

India, China top 2013's GMP failures: EMA

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Singapore: In a bid to bring about transparency, the European Medicines Agency (EMA) has released the public version of the EudraGMDP database to put together the statements of non-compliance with GMP.

The community database has put together the manufacturing, import and wholesale distribution authorizations, the good manufacturing practice (GMP) and good distribution practice (GDP) certificates and the publication of statements of GMP violations.

The agency said in a statement that this new initiative has been taken as part of its general goal to increase transparency and openness of its operations.

Currently, the database includes over 80 non-compliance reports since 2007. As per the report, in 2013, there were 34 cases of facilities failing to comply by GMP, effecting sterile, non-sterile and API manufacturing.

These issues also included quality control testing, packaging and product production issues.

While China had 10 manufacturing plants failing to comply, India had 14 such plants in 2013.