

The MII Scale-Up Clinic

“The Surgical Intervention Platform for India’s Biotech Cohort”

Overview

The **Make in India (MII) Scale-Up Clinic** is a strategic intervention platform established by the MII Secretariat at BIRAC. With the intent of “We don't just advise; we **resolve**”, the MII Scale-Up Clinics are a high-level, closed-door resolution platform designed for high-growth biotech entities that have crossed the innovation stage but are facing systemic hurdles in industrial scaling.

Our mission is to reduce the "Regulatory Lag" to ensure India’s biotech innovators can compete effectively on a global scale.

Core Focus Areas

- **Regulatory Navigation:** Direct interface with CDSCO, RCGM, and IEC to resolve licensing and clinical trial roadblocks.
- **Global Export Readiness:** Guidance on international certifications (USFDA, CE, WHO-PQ) to move from "Make in India" to "Make for the World."
- **Industrial Infrastructure:** Facilitating access to shared biomanufacturing facilities.

The "Surgical" Process

Unlike traditional advisory services, the Scale-Up Clinic follows a time-bound, executive process:

1. **Stage 1: Diagnostic Submission:** Start-ups submit a concise **Problem Statement** outlining a specific, non-financial bottleneck.
2. **Stage 2: Secretariat Vetting:** The MII Secretariat reviews the case for "Scale-Up Readiness" based on commercial viability and alignment with national goals.
3. **Stage 3: The Intervention Session:** A structured, 60-minute resolution meeting chaired by the **Mission Director (MII Cell)** in the presence of relevant **National Authorities** (CDSCO, DBT, FSSAI, Animal husbandry etc.).
4. **Stage 4: Post-Clinic Monitoring:** The Secretariat issues a "**Path to Resolution**" record and monitors the resolution.

Eligibility & Selection Criteria

To maintain the quality of interventions, the Clinic utilizes the **Triple-A Filter**:

- **Achievement:** Post-PoC start-ups with existing revenue or successful Phase II clinical trials.
- **Alignment:**
 - Direct relevance to the **BioE3 Verticals** .
 - **Import Substitution:** Technologies that reduce dependence on foreign APIs or medical hardware.

- **National Health & Security:** Solutions for pandemic preparedness, rare diseases, or agriculture security.
- **Actionability:** A clearly defined systemic hurdle that can be resolved through inter-agency coordination. The hurdle must be **procedural or administrative**. (The Clinic is for fixing the system, not for solving R&D failures).

Operational Impact

- **100% Survival Rate Support:** Protecting the investments already made in the biotech cohort.
- **Time-to-Market Acceleration:** Targeted reduction of administrative delays
- **Investor Confidence:** Providing the "Regulatory Certainty" required to attract Foreign Institutional Investors.

How to Apply

Start-ups and biomanufacturing entities seeking a diagnostic session are invited to submit a 2-page "Problem Statement" to the MII Secretariat at given email.

Contact the Secretariat

Make in India (MII) Cell, Biotechnology Industry Research Assistance Council (BIRAC)

New Delhi, India

Email: mii02-birac@nic.in

Location: MII Secretariat, BIRAC Office, 5th Floor, NSIC Business park, NSIC Bhawan, Okhla Industrial Area.