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USFDA completes PAI of Biocon facilities in Bengaluru

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Biocon gets 8 observations for 2 new biologics



Biocon Biologics has received a total of eight observations from the US health regulator for its two new biologics manufacturing facilities in Bengaluru.

The United States Food and Drug Administration(USFDA) conducted a pre-approval inspection (PAI) at two of the company's new biologics manufacturing facilities in Bengaluru from Sep 10 to Sep 19, 2019, the company said.

The inspection included a new Drug Substance (DS) and a Drug Product (DP) unit.

“At the conclusion of the inspection we received a Form 483 with four observations for the new DS facility, three observations for the new DP facility and one general observation,” Biocon spokesperson said in a statement.

“We are confident of addressing these observations effectively through a Corrective and Preventive Action (CAPA) plan, expeditiously. The Pre-Approval Inspection of our new facilities does not have any impact on our current commercialization plans from our existing facilities." the statement said.