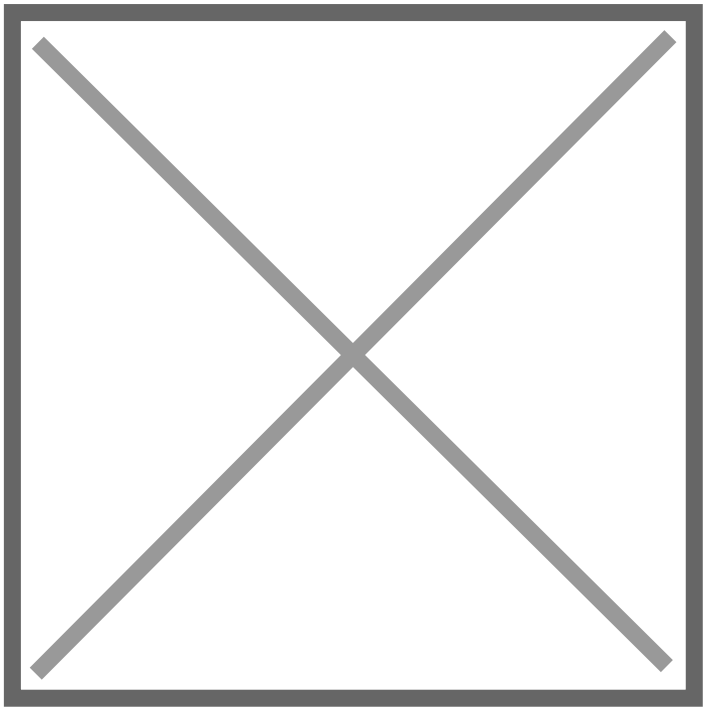
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UK's MHRA keen to make closer ties with Indian regulatory authority

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MHRA is keen to strengthen its relationship with Indian regulatory authorities, with potential collaborations in the areas of inspections and information sharing.



UK MHRA (Medicines and Healthcare Products Regulatory Agency) is open for joint and mutual inspections with Indian inspectors during the process of regulatory clearances of pharma and biotech production plants in the country.

A team from the UK MHRA, the US equivalent of US FDA, who were in India recently, met up the drug controller general of India at Central and state level to have a mutual understanding of the respective regulatory systems, and discuss areas of potential collaboration.

Set up in 2003, the UK MHRA is the government agency responsible for the safety, quality and effectiveness of medicines, and medical devices has been carrying out more than 50 inspections every year on Indian plants exporting to the UK.

“This is the beginning of a new collaboration and the way forward. Indian drugs are critical to UK healthcare and is the major source of generic products. Around 26 percent of current UK marketing authorizations name manufacturing sites in India, and 24 percent of all UK Mas name an API manufacture in India,” said Prof. Kent Woods, chief executive, MHRA.

“Serious unacceptable production practices can be devastating. MHRA is now committed to work with pharma industry in India. We are following our inspections with a request initiative. At the moment, we do not have any plans to set up an office in India. But we are committed to making closer ties with the India regulatory authority,” he adds.

Vigilance is a key aspect of regulation, and MHRA is looking for collaboration and cooperation. “The way we have collaborated is different in each country. But the key issue is the ability to share the details of the information about the inspection. In this regard, we have initiated valuable discussion on how the industry and the regulatory body can work together. We want to move to a position where we can share independently the outcome of the joint inspection,” said Prof. Woods.

“The standards of manufacturing required by pharma companies in the UK and India are the same. Most of the inspections have satisfactory outcome although there are areas of improvement identified,” said Shaun Gallagher, director of policy, UK MHRA.

“In India, we are looking at pharmacogenomics and targeted therapies opportunities. In this regard, we are working with the industry and have put together a forum of industry experts for the same. Another focus is to improve the regulation of medical devices both from a regulator and developer point of view. For this, a relevant regulatory framework is being set up,” he said.

Biotech drugs are more complex than chemical based drugs. With the need for low cost drugs, MHRA already has a regulatory framework for biosimilars in place. When biosimilars approved for physician use companies provide a lot of data supporting the medication and its efficacy in treating diseases. This gives the medical expert, the option of choosing a biosimilar over a branded drug, said Gerald W Heddell, director of Inspection, Enforcement and Standards, MHRA.

In the area of clinical trials, MHRA has undertaken four bioequivalence studies in India. Its approach is based on risk assessment, and is currently looking at the study and not the facility carrying out the bioequivalence study.

Ruling out the possibility of any collaboration of MHRA with DCGI, Gallagher said, “There is no recognition for such agreements. We will conduct inspections with independent responsibility.”

Jahanara Parveen