BioSpectrum the business of Bio & Health Sciences

India becomes GLP compliant

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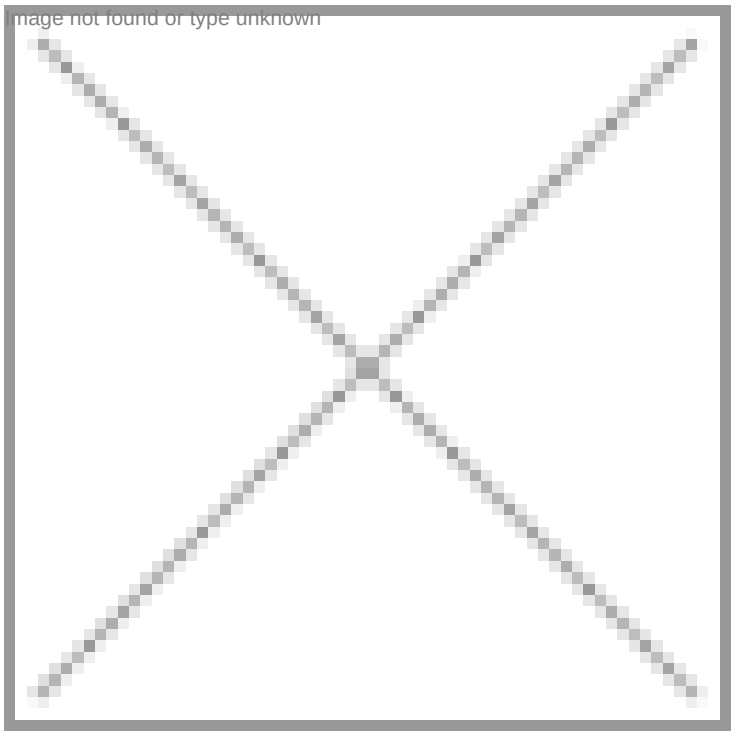

In a move welcomed by the industry and regulatory bodies, India, after continuous efforts of nine years, has managed to get the status of full adherence to Good Laboratory Practices (GLP). This international recognition was eagerly awaited by industry and is expected to eliminate the technical barriers to trade. With India achieving the status of full adherence to GLP, the manufacturers of pharmaceuticals and agro products will no longer have to get the mandatory tests done overseas. The GLP is certified by the Organization of Economic Co-operation and Development (OECD). The 34-member OECD includes some of the world's most advanced countries such as the US, UK, Canada, Australia, Sweden, Switzerland, Denmark, Hungary and Korea. The recognition has come after continuous efforts for nine years after National GLP-Compliance Monitoring Authority was set up in 2002.

Agri-R&D budget needs to increase: PM

Prime Minister of India, Dr Manmohan Singh, has emphasized on the need to spend more on agricultural research. While delivering the 83rd foundation day lecture of the Indian Council of Agricultural research and award ceremony on July 16, 2011, at New Delhi, the prime minister talked about the need to increase the budget for agricultural research. â€œIndia currently spends about 0.6 percent of its agricultural GDP on agricultural research and development. This needs to be enhanced two-three times by 2020 since a substantial portion of our agricultural growth would come through the application of new technologies and new knowledge,â€? said Dr Singh. He also emphasized on careful application of biotechnology to improve productivity, enable better resilience to stress and also enhance the incomes of farmers.

Gilead expands global access program

The US-based pharmaceutical company, Gilead Sciences, has expanded its global access program in an effort to provide accelerated access to Gilead medicines for the treatment of HIV/AIDS. The changes announced include new licensing terms with four India-based drug manufacturers - Hetero Drugs, Matrix Laboratories, Ranbaxy Laboratories and Strides Arcolab -

for three drugs which are currently in late-stage clinical development. These Indian partners have played an active role in supplying treatment to patients in the developing world. In addition, Gilead is the first pharmaceutical company to enter a licensing agreement with the Medicines Patent Pool Foundation.

The expanded licensing terms grant to the company's Indian partners and the Medicines Patent Pool Foundation futurerights to elvitegravir, an investigational integrase inhibitor; cobicistat, an investigational antiretroviral boosting agent; and the â€œQuadâ€?, which combines four Gilead HIV medicines in a once-daily, single-tablet regimen. Gilead licensed rights to commercialize elvitegravir from Japan Tobacco (JT). JT is working in close partnership with Gilead to ensure future access to elvitegravir in the developing world.

Biotech education hubs in North East

The Department of Biotechnology, Ministry of Science & Technology, has initiated the process of establishing biotech hubs under a special program. The institutions will be identified by the DBT for providing necessary infrastructure support for teaching and research activities, and will be funded accordingly. Each biotech hub will be looked after by a coordinator to be nominated by the host institute and guided by a small committee constituted as per the guidelines framed by the DBT. The host institution will have to provide necessary space and accommodation. The initial support will be for three years. The broad purpose of the program is to promote education and research in various branches of life sciences, including biotechnology, to attract students.

GEAC rejects Mahyco's appeal

The Genetic Engineering Appraisal committee (GEAC) has rejected the appeal from Jalna-based hybrid seeds company, Mahyco, to reconsider its decision on using non-Bt cotton hybrids as refuge. The appeal from Mahyco came against the decision of GEAC regarding the use of non-Bt RRF cotton hybrids containing cp4epsps gene (event Mon 88913) as refugia during Biosafety Research Level (BRL)-II trials.

Considering the fact that GEAC has rejected the approach taken by Mahyco to conduct trials, the company has no option but to go for fresh round of BRL-II trials. Moreover, the company has also been asked by the GEAC to strictly adhere to the protocols approved by it for conducting the fresh trials.