US FDA warning letters to Indian pharma decline

Laxmi Yadav, Mumbai

INDIAN pharmaceutical companies have received 29 per cent of US FDA warning letters in 2017 as compared to 50 per cent warning letters in 2015 due to improvement in quality standards and regulatory compliance.

In 2016 India accounted for 29 per cent of US FDA warning letters which remained the same last year as well. In 2017 US FDA had issued 49 warning letters to non US sites as compared to 16 letters in 2015. In 2016 non US FDA plants received 35 warning letters.

India has received 30 per cent import alerts in 2017 as against China's 50 per cent import letters and ROW's 20 per cent.

To tide over the quality compliance issues raised by US FDA, six drug makers – Cipla, Zydus Cadila, Dr Reddy's, Torrent, Sun Pharma and Lupin which accounted for significant chunk of pharma export in US market had three years back started work on improving data reliability at their sites focusing on technology systems, process design, risk management, governance, culture and capability. These six elements are also part of data reliability guidelines issued by Indian Pharmaceutical Alliance. The pharma lobby called on Indian Pharmaceutical Alliance and non Indian Pharmaceutical Alliance members to implement the guidelines to enhance safety, quality and efficacy of drugs.

Over the last couple of years there has been a significant improvement in quality standards of India pharmaceutical companies despite rise in regulatory scrutiny, said Vikas Bhadoria, senior partner of McKinsey& Company.

There has been a reduction in data related errors, gap in investigations of root cause assessments is now a leading source of non-compliance, he said.

Replying to a query he said "Building capacity of human resource at shop floor of a plant will help pharma firms fill gap in investigations of root cause assessments. Digitisation and automation introduced in manufacturing plants along with capacity building of human power would lead to further decline in regulatory challenges faced by Indian pharm industry." ◆

A new formulation for viral hepatitis

Our Bureau, Mumbai

FOR prevalence of hepatitis infections, Dr. Sanjay Agrawal - patent holder of research formulations like RTFit, GMFit, ZONURON-T, Crampfort - has developed a formulation for treatment of viral hepatitis, and it will be a formulation in the medical sciences for preventing, treating hepatitis infections after getting patent from the authorities concerned. The treatment can be specified into 2 types, drugs which are directly acting against the virus replication (which protects the liver from direct injury) and drugs which are helping the liver.

Hepatitis B virus (HBV) is a small, circular and partially double-stranded DNA virus in the Hepadnaviridae family. Hepatitis refers inflammation of liver cells and finally getting damage to the liver. The functions of liver include detoxifying the blood, storing vitamins and producing hormones. Hepatitis can disrupt these processes and create severe health problems throughout the human body. There are many causes. Heavy alcohol use, toxins, some medications, and certain medical conditions can also be caused hepatitis. However, hepatitis is most often caused by a virus. The most common types of viral hepatitis are Hepatitis A, B, C. Hepatitis A can last from a few weeks to several months. Hepatitis B can range from a mild illness, lasting few weeks to a serious life long or chronic condition. Hepatitis C also can range from a mild illness, lasting few weeks, to a serious life long infection. Most people who get infected develop chronic Hepatitis C. ◆

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