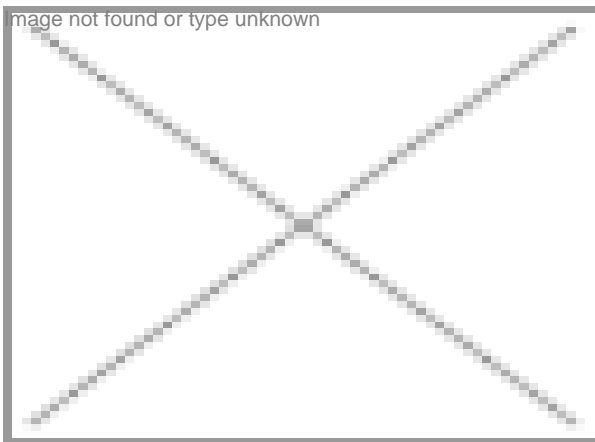


## Liposomal Drug Pioneer

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*Despite a thriving generic, formulation and bulk drug industry, India has lagged in developing skills to support discovery-oriented innovative research. However, the Indian drug discovery research is catching up slowly and steadily. In this special series BioSpectrum profiles inimitable contribution of Dr Jitendra N Verma and this emerging area of liposomal drugs*

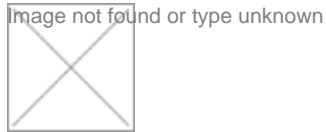


After upholding the Trade Related Aspects of Intellectual Property Rights (TRIPS), committing to recognize product patents, Indian companies, in the last decade, have invested in innovation-led drug discovery and processes.

This month, in CSO Series, BioSpectrum brings you the achievements of Dr Jitendra N Verma, a senior scientist and managing director of Lifecare

With a masters degree in science from Allahabad University and PhD from PGIMER, Chandigarh, Dr Verma has 32-year of academic and industrial research experience. He specializes in infectious diseases, NDDS and vaccine development with an expertise in a variety of disciplines, including protein and lipid isolation and characterization, human hybridoma development, drug targeting, liposome technology, vaccine delivery, molecular biology and immunochemistry. His areas of research have been application of liposome technology for development of pharmaceuticals, vaccines and diagnostics, development of nano-drugs, bio-chemistry and metabolism of lipids.

Besides the scientific background, Dr Verma's management background includes implementing successful research, development and marketing strategies, including commercialization.



Known as a person with straightforward approach, he has numerous achievements to his credit. Distinct achievements include the development of first liposomal product of India which is a syphilis test. He is also the founder of the first company, which focuses on controlled release drug formulations, in India.

Lifecare Innovations has launched Fungisome, which is said to be the most effective anti-fungal drug in the world. The company has also launched two other new liposomal drugs. Now Dr Verma is developing a sustained release oral nano-drug against tuberculosis. He has several patents, four national awards, a state award and a research foundation's Scientist of the Year award in his kitty.

### **Leading liposomal revolution**

Dr Verma was engaged in medical research at University of Pennsylvania, Northwestern University, Georgetown University and Walter Reed Army Institute of Research in the US. Known for his expertise in life sciences and biotechnology, Dr Verma was acclaimed for promotion of R&D and later, commercializing their outcome by industry-academia interactions and public-private partnerships. He has pioneered development of NDDS-based liposomal and nano-drugs. As a world leader in liposome technology application for drugs, diagnostics and vaccines, he developed and commercialized India's first liposomal product and world's only liposomal diagnostic-liposome agglutination test for Syphilis.

He has contributed to Asia's first anti-fungal drug Fungisome — a liposomal amphotericin B. Working on malaria vaccine, Dr Verma was the first to report that liposomal vaccines elicit cellular immune response necessary for protective immunity. He is presently involved in developing liposomal and nano-drugs for the treatment of tuberculosis, cancer, leishmaniasis and fungal infections. By applying science and technology in everyday life, Dr Verma has been keenly involved in translational research resulting in a number of publications, reviews and patents to his credit.

In May 2009, a jury comprising officials from British High Commission, International Business Wales (IBW) and Ernst & Young selected Lifecare Innovations as the winner for Technium 2009 – a global business contest based on emerging technologies and innovations. The Technium Challenge, established in 2003, is a business planning competition, which identifies and supports innovative businesses with high growth potential to invest in Wales, UK.

