



Biotechnology Industry Partnership Programme (BIPP)

(An Advanced Technology Scheme)



Special call for Proposals on Biosimilars

(1st August - 15th September, 2010)

Department of Biotechnology (DBT) invites proposals from Indian Companies working on Biosimilars under Biotechnology Industry Partnership Programme (BIPP), a Government partnership with industry for support on a cost sharing basis for development of novel and high risk futuristic technologies mainly for viability gap funding and enhancing existing R&D capacities.

For the first time under BIPP, proposals are invited exclusively in the field of Biosimilars, which may include one or more of the following innovative element(s), but not limited to:

- ✓ **Product Development**
 - Establishment and Maintenance of Master and Working cell banks.
 - Cell Culture Media Optimization
 - Protein Expression
 - Final and Inprocess product characterization techniques : e.g charged species, isoforms, glycoforms, product
 - Formulation
 - Protein Purification
 - Bioanalytical assay development including in-vitro and in - vivo bioassays, immunogenicity assays etc
 - Viral clearance methodologies and challenge tests - method establishment and validation
 - Delivery device development that are intimately associated with biologics e.g. prefilled syringes, disposable cartridges, pens, inhalers etc.
- ✓ Evaluation in suitable cell-culture and animal model systems
- ✓ Clinical Trials and safety
- ✓ Scale up
- ✓ Technology Transfers
- ✓ Product or Process Validation
- ✓ Quality unit setup
- ✓ Comparability Studies
- ✓ Stability Studies and
- ✓ Any other innovation involved during the development of Biosimilar(s)

Who can apply?

A single or consortia of Indian "for profit" biosimilar company (ies) - Small, Medium or Large having DSIR* recognized in-house R&D unit(s). An Indian Company is defined as one in which more than 51% of the ownership is held by Indian citizens (including NRIs).

The proposals can be submitted:

- solely by an Indian Company; or
- jointly by an Indian Company and National R&D Organizations or Institutions; or
- by a group of Indian Companies along with National Research Organizations etc.

*(*Companies in the process of obtaining DSIR recognition may also apply along with the proof of application to DSIR. However, the final decision on such applications would be subject to their getting DSIR recognition.)*

How to Apply?

Proposals are required to be submitted online only. To submit a proposal online, please log on the BIRAP website (www.birapdbt.nic.in).

Detailed guidelines are available at: http://dbtindia.nic.in/uniquepage.asp?id_pk=680;
<http://www.birapdbt.nic.in/programmes.php>

Company User Registration is open round the clock
Online Proposal Submission would begin from **1st August,2010**

No Hard Copy to be submitted, Proposals submitted online only would be considered
Last date for Submission of Proposals: 15th September,2010

For further details, please contact:

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