

Public Information Summary

Host Country(ies)	India
Name(s) of Borrower(s)/Guaranteed Party(ies)	GeneSys Biologics Private Limited
Project Description	The company is developing a commercial insulin manufacturing plant in Telangana, India to help treat people suffering from diabetes around the world.
Proposed DFC Loan/Guaranty	Up to \$50 million senior, secured loan for up to 12 years.
All-Source Funding Total	\$97 million total project costs for the expansion facility being supported by DFC funding.
Policy Review	
Developmental Objectives	The Project is expected to have a positive development impact on diabetic patients globally by expanding access to insulin. According to the U.S. Center for Disease Control (CDC), approximately 415 million people worldwide are living with diabetes, a number that is expected to increase to more than half a billion by 2040. It is estimated that diabetics in poorer countries are spending up to 10 times more of their income on insulin than those in wealthier countries. The Borrower has developed affordable insulin biosimilars that can substitute for existing brands. DFC will support the construction and operation of a new facility designed to produce approximately 900 kilograms of insulin drug substance. Distribution is expected to be global, with insulin cost savings passed on to customers.
Environment and Social Assessment	<p>SCREENING: This Project has been reviewed against DFC’s categorical prohibitions and determined to be categorically eligible. The Project was screened as a Category B under DFC’s ESPP because impacts are site specific and readily mitigated. The Project is subject to climate change resiliency screening per EO 13677.</p> <p>APPLICABLE STANDARDS: Under DFC’s ESPP, the Borrower is required to comply with applicable local and national laws and regulations related to environmental and social performance. DFC’s environmental and social due diligence indicates that the Project will have impacts which must be managed in a manner consistent with the following International Finance Corporation’s (IFC) 2012 Performance Standards (PS):</p> <p>PS 1: Assessment and Management of Environmental and Social Risks and Impacts;</p>

PS 2: Labor and Working Conditions;
PS 3: Pollution Prevention and Abatement; 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.

The land for the Project, including the existing facility, is located in Hyderabad in Genome Valley, a business park established in 1999 focused on life sciences research and development. Some of the land for the Project was purchased in 2017 through a voluntary transaction, and GeneSys will purchase an additional parcel from the state government agency that developed the business park. The new plot is vacant and is located adjacent to the current property, within the boundaries of the business park. A desktop review and due diligence site visit indicate that significant adverse impacts with respect to land acquisition and resettlement, biodiversity, indigenous peoples, and cultural heritage are not anticipated. Therefore, PS 5, 6, 7, and 8 are not triggered at this time.

ENVIRONMENTAL AND SOCIAL ISSUES AND MITIGATION:

The major environmental and social concerns include the need for effective implementation and sufficient oversight and monitoring of quality control aspects of the manufacturing process as well as environmental, labor, health and safety management related to labor and working conditions, occupational health and safety, waste management, fire life and safety, contractor management for construction, emergency preparedness and response, and grievance redress mechanisms.

The Borrower has a Corporate Environmental Responsibility Policy, an Environmental Health and Safety Manual and a suite of Human Resource Policies that collectively represent their Environmental and Social Management System which adequately address risks in the production process. The Borrower also has a rigorous QA/QC system that has received GMP and ISO 9001:2015 certifications.

The facility currently operating is a small pilot facility which will be expanded as part of the Project. There is an Environmental and Safety Manual that identifies safety principles and goals; roles and responsibilities; training requirements; and waste disposal procedures, which are fit for purpose for the current small pilot facility. However, DFC will require that the manual be revised to address risks posed by the expanded facility. Additional details should be provided on risk assessment procedures; energy management; waste segregation and

	<p>disposal; fuel management; and air emission monitoring. The manual should also identify the person responsible for maintenance of the permit register.</p> <p>GeneSys has an Environmental Grievance Handling Policy for receiving and handling complaints from external parties related specifically to environmental issues. DFC will require GeneSys to expand the scope of the grievance policy to also allow grievances that may not be related to environmental issues.</p> <p>GeneSys has in place a human resources management system that includes an internal grievance mechanism, written contracts for all employees, and human resources policies that address hours of work, leave, pay, termination, disciplinary procedures, anti-harassment, and Equal Employment Opportunity, among other topics. The Borrower will be required to update its policy with regards to freedom of association. Several of the Borrower's human resources policies cover contracted workers and the Human Resources Department conducts due diligence and monitoring of contractors to ensure they comply with labor requirements.</p>
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