BioSpectrum the business of Bio & Health Sciences

India unveils agenda for novel R&D

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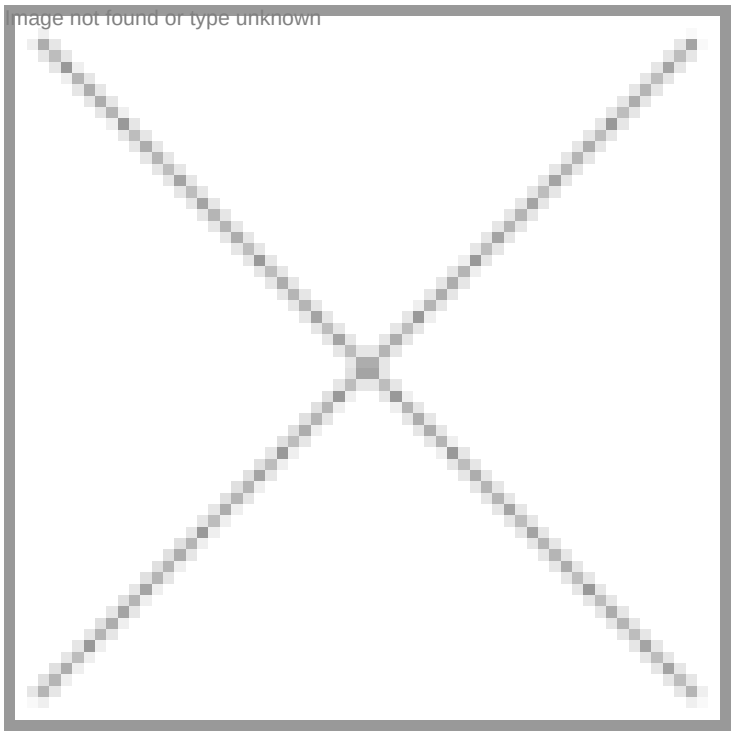
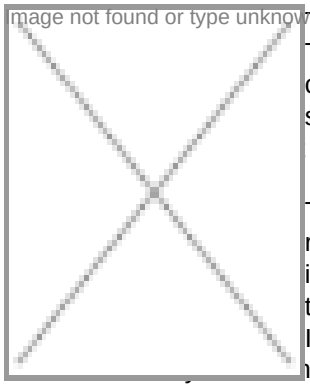
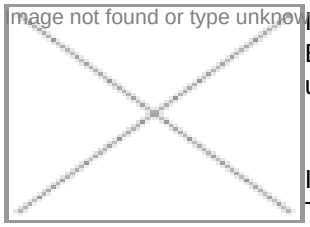




To realize the vision of making India an innovation hotspot, Mr Kapil Sibal, Minister for Science & Technology, Government of India, has announced plans to encourage multidisciplinary collaboration among business, government, academia and R&D to create an environment that supports technological development; recognizes contribution of young researchers; and introduces young researchers.

The agenda for innovation also includes the long-term academia-industry collaborative relationships with open access to entanglement-free intellectual property (IP) resources; and better integration of corporate companies with higher educational and research institutions. According to the minister, the National Innovation Council (NIC) which will prepare a road map for the Decade of Innovation will include approaches and methodologies to create an inclusive and sustainable ndia.

DBT to use RNAi for health, agri needs



In order to address issues related to healthcare, agriculture and environment, the Department of Biotechnology (DBT), under the Ministry of Science and Technology, Government of India, plans to utilize RNAi technology approaches for developing tools for research, early translation or product

In this regard, the DBT will initiate projects focusing on miRNA biomarkers for known diseases. That would include developing genome-wide shRNA libraries, target-specific delivery, translational

research using RNAi-based approaches, and developing transgenics with economic traits using RNAi approaches.

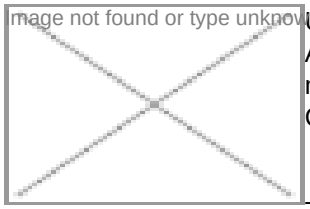
The DBT has invited the concept notes from researchers across academia and industry. These concepts will be in the areas related to identification of genome wide RNAi factors in various organisms to manipulate the RNAi potential. In an approach towards finding cure for the diseases, the target areas include the identification of total cellular factors responsible for disease susceptibility, unraveling the underlying molecular process for various diseases, metabolic/ physiological processes in animal or plant model using RNAi approach, and profiling and prediction of miRNAs responsible for organism development.

FDA to improve review mechanism

The US Food and Drug Administration (FDA) has announced its plan to improve the most common path to market medical devices. The action plan is intended to get implemented by the end of 2011. Before marketing most low-risk medical products such as certain catheters or diagnostic imaging devices, manufacturers must provide the FDA with a premarket notification submission.

These submissions are known as 510(k)s for the section of the Federal Food, Drug, and Cosmetic Act that describes this notification requirement. Generally, 510(k)s must demonstrate that a proposed product is substantially equivalent to another legally marketed medical device. In September 2009, Center for Devices and Radiological Health (CDRH) set-up two internal working groups to address concerns relating to the premarket notification process, industry argued that the 510(k) process was unpredictable, inconsistent and opaque, while consumers and health care professionals argued that the review process was not robust enough.

Cambrex Zenara gets GMP approval



US-based life sciences company, Cambrex Corporation has announced that the Danish Medicines Agency (DKMA) has issued a Certificate of Good Manufacturing Practice (GMP) compliance for its manufacturing site in Hyderabad, following an audit conducted in October 2010. The DKMA Certificate is accepted by all EU health authorities and by authorities of several other countries that

The DKMA certification allows Cambrex to expedite the European launch of Nicotine Replacement Therapy (NRT) products, in addition to offering
finished dosage forms of other pharmaceutical products to our European customers through an integrated value chain.