Position: Manager (Regulatory) **Position Code:** MII-MR-01

Number of Positions: 1 (one)

Duration: Biotechnology Industry Facilitation Cell Program Management Unit (PMU) for Make In India is set up by the Department of Biotechnology (DBT) at BIRAC. This position is purely temporary (on contractual basis) and co-terminus with the project. The present duration of the project is up to March 2026.

Consolidated Remuneration: Between Rs.90,000/- to Rs.2,70,000/- Lump sum per month depending on Qualifications and Experience.

Job Description: National Mission Program - Make in India (MII) for Biotech sector is led by DBT and supported by BIRAC since 2015. The PMU undertakes policy advocacy, data research and analysis, stakeholders' consultations and provides strategic inputs. It supports Biofoundry/ Biomanufacturing initiative. The Project Development Cell, Investment Clearance Cell for biotech sector set up under this PMU will work closely with Invest India & DBT for the growth of the Bioeconomy and Biotech Innovation ecosystem of the country. The selected person would be responsible for execution and implementation of ICC activities. Facilitate regulatory support to investible projects from Industry/ Investors through inter-ministerial engagement including DBT, DPIIT, Invest India, others. Participate in the development of a single window clearance system.

Reporting: The person will be reporting to Mission Director – MII

Key Responsibilities:

- Interacting with regulatory agencies, Industries, Startups/ SMEs.
- Facilitating interactions for regulatory support to Industries, Startups/ SMEs.
- Responding to queries through Single Window System and promote Ease of doing business for the biotech sector.
- Coordinating regulatory meetings, briefing preparations and preparing meeting minutes.
- Stay updated of evolving regulatory requirements, guidelines, and industry trends and assess their impact on product development and registration.
- Contribute for organization, coordination and documentation of Strategy meetings, vision documents, sectoral gaps and recommendations through Stakeholder interaction.
- Contribute in other assignments aligned with the mandate of Make in India

Essential Qualifications:

4-years Bachelors/ Master's degree program from a recognized institute in life sciences/ other allied areas

Desirable Qualifications:

PhD in Lifesciences/ other allied areas

Strong written and oral communication skills

Experience:

6-8 years of experience with a minimum of 3 years in industry managing regulatory compliances in Product development and/or Manufacturing biologicals/ pharma/ Agritech & Food/ other related areas at CDMO/ CRO/ life sciences industry/ Government agency/ Consultancy firm.

Desirable: Exposure and understanding of setting up of a new facility/ new product manufacturing, GMP, mammalian and bacterial systems facilities, working knowledge of best practices from experience in Industry, Contract Research Organization, Start-up, others.

Age Limit: 38 years as on closing date of vacancy.