**Frequently Asked Questions (FQAs)**

**General Questions**

**Q1. What is the last date for submission of applications under the scheme?**

Ans: The last date of submission was extended from 10th January 2025, to ***31st January 2025.***

**Q2. Who is the Project Management Agency (PMA) for the "Scheme for Strengthening of Medical Device Industry (SMDI)"?**

Ans: the Life Sciences Sector Skill Development Council (LSSSDC) is the authorized PMA for the following Sub-schemes under the SMDI scheme:

- *Marginal Investment Scheme for Reducing Import Dependence*
- *Medical Device Clinical Studies Support Scheme*
- *Capacity Building and Skill Development for Medical Devices (for Component B only)*

**Q3. Whom should I contact if I have any queries regarding the *"Scheme for Strengthening of Medical Device Industry (SMDI)"*?**

Ans: If you have any queries, you can contact anyone from the LSSSDC, PMA Team:

- Mrs. Madhu Rupa | Sr. Consultant | MADHU@LSSSDC.IN | + 91+91 9810186773
- Mrs. Neha Sharma | Project Manager | NEHA.SHARMA@LSSSDC.IN | +91 8178357429
- Ms. Chitra Kanwar| Project Coordinator | CHITRA.KANWAR@LSSSDC.IN | +91 9773982613

**Q4. What is the role of the Project Management Agency (PMA)?**

Ans: The PMA is appointed by the Department of Pharmaceuticals (DoP) to manage the scheme. Its responsibilities include:

- *Receiving and appraising applications.*
- *Verifying the eligibility of applicants.*
- *Examining disbursement claims.*
- *Assisting the Scheme Steering Committee (SSC).*
- *Sensitizing potential beneficiaries about the scheme and guiding them through the application process.*
- *Monitoring approved projects and submitting monthly and quarterly reports to DoP/Scheme Steering Committee (SSC).*

**Marginal Investment Scheme for Reducing Import Dependence Questions**

**Q1. What is the main goal of the Marginal Investment Scheme?**

Ans: The primary objective is to promote domestic manufacturing of key components, raw materials, and accessories used in making medical devices, including in-vitro diagnostic devices. This aims to reduce the reliance of Indian manufacturers on imports and enhance the depth of domestic value chains.

**Q2. Who can benefit from this scheme?**

Ans: Beneficiaries include Central/State Government organizations, companies or LLPs registered in India, and Special Purpose Vehicles (SPVs) that intend to manufacture key components or raw materials for medical devices. This also includes medical device or in-vitro diagnostic manufacturers with manufacturing facilities in India that intend to produce key components or raw materials, manufacturers of critical raw materials that intend to produce medical grade materials, and manufacturers or importers who intend to manufacture medical devices that are currently on the GTE list.

**Q3. What kind of financial incentive is provided?**

Ans: The scheme provides a one-time capital subsidy on a reimbursement basis. The incentive varies based on company turnover: 20% of the investment or Rs. 10 crore (whichever is less) for companies with turnover up to Rs. 250 crore, 15% of the investment or Rs. 10 crore (whichever is less) for companies with turnover between Rs. 250 and Rs. 1000 crore, and 10% of the investment or 10 crore (whichever is less) for companies with turnover above Rs. 1000 crore. Central/State Government Organizations receive a grant of 20% of the investment or Rs. 10 crore, whichever is less.

**Q4. What costs are included when calculating the incentive?**

Ans: The total project cost can include land, building, infrastructure, machinery, and related utilities. However, the subsidy is calculated only on fixed investment, excluding land costs.

**Q5. What kind of activities or products are eligible?**

Ans: The scheme supports manufacturing of a wide range of components, raw materials, and accessories, including, but not limited to: sensors, embedded software, closures, pumps, optical filters, electrodes, antigens, membranes, tubing, and raw materials like polymers, metals, and packaging material. The SSC can also include additional items or revise the list.

**Q6. What is a "Special Purpose Vehicle" (SPV) in the context of this scheme?**

Ans: A Special Purpose Vehicle (SPV) is a legal entity registered under the Companies Act, 2013, or the Societies Registration Act, 1860. It is formed by medical device manufacturing units in a cluster to execute projects, such as developing a common facility

**Medical Device Clinical Studies Support Scheme Questions**

**Q1. What is the main goal of the Medical Device Clinical Studies Support Scheme?**

Ans: This scheme aims to support the medical device industry by fostering the development of devices supported by clinical evidence. This involves generating clinical data to show the safety and effectiveness of devices manufactured in India, promoting quality products and opening opportunities for manufacturers in international markets.

**Q2. Who can benefit from this scheme?**

Ans: This scheme is for medical device manufacturers in India who want to conduct:

a. Pre-Clinical Animal Studies,
b. Clinical Investigations on Human Subjects
c. Post-Market Clinical follow-up studies.
d. Performance Evaluation of New IVDs

**Q3. What kind of financial support is provided?**

Ans: The scheme offers financial support in the form of a grant on a reimbursement basis, with different limits for various types of studies:

a. Pre-Clinical Studies (Rs. 2 crore or 25% of expenditure)
b. Clinical Investigations on Human Subjects (Rs. 5 crore or 25% of expenditure)
c. Post-Market Clinical Follow-Up (Rs. 1 crore or 25% of expenditure)
d. Performance Evaluation of New IVDs (Rs. 1 crore or 25% of expenditure)

**Q4. What activities are eligible under the scheme?**

Ans: Eligible activities include Clinical Investigations of Medical Devices, Clinical Performance Evaluation of In-Vitro Diagnostic Medical Devices, Pre-Clinical Animal Studies and Post-Market Clinical Follow-Up Studies.

**Q5. What costs are included when calculating the incentive?**

Ans: The project cost includes expenses for subject enrolment and principal investigator fees, but not for the manufacturing of the devices used in the study.

**Q6. What does the applicant need to provide for reimbursement?**

Ans: The incentive is disbursed on submission of a statutory auditor certificate for the expenses incurred, as well as proof of publication of the study results.

**Capacity Building and Skill Development in Medical Device Sector Scheme (Component B only) Questions**

**Q1. What is the main objective of Component B of the Capacity Building and Skill Development scheme