

## Role of regulatory affairs for health care products

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The Government of India (GOI) regulatory regime designed to ensure the quality, safety and performance of health care products. Legislation is under way in the Parliament and officials in the Ministry of Health and Family Welfare (MoHFW) and Drugs Controller General of India (DCG(I)), to ensure maintain quality of health care products by licensing, certification and accreditation. National regulatory decisions are in line with international guidelines and ensure that the policies are adopted. GOI wanted to ensure the continued flow of safe and effective health care products in India. India's medical device and pharmaceutical regulations and the centralized regulatory authority includes DST and CDA that distinguishes between pharmaceuticals and medical devices and has adequate powers to ensure standards, efficacy, safety and availability of health care products manufactured or marketed in the country. The MoHFW, DCG(I), BSI and Nuclear Medicine Board of the BARC regulate different aspects of the healthcare sector. Companies must register all products with the CDSCO before the company's products can be introduced into the Indian market. Representatives from industry and GOI officials discussed a "road map" included a current status review as well as guiding principles and a regulatory process implementation phases to make it an all inclusive process. At present the drug and pharmacy Acts and Rules are govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India. And essentially empowers the Indian Government to formulate rules specifying the operational conditionality's of health care products in India by an efficient regulatory system.

### Biography

Mr. TS Jaishankar has completed his B.Sc Honours Chemistry degree from Mumbai University. He is the managing director of Quest Lifesciences (P) Ltd, Member advisory board in the journal of clinical studies UK, Member advisory board in Pharmabiz publication, Chairman of Chemech laboratories and CIPI chairman of Confederation of Indian Pharmaceutical industry. He has published several articles in the clinical trials in leading pharmaceutical magazines and he has given several talks on clinical research in reputed research academic organizations especially on BABE studies and Good Clinical Practice.

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