

Syngene to approach regulators for Mangalore unit audit in 12-18 mos

By **Apoorva Choubey** | Thursday, May 5, 2022

<https://www.informistmedia.com/syngene-to-approach-regulators-for-mangalore-unit-audit-in-12-18-mos/>

MUMBAI – Syngene International Ltd plans to approach drug regulators such as the US Food and Drug Administration to inspect its \$100-mln contract manufacturing facility at Mangalore in the next 12-18 months, Chief Operating Officer Mahesh Bhalgat told Informist.

“We are working on projects right now which will help us generate the required data and go to regulators like the US FDA, after which they will come and inspect the facility and then give approval,” Bhalgat said.

The Mangalore plant, which will produce active pharmaceutical ingredients and advanced intermediates, is crucial for the growth of Syngene’s contract manufacturing and development business.

In March, Informist had exclusively reported that regulatory approvals for the unit could take more time, as the generation of plant validation data on various products was yet to be completed.

The plant is yet to begin commercial supplies in full force as it hasn’t received good manufacturing practice certification from various regulators.

Regulatory agencies, including the US FDA, the UK’s Medicines and Healthcare products Regulatory Agency, Therapeutic Goods Administration of Australia, and Brazilian Health Regulatory Agency will be able to inspect the plant only when its validation and compliance data is submitted.

For the Mangalore unit, there is no delay in getting the approvals but the process itself is quite long, Bhalgat said.

At 1255 IST, shares of Syngene International were up 0.4% at 611.30 rupees on the National Stock Exchange. End

US\$1 = 76.27 rupees

IST, or Indian Standard Time, is five-and-a-half hours ahead of GMT

Edited by Avishek Dutta

Cogencis news is now Informist. This follows the acquisition of Cogencis Information Services Ltd by NSE Data & Analytics Ltd, a 100% subsidiary of the National Stock Exchange of India Ltd. As a part of the transaction, the news department of Cogencis has been sold to Informist Media Pvt Ltd.

Informist Media Tel +91 (11) 4220-1000

Send comments to feedback@informistmedia.com

© Informist Media Pvt. Ltd. 2022. All rights reserved.