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"Biotechnology is now an integral part of the product development process."

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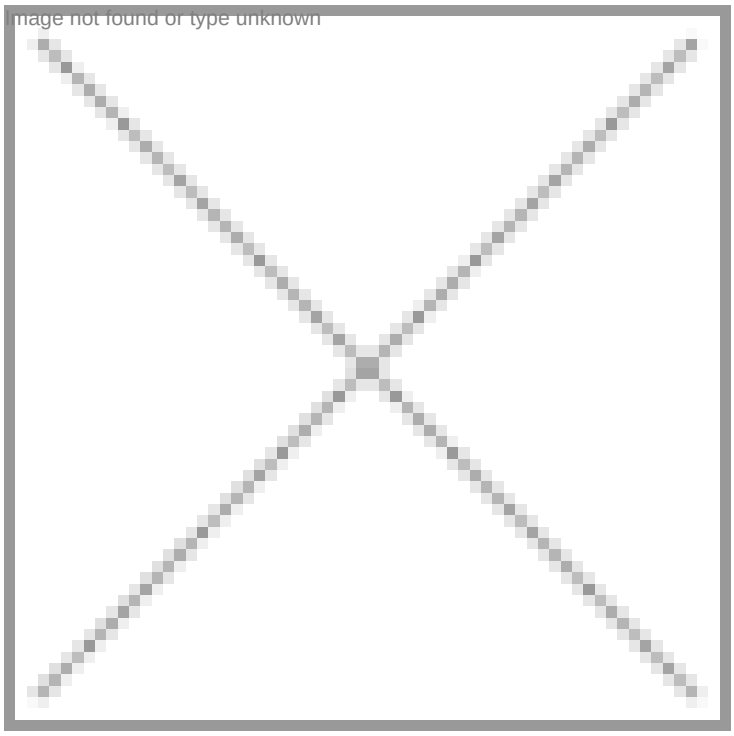

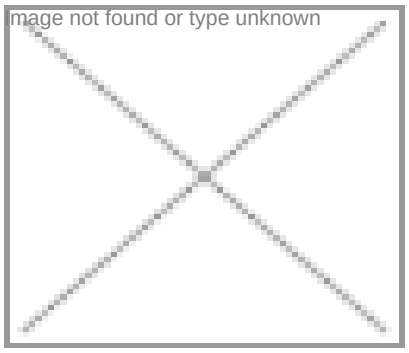

Amongst the galaxy of scientists of Indian origin working abroad and making India proud is Dr Mahesh Kumar, the senior director of Fort Dodge Animal Health division at Wyeth, which is one of the global leaders in pharmaceuticals, consumer and animal health care products.

Dr Kumar oversees the global poultry research and development operations at Fort Dodge Animal Health. With a rich industry experience of about 14 years in the research, development and licensing of biologics, he is currently involved in the development avian biologics, management of the Transmissible Spongiform Encephalopathy (TSE) diagnostic program and the development of in-vitro diagnostic tests. Prior to this, Dr Kumar was the director of research at Maine Biological Laboratories, Waterville, US, where he developed/licensed a range of products including several unique formulations of oil-emulsion to reduce reaction while maintaining efficacy.

Dr Kumar is presently on the board of directors of the Biotechnology Research and Development Corporation, Peoria, Illinois and earlier served in a similar capacity at the Center for Innovation in Bio-medical Technology, Maine. With many publications to his credit he is the inventor on several pending patents in the avian vaccine field.

Dr Kumar received BSc degree in Biochemistry from the University of Madras, India, MS in Microbiology from the University of Maine, and PhD from the Minnesota university in the US. In an exclusive interview with BioSpectrum, he talks about the

current trends, issues facing the animal health care industry and the role that Indian animal health companies can play in a global scenario.

What are the current trends in animal health care products? How important is biotechnology in developing animal health care products?

The general trend in animal health is towards safer and more efficacious products. For example, vaccines and pharmaceuticals are formulated to be less reactive in animals and designed to provide a longer duration of immunity. Biotechnology as a science has provided elegant methods and tools that aid us in the design, evaluation and development of products. Gene modifications/deletions are now used commonly to develop safer "live" vaccines. Recombinant technologies are used to create efficient means of presentation and protection against multiple antigens. The new DNA vaccine technology is also on the verge of becoming viable. Fermentation techniques are more efficient due to biotechnology allowing small molecules to be prepared in a cost effective manner. Biotechnology is now an integral part of the development process. While many applications using sophisticated biotech are possible, we are severely limited by the cost of the finished product for animals. Many of the processes are cost prohibitive and will require serious improvements in manufacturing before they are marketable.