Lifecare Innovations' business plan on Fungisome emerged as the winner owing to its merits in treating systemic, invasive or topical infections. This anti-fungal drug is said to be the only drug and Lifecare Innovations the only pharmaceutical company among the six country winners of Technium Challenge 2009, which included a company each from the US, Canada, South Africa, Australia, New Zealand and India.

### **Exploring new possibilities**

Under the leadership of Dr Verma, two new liposome technology-based formulation for the treatment of psoriasis, viz Lipotar and Lipotar-S, are scheduled for launch. Also, the Drug Controller General of India (DCGI) has approved the company's two novel nano-drug formulations for treating TB.

Lifecare Innovations is also working on a project for the development of effective anti-malarial treatment options. For the project, it has partnered with International Center for Genetic Engineering and Biotechnology (ICGEB) New Delhi; Birla Institute of Planning and Technology (BITS), Pilani; and University Health Network (UHN), Canada. This research project would facilitate licensing and commercialization of the discoveries.

Also, the company's R&D, product development, process development, scale-up, pilot plant and production center at Biotech Park, Lucknow, is expected to become operational by the end of 2010.

As an extension to its R&D center, the company has set up Lifecare Innovations Laboratory for Translational Research in Nanomedicines at Biotech Center, University of Delhi. The laboratory has attracted attention of researchers on novel drug delivery systems.

The current interests of Dr Verma include the application of nanotechnology and liposome technology for the development of pharmaceuticals and vaccines. Talking about the nanotechnology research in India, he says "There is a need for the allocation of funds separately for nanobiotechnology and specifically for the product development and clinical trials. Only then

we can see some visible progress in this field.”

Lifecare innovations has also partnered with PGI Chandigarh, Punjab University and IIT on the development of nanoliposomal drugs. Dr Verma feels that more partnerships between the academia and industry in this particular sector will help in bringing the products to the market.

“The research going on in the academic and research institutes have not reached to the manufacturing stage and tends to get lost only due to lack of coordination between the public and private sector.” concludes Dr Verma.

## **Eradicating leishmaniasis and kala-azar**

Leishmaniasis is caused by macrophage resident intracellular protozoan parasites *Leishmania donovani*, *Leishmania infantum* and *Leishmania chagasi*. Parasite transmission occurs through the bite of infected female phlebotomine sandfly. One-third of the new cases of leishmaniasis are visceral leishmaniasis (VL) and 90 percent of the VL cases are prevalent in Bangladesh, Brazil, India, Nepal and Sudan. India alone accounts for one-fourth of the total worldwide incidents.

Strategic suitability of lipid formulations of Amphotericin B for the treatment of visceral leishmaniasis emanates from several factors viz. leishmania resides in the macrophages, liposomes are rapidly taken up by the macrophages, Amphotericin B is an effective anti-leishmanial drug, and Amphotericin B can be formulated as liposomal preparation. All of these facilitate targeted delivery of Liposomal Amphotericin B to the desired site for anti-parasitic action and thus reduces the drug's toxicities.

Additionally, liposomes offer an amplification effect, through concentrated encapsulation of numerous molecules in each liposomes particle which are delivered at the desired site of action. Liposomal Amphotericin B has been used extensively throughout the world as the best option for treatment of VL even in cases resistant to standard drugs. Fungisome has shown to have proven advantage over conventional drug regimen in the treatment of visceral leishmaniasis in India.

Tissue distribution of Fungisome has been studied in experimental animals infected with *Leishmania donovani*. At the maximum tolerated doses of conventional treatments and Fungisome, higher levels of Amphotericin B were achieved in liver and spleen in the mice treated with Fungisome. In comparison, conventional Amphotericin B was found to be less effective at the tolerated doses.

Similarly, kala-azar is a major public health problem in certain parts of India. Standard treatment involves use of antimonials and sodium stibogluconate. Considerable resistance to the standard drugs has pushed the need to look for alternative drugs. Amphotericin B has been found clinically effective even in resistant cases of kala-azar. Use of Amphotericin B, however, is restricted due to its well-known toxicities.

**Rahul Koul** in New Delhi