



CLIENT

Merck (Bio E)

LOCATIONS

Hyderabad, India

CORE CAPABILITIES

- Project Management
- Multidisciplinary engineering: process, mechanical, electrical, control and automation engineering
- 3D modelling
- Commissioning
- GMP validation and compliance services
- V-model engineering lifecycle
- Construction support

PROJECT SUMMARY

Bio E required expertise for the Project Management, Construction Management, Commissioning, and Qualification Services for a fit-out of a new suite within an existing building.

THE CHALLENGE

Within an existing facility footprint, specialist engineering was required to meet the complex design and construction requirements of an FDA compliant suite to manufacture conjugated vaccines.

SYNERTEC'S SOLUTION

Synertec provided Project Management, Construction Management, Commissioning, and Qualification resources to deliver the management of the design, procurement, construction and validation activities for a new suite for the manufacture of conjugated vaccines to meet FDA compliance and approval. The new facility, with full HEPA filtration and containment zones for fume control incorporates the following main processes:

- Preparation and washing – glass washer
- Sterilisation – autoclave
- Dissolution and Homogenisation – glass vessels and homogenizer
- Ultrafiltration - TFF skids
- Conjugation – Glass reactors
- Final Purification- TFF skids, Buffer tanks
- Waste Treatment – Cyanide treatment skid

The process used mobile vessels and skids with mobile CIP and SIP skids for cleaning and sanitization. All new Purified Water, WFI and Clean Steam skids and distribution systems are also part of the project scope. Infrastructure upgrades included new chillers, transformer and associated electrical switch gear