BioSpectrum the business of Bio & Health Sciences

FDA completes successful inspection of DCA Bavla site

06 November 2018 | News

The five-day inspection focused on the Active Pharmaceutical Ingredient (API) units and ancillary areas of the Bavla site.

India-based Dishman Carbogen Amcis Limited (DCA), a global outsourcing partner for the pharmaceutical industry, has announced that its manufacturing and development facility in Bavla, Gujarat has successfully completed an inspection by the U.S. Food and Drug Administration (FDA).

The FDA's Current Good Manufacturing Practices (CGMP) audit, which is performed to ensure proper design, monitoring and control of manufacturing processes and facilities, was held from October 22-26. The five-day inspection focused on the Active Pharmaceutical Ingredient (API) units and ancillary areas of the Bavla site, specifically the quality system, production and packaging operations. The inspection also included examinations of the warehouses and quality control areas. No critical observations were reported and the final Establishment Inspection Report (EIR) is expected within the next six months.

"I am extremely pleased with the positive outcome of this FDA inspection. It is the result of our ongoing dedication to maintaining high quality standards and continuously meeting our customers' expectations," said J. R. Vyas, Chairman and Founder of the Dishman Carbogen Amcis Group.

"It was especially rewarding for us to hear that the auditor appreciated our teams' open communication and transparent way of working. I am very proud of our staff. Their commitment to excellence every day is the key to our performance and our long track record of successful audits," said Dr. Himani Dhotre, CEO of the DCAL Bavla site.

The Bavla facility manufactures products according to CGMP standards and is routinely inspected by legal authorities and external customers. The facility underwent successful FDA inspections in 2006, 2012, 2015 and 2016.