At Wyeth, the mission is to develop global pharmaceutical and health care products that improve lives and deliver outstanding value to its customers and shareholders. Our goal is to develop products that are novel and we pride ourselves in being the first against a variety of diseases over the years. Our latest achievement has been against the West Nile Virus in horses.

What are the issues confronting the animal health care industry?

The biggest issue we face is the change in regulations that govern the licensing and registration of products in a global economy. A product registered in the US is recognized by some countries and in due course can be registered. There are other countries that require different studies sometimes conducted locally, resulting in repeated work increasing cost and development time. The opposite is also true, where a product developed by our European group is not accepted by the USDA and requires additional studies at a minimum. In several instances they are considered exotic agents and are not allowed to be marketed in the county (even if the product is an inactivated vaccine). When we design unique products for each "region", it increases our development costs significantly. While a truly global product, where the agent is the same, was common in the past, its acceptability is becoming increasingly difficult as one is forced to demonstrate relevance of a certain strain used in the vaccine to that country.

Another issue facing the industry is the Transmissible Spongiform Encephalopathy/Bovine Spongiform Encephalopathy (TSE/BSE) problem. We are required to produce products where the raw materials are certified free of TSE/BSE. While we are compliant, a new isolate anywhere, restricts the movement of products and sometimes results in trade barriers that are not science based. Other diseases such as the recent avian influenza outbreaks have had similar restrictions placed on products.

What is the rate of development of animal health products and the average time frame required?

On an average, in the animal health care industry, the number of products developed from discovery to final stage is approximately 1 in 5. In many cases where a company focuses on the development activities rather than discovery, it can be as low as 1 in 3, which is quite remarkable when compared to human health where only 1 in 50 make it to just the first Phase.

A typical animal health biologic can take anywhere from three to five years to develop and several more to obtain registration in all the countries.

What is the typical cost to make an animal health product?

The average cost to develop a vaccine is around $ 1-2 million depending on the region where the product is sold. Usually the development cost for products entering the European Union is more as compared to the US. This cost approximates only the direct expenses and not the overhead expenditure.

Is the animal health sector more regulated than the pharma segment?

The animal health sector in the US is governed by the USDA for biologics (vaccines) and the FDA for pharmaceuticals. Though both the governing agencies have a different set of regulations, the pharmaceutical (animal) development is straight forward as the testing is mainly of the active ingredient, whereas the vaccines are unique by region and need studies that must satisfy the government officials from many countries who have unique and local requirements. However, all things considered, the human health pharma industry is probably more regulated and requires significantly more cost and development time with stricter regulations.

How comfortable are animal health care companies towards outsourcing?

Outsourcing services when possible is quite common and we are quite comfortable with it. We have used tollers to manufacture active ingredients when necessary and utilize contract services to conduct studies when required. A large company has to utilize any resource that is available to cost-effectively develop products.

What are the strengths of Indian animal health companies and what portions of work can be outsourced to Indian companies?

The obvious strength of Indian companies is the bright and well-educated workforce available in the country. The other obvious strength is the low cost of development. While some of the pharmaceutical studies could be outsourced, there are severe limitations to outsourcing biologics/vaccine related work. Import and export of strains (viruses or bacteria) for development purpose or challenge are restricted and it is difficult to obtain permits. We are forced to outsource to companies in the US or the European Union depending on whether the strains originate in our European site or the American site. Still, there are areas where one could outsource such as in formulation studies, preliminary efficacy studies, safety and stability determination studies.

Many gene-based products are essentially synthetic and are not restricted as strictly as whole organisms. Indian companies can help in these processes. Microarray development for screening, primer development, etc are the other areas where they can help in product development.

How will the growing opposition to animal trials from NGOs worldwide impact the rollout of new products and cutting edge research in the near future?

We are committed to find alternatives to animal trials and in fact, we are the pioneers in developing in-vitro tests for batch release of products. However, we are governed by regulations that require us to conduct the pivotal safety and efficacy studies in animals. The NGO's need to push for meaningful changes at the regulatory/government side as we have to comply with the requirements in order to develop much needed products for animal health. We believe our products have improved lives by preventing major diseases in companion animals and increased the level of livestock production resulting in a major source of protein for the world. Our company is committed to investment in R&D and we will continue to rollout new products that are innovative while dealing with issues as they arise.