BioSpectrum the business of Bio & Health Sciences

Biocon’s API facility gets 5 observations

27 January 2020 | News

Biocon's API manufacturing facility completes pre-approval and GMP USFDA inspection

Biocon is Asia's premier biopharmaceutical company that is driven by the vision to make a difference to global healthcare through improved access to high quality, life-saving biotherapeutics by making them affordable for patients across the world.

The company has announced that its API manufacturing facility has completed the pre-approval and GMP U.S. FDA inspection. The US drug regulator issued a Form 483 with five observations for the company's API manufacturing facility.

The US Food and Drug Administration (FDA) conducted a pre-approval inspection (PAI) and Good Manufacturing Practice (GMP) inspection of the Active Pharmaceutical Ingredient (API) manufacturing facility of Biocon.

At the conclusion of the inspection of the Bengaluru facility, which took place between 20 and 24 January 2020, the agency issued a Form 483, with five observations.

Biocon will respond to the FDA with a corrective and preventive action plan (CAPA) and is confident of addressing these observations expeditiously.

The company said it remains committed to global standards of quality and compliance.