

Public Information Summary

Host Country	India
Name of Borrower	Biological E. Limited (Bio E.), a company organized and existing under the laws of India
Project Description	Expansion of pharmaceutical operations and vaccine manufacturing capability in Hyderabad, India, including manufacturing of COVID-19 vaccines for distribution across India and other developing countries and financing three fill-and-finish lines
Proposed DFC Loan	\$50,000,000
All-Source Funding Total	\$113,000,000
Policy Review	
Developmental Objectives	The project is expected to have a highly developmental impact in India by expanding COVID-19 vaccine manufacturing at two existing production sites in the country for the purpose of ramping up urgently needed COVID-19 vaccine doses. Project funds will support ramping up the capacity of the company including installation and validation of three fill-finish vaccine manufacturing lines, with potential capacity to vaccinate a substantial share of the Indian population, as well as supply potential future export demand. Despite India being a world leader in vaccine production, insufficient COVID-19 vaccine production has contributed to low vaccination rates in the country. By July 2021, only a small share of Indians was fully vaccinated, while the country had suffered the highest number of confirmed deaths from the pandemic.
Environment and Social Assessment	SCREENING: This Project has been reviewed against DFC's categorical prohibitions and determined to be categorically eligible. Corporate loans used to expand pharmaceutical operations that do not involve integrated chemical installations are screened as Category B under DFC's environmental and social guidelines because impacts are site specific and readily mitigated. The major environmental and social concerns include the need for effective implementation and sufficient oversight and monitoring of quality control aspects as well as environmental, labor, health and safety aspects, in particular, labor and working conditions, occupational health and safety, waste management, fire life and safety, emergency preparedness and response, and grievance redress mechanisms.

APPLICABLE STANDARDS: DFC's environmental due diligence indicates that the investment will have impacts which must be managed in a manner consistent with the following International Finance Corporation's (IFC) 2012 Performance Standards (PS):

- PS 1: Assessment and Management of Environmental and Social Risks and Impacts;
- PS 2: Labor and Working Conditions;
- PS 3: Resource Efficiency and Pollution Prevention; and
- PS 4: Community Health, Safety, and Security.

Additionally, the Project will be required to meet applicable provisions of the IFC's April 30, 2007 Environmental Health and Safety (EHS) General Guidelines and IFC's April 30, 2007 EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing.

A desk-review based due diligence assessment indicates that because the Project involves the expansion of manufacturing within existing facilities located in designated industrial areas and does not involve greenfield construction, land acquisition nor significant adverse impacts with respect to biodiversity, impacts to or related to resettlement, indigenous peoples, and cultural heritage are not anticipated. Therefore, PS 5, 6, 7, and 8 are not triggered at this time.

Based on available data on diesel and electricity consumption, the current GHG emissions (Scope 1 and Scope 2) are estimated to be around 40,000 tons of CO₂ equivalent annually. Sources of emissions are primarily related to electricity use.

Impacts and Mitigation Measures: Based on IFC's ESRS and supervision findings Bio E. has in place an environmental and social management system that aligns with PS 1 and sufficient capacity to implement the ESMS, including a corporate level E&S manager and E&S coordinators at each of its facilities in Shameerpeta. Importantly, its manufacturing management systems and practices are aligned with good manufacturing practices (GMPs).

Bio E. represents that it undergoes internal and external audits from local regulatory bodies, ISO systems, GMP audits, and IFC audits. Monthly safety inspection audits are conducted by the Safety, Health and Environment (SHE) team. Periodic audits on biomedical waste vendors are conducted by the SHE team. Audits are carried out by certified internal and lead auditors on ISO systems. Internal audits conducted on Bio E.'s EMS are conducted semi-annually and external audits (recertification/surveillance audits) of external certification

	<p>bodies for ISO 45001:2018, ISO 14001:2015, and ISO 50001:2011 are conducted yearly.</p> <p>The Project's human resources policies include appropriate procedures on recruitment, principles of non-discrimination and equal opportunity, prevention of sexual harassment, prevention of child and forced labor, leave, insurance, retirement, exits and entry of employees and use of technology. The company has in place a formal and documented grievance redressal procedure to address and resolve grievances for direct and contracted workers, including an anonymous channel. Operational contractors are managed through the human resources department; however, the Project has not yet provided policies or procedures on how the environmental and social performance of construction or renovation works are managed or monitored. DFC will require that the Project submit the policy that will guide the management of construction contractors.</p> <p>There is reporting to the senior management on standard safety related key performance indicators (KPIs) such as (lost time accidents, recordable injury, first aid cases, etc.) and safety inspections are done on a monthly basis. Safety committee meetings are conducted regularly at each facility to review EHS performance and safety audits are carried out at on a regular basis by an internal team.</p> <p>Ambient air quality and stack emissions are monitored on a monthly basis. Stack emissions and ambient air quality monitoring results provided are compliant with the limits specified for the facilities by the SPCB and with the National Ambient Air Quality Standards (NAAQS).</p> <p>The source of water for consumption is predominantly municipal supply. The company has adopted a zero-discharge policy for process wastewater and domestic wastewater.</p> <p>The major streams of hazardous waste generated include ETP sludge, used oil, electronic waste from office, expired/discarded chemicals and empty containers. The wastes are stored in designated and appropriately designed storage areas and sent to government licensed service providers for disposal.</p> <p>The Bio E. infrastructure and processes have been designed to meet global standards with a high focus on quality aspects. The Company's quality policies have been formulated in accordance with WHO standards and the Drug and Cosmetics Act 1940 (GOI).</p>
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