeat insult patch test, photo patch test or repeat insult photo patch test. Also ocular irritation study, phototoxicity study and routine microbiological testing of the final product are essential. The efficacy measures of clinical improvement should be expressed in terms of skin hydration, pigmentation, wrinkles, skin gloss, roughness, skin texture and tone, elasticity etc. While designing cosmeceutical trials one should have legal compliance with statutory norms which are country specific such as COLIPA for EU, USFDA, ASEAN directives, Bureau of Indian standards (BIS Act) and others.

#### **Clinical Trials and India Inc.**

India has bloomed as a hub for conducting clinical studies in South East Asia. The BioSpectrum-CMR Asia Pacific Clinical and Contract Research Organizations Survey 2011 depicted dermatology as one of the top

five therapeutic areas of focus for CROs in Asia<sup>3</sup>. Cosmeceutical companies outsource their clinical trials to CROs in India due to several advantages they offer.

### **Technology:**

India's state-of-the-art technology and infrastructure is at par with international standards. India is well equipped with sophisticated armamentarium such as mexameter/chromameter (to check skin color), corneometer (to measure skin hydration), sebumeter (to measure skin surface lipids), cutometer (to measure resiliency), derma spectrometer, sebuxif, optical profilometry, fluorescent photography, ultrasound, laser doppler, colorimetry, etc<sup>4</sup>. Dermatology centers have an excellent range of instruments from makers such as Courage + Khazaka (GmbH), Konica Minolta, Optometrics LLC, Varian, Canon, etc.

### **Medical expertise:**

The Indian panels of dermatologists have extensive experience in skin therapy procedures like skin diode laser, pulsed dye laser, etc. Skin compatibility testing and monitoring adverse reactions is conducted only by technically qualified persons and under the supervision of a clinically competent medical doctor/physician.

### **ICH-GCP compliance:**

The trials in India are conducted in accordance with Good Clinical Practice and other required regulations to deliver quality and credible data. Several CROs in India have an added advantage of a vast experience in handling natural products which makes India a center of choice for testing natural cosmetics.

### **Genetically diverse population:**

The country has a huge genetically, culturally and socio-economically diverse population base and a vast pool of heterogeneous population. As tolerance, efficacy and safety parameters change with different skin types; products should ideally be tested on all the skin types as developed by Fitzpatrick, - a recognized tool for dermatologic research. Thus, the diverse genetic population of India which covers Fitzpatrick skin type III to V allows wider testing sample for cosmeceuticals.

### **Time and cost effectiveness:**

The enrollment rates in India are 5-10 times higher than the United States<sup>5</sup>. Another distinct advantage is the low cost for product R&D. A joint study by the Federation of Indian Chamber of Commerce and Industry (FICCI) and Ernst and Young found that clinical trials cost in India is 50-60% less than in the developed markets<sup>6</sup>.

### **Cosmeceutical trials at Vedic**

In the past decade cosmeceutical companies have collaborated with Vedic for conducting clinical studies in India. Some of the indications of trials conducted were acne, hair growth, melasma, tinea versicolor etc. Vedic offers all the key components for a well done cosmetology trial: qualified panel of

dermatologists, volunteer database, testing facility, scientific and medical team for designing study protocol and evaluation of results, quality assurance team, back-end team like data management, statistics, etc. Vedic has been able to deliver appropriate study designs with clinical end points to measure safety and efficacy of the products.

### **About Vedic Lifesciences**

A full service Contract Research Organization (CRO) serving Nutraceutical, Cosmeceutical and Traditional Medicine industry. Vedic provides affordable, credible and efficient solutions to substantiate label claims and meet regulatory requirements. To learn more, log on [www.vediclifesciences.com](http://www.vediclifesciences.com)

### **References:**

<sup>1</sup>Cosmeceuticals to 2012 - Market Research, Market Share, Market Size, Sales, Demand Forecast, Market Leaders, Company Profiles, Industry Trends. Available from: Available from: <http://www.freedoniagroup.com/Cosmeceuticals.html> [Accessed on: June 24, 2011]

<sup>2</sup> Cosmeceutical trends and technologies: A Review of Global Technology Trends, Market Information, and Business Opportunities. Available from: [www.technology-catalysts.com](http://www.technology-catalysts.com) [Accessed on 15<sup>th</sup> July 2011]

<sup>3</sup>BioSpectrum-CMR Asia Pacific CRO Survey. Sept 2011. Available from: <http://biospectrumindia.ciol.com/content/BSTOP20/BSTop2004/11109131.asp> [Accessed on 28<sup>th</sup> Sept 2011]

<sup>4</sup> Peter Elsner, Howard I. Maibach. Cosmeceuticals: Drugs vs. Cosmetics 2000.

<sup>5</sup>Rangawala S. Clinical Trials in India: The Current Drug Development Environment. Available from: [http://incresearch.com/resource/inDepth-Series/INC-inDepth-India-2\\_11.pdf](http://incresearch.com/resource/inDepth-Series/INC-inDepth-India-2_11.pdf) [Accessed on 18<sup>th</sup> July 2011]

<sup>6</sup>Nutraceuticals critical supplement for building a healthy India. White paper by FICCI and Ernst & Young

### **Read it in Inside Cosmeceuticals:**

<http://www.insidecosmeceuticals.com/articles/2012/03/india-next-hub-for-cosmeceutical-trials.aspx>