

Call for “Expression of Interest” for commercial scale purification of WSSV DNA vaccine

Background

1. ICAR-Central Institute of Fisheries Education, Mumbai has developed a WSSV DNA vaccine for shrimp that provides 70% protection in lab challenge studies and invites an Expression of Interest (EOI) from public and private sector vaccine manufacturers for undertaking the work related to commercial scale purification of plasmid DNA. The work involves purification of 5 commercial batches of DNA vaccine, optimization of downstream processing conditions and generation of data regarding quality parameters required by Review Committee on Genetic Manipulation (RCGM), New Delhi.

2. Description of work/deliverables

- Five batches of reproducible fermentation data (Batch size adequate to give enough purified product after purification to generate preclinical data; preferably not less than 20L) with detailed kinetics of one single batch
 - Fermentation kinetics data from one representative batch indicating cell growth, product formation, pH, temperature, dissolved oxygen, major nutrient consumption pattern, RPM for agitation
 - Concentration of product/L, yield and volumetric productivity (Provide details to show that the specific plasmid yield remains more or less constant at different cell concentrations during fermentation)
 - Detailed protocol of quality assessment of DNA vaccine to be provided
3. ICAR-CIFE expects to enter into a public-private partnership for technology up-scaling with the right of ‘first refusal’ to the industry partner for future commercialization of the WSSV DNA vaccine for shrimp. The institute shall enter into a confidentiality agreement and MoU with the selected party. The selection criteria shall be the total cost and the company profile. Interested parties may submit the Compliance statement not later than **05.09.2019** at the contact address below.

Disclaimer: ICAR-CIFE reserves the right to cancel this EoI without assigning any reason.

Annexure I

Compliance statement

S.N.	Requirements as detailed on EoI	Compliance/Remarks
1	Five batches of reproducible fermentation data with detailed kinetics of one single batch of 20L	
2	Fermentation kinetics data from one representative batch as mentioned above	
3	Concentration of product/L, yield and volumetric productivity	
4	Detailed protocol of quality assessment of DNA vaccine to be provided	
5	Documents regarding the Company's profile and capability in the relevant field	
6	Total project cost in INR	

Contact

The Director

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Envelope label: Commercial-Scale DNA Vaccine