



Project Proposal for Ph.D.

Project Details (The research problem must clearly indicate the need for an interdisciplinary approach)

Project Title

Policy support as a driver of growth for the Indian biologics industry

Project Summary

(Minimum 500 and maximum 2000 characters)

Introduction:

Biologics are medicines made from living systems, so the sector covers products like monoclonal antibodies, insulin, erythropoietin, vaccines, and biosimilars. India’s biologics sector is growing quickly, with strong momentum in biosimilars, vaccines, and contract manufacturing. These sectors can have a huge impact on public health, as they can shape the treatment of common diseases like diabetes, hospital related infections and communicable diseases. Industry estimates put the current size of the industry at between \$13 and \$16 million with strong prospects of growth. Factors driving growth include rising domestic demand for advanced therapies, global off-patent biologics opportunities, and lower-cost manufacturing talent and infrastructure in India. The sector also faces constraints from high development costs, long timelines, complex regulatory and comparability requirements, and the need for deeper R&D and clinical capabilities. Although India has scale in manufacturing, the move from biosimilars and basic biologics into novel biologics and globally differentiated platforms is still a distant dream, and this PhD proposal aims to uncover the main reasons holding the Indian biologics sector back.

Policy context

India’s biosimilar pathway has been shaped by CDSCO and DBT guidelines, including the 2012 and revised 2016 “similar biologics” framework, which helped standardize development and approval expectations. The biggest recent push is the **BioE3 Policy**, approved in August 2024, which is designed to support high-performance biomanufacturing through Bio-AI hubs, biofoundries, and shared infrastructure for pilot and pre-commercial scale production. It explicitly aims to help startups, SMEs, industry, and academia access facilities that lower the cost and risk of moving from lab work to manufacturing.

Objectives and Methodology

The project will assess the impact of policy supports on the growth of knowledge and technology commercialization via universities in three areas of Biologics viz. rDNA protein for the manufacture of insulin, Recombinant human erythropoietin (rhEPO) used in treatment of certain kinds of kidney disease and Biologic vaccines for influenza and HPV. Specifically

- (i) Impact assessment of existing policy supports in these three areas
- (ii) The role of IP policies in enabling or constraining technology transfer
- (iii) The barriers faced by scientists who want to advance basic knowledge in these fields.

The project will use mixed methods. The study will use available secondary data and regression analysis designed to assess the causal impacts of policy on extent of imports, domestic productivity and new product introductions. In order to understand the mechanisms at play we will conduct interviews with scientists based in the large Indian biologics firms, public sector and scientists based in academic institutions at the forefront of biologics across the three sub-sectors and analyze the textual data using NLP methods. Such enquiry needs considerable domain knowledge on biologics in order to be effective.

Conclusion:

Many areas of the newly emerging biologics technologies have the potential to improve public health and quality of life in India. The project proposal aims to assess the policy supports that are needed to achieve this objective.

Ph.D. Supervisors* (Supervisor 1 and Supervisor 2 cannot be from the same department of IITD)			
Role	Name of Faculty	Academic Unit in IITD/Institute/University	Email ID (Official)
Supervisor 1*	Prof. Suma Athreye	School of Public Policy	suma@iitd.ac.in
Supervisor 2	Prof. Vivekanandan Perumal	Kusuma School of Biological Sciences	vperumal@bioschool.iitd.ac.in

*Supervisor 1 must be from IIT, Delhi.
 +All cells in this table are mandatory fields that need to be filled by faculty for consideration of proposal.
 §The date of superannuation of supervisors should be at least three years from the date of registration of selected candidates.

Project requirements (Student qualifications, experience required, etc) *The candidate will be shortlisted based on common shortlisting criteria decided by ScRC (SIRe)
• MTech/MBA/MPP/MSc equivalent with knowledge of both quantitative and qualitative methodologies • 60% through the career • Academic background/ experience in Bioengineering/Bioscience is desirable

Source of fellowship/funding and project number (CSIR/UGC/DBT/ICMR/ICAR/NEET-PG/DST-INSPIRE/IRD/FITT Project details, if any)
JRF for full-time applicants.

Role of Faculty Members involved:	
Supervisor-1	To provide academic guidance and practical support from the inception of the project to the submission of the thesis with particular emphasis on identification of policy gaps.
Supervisor-2	To provide academic guidance and practical support from the inception of the project to the submission of the thesis with emphasis on potential gaps in biotechnology.

- Note :-**
1. Approval from the respective DRC/CRC/ScRC of your Department/Centre/School will be required for using the "Full-time Institute Assistantship (Category-wise) (FIA)" for selecting the students in SIRe.
 2. Declaration:- Faculty members, please ensure that you have at least 3 years of service left before superannuation along with adequate sitting space & lab facilities for the SIRe student.
 3. PI/s are also encouraged to submit joint proposals with AIIMS, NII, JNU and institutes with which IITD has an existing MoU. If the Co-PI (Supervisor 2) is from outside IITD, kindly share his/her detailed CV.
 4. If a research scholar is to be considered for selection under the project fellowship, then the project should have a minimum of two-year duration remaining.
 5. A candidate applying with a valid JRF/INSPIRE/any national level fellowship should have at least two-year validity from the date of joining the Ph.D. program.
 6. The third supervisor’s name (if required) can be added only after the formation of Student Research Committee (SRC) subject to a strong recommendation of SRC and subsequent approval from the competent authority.

7. If Institute fellowship is being sought, then DRC approval of the parent department of Supervisor 1 is required at the time of selection.