



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 September 2014  
EMA/CHMP/590962/2014

## CHMP List of questions

To be addressed by GVK Biosciences

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1408



The GVK Biosciences-Hyderabad site has been subject of an inspection on GCP compliance. The ANSM final report of this inspection indicates serious deficiencies and lack of GCP compliance at the site.

GVK Biosciences is requested to respond in writing to the following question:

Discuss the root cause of this issue affecting the GVK Biosciences-Hyderabad site and provide assurance that these issues are confined to:

1. the GVK Biosciences-Hyderabad site and,
2. the period under evaluation (July 2008 to date).

Indicate which measures have been undertaken to investigate if this is a corporate issue.