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## Biotech patenting in India

**Rinki Upadhyay, B. P. Nagori and Vipin Mathur**
Lachoo Memorial College of Science and technology, India

The Convention on Biological Diversity (CBD) defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives to make or modify products or processes for specific use". The biotechnology market in India including bioservices, biopharmaceuticals, bioagriculture and industrial enzymes, stood at $4.13 billion in 2011. Through the Department of Biotechnology (DBT), the Indian government provides funding to universities and other public institutions for research on agricultural, medical, and environmental and industrial biotechnology. Biotechnology field has developed a worldwide interest about its patentability, especially in case of the genetically modified organisms. India's post-TRIPS patent law include several provisions that make biotechnology patenting more attractive and a basis to gain competitive advantage in the rapidly expanding market of biogeneric. Provisions of special interest in the Indian patent law relating to biotech patenting include exclusionary provisions under Section 3, that prohibit patenting of any living thing occurring in nature as such, plants and animals in whole including seeds, varieties and species but excluding microorganisms. The new patent law makes a number of biotech inventions patentable in India like compositions and process to produce nucleic acid sequences, protein sequences, antibodies, small molecules, and machines and devices useful to carry out biotech processes. Opportunities and challenges in biotech patenting in India are analyzed in this presentation that could help Indian biotech companies to formulate their future business strategies in an effective manner.

### Biography

Ms. Rinki Upadhyay is presently pursuing M. Pharmacy in Pharmaceutical Management & Regulatory Affairs branch at Lachoo Memorial College of Science & Technology, Pharmacy Wing, Jodhpur, India.

## ICH guidelines towards producing quality generic medicines

**Renu Solanki**
Lachoo memorial College of Science and Technology, India

ICH stands for International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Although, ICH guidelines are primarily intended for new drug approvals but the generic drug industry is also being benefited by it significantly. The main objective of ICH is to reduce or avoid duplication of testing carried out during the research and development of new human medicines. ICH process has effectively shortened the time needed for regulatory review and thus resulted in more rapid access to new medicines. ICH guidelines are commonly agreed guidance for meeting technical requirements for registration of drug products within the three ICH regions viz. EU, Japan and US. It should be however noted that these guidelines are non-binding in nature and each regulatory authority is free to implement these guidelines as per their own regional or national requirements. ICH guidelines pertain to Quality (Q), Safety (S), Efficacy (E) and Multidisciplinary (M) topics. Notably, out of all the ICH guidelines the Quality (Q) guidelines are of particular significance to the generic drug manufacturers since quality related data forms a major part (around 70%) of the generic drug dossiers. ICH Quality guidelines are state-of-the-art guidelines that lead to more robust processes and production of high quality drug products on consistence basis. There are total 25 guidelines issued by ICH under 10 Quality related topics. This paper provides an overview of the ICH Quality (Q) guidelines with an especial emphasis over the role of these guidelines in producing quality generic medicines in an efficient and cost effective manner.

### Biography

Ms. Renu Solanki is presently working as Assistant Professor at Lachoo Memorial College of Science & Technology, Pharmacy Wing, Jodhpur, India. Ms. Solanki has completed M. Pharmacy in Quality Assurance and she is currently pursuing Ph.D. She received gold medals for securing 1st rank at University level in B. Pharmacy and M. Pharmacy. She has also received Bhamashah Award, sponsored by Mewar Foundation, Udaipur for outstanding achievement in B. Pharm. Ms. Solanki was the Rajasthan State Level Winner of the National Elocution Competition, 2003 organized by the Indian Pharmaceutical Association (IPA). She is mentoring M. Pharmacy students in their dissertation work on the topics of stability testing, method development and validation etc. She has filed 1 patent and published 20 papers in reputed journals. Ms. Solanki has presented 15 papers in international and national conferences.

solankirenu@yahoo.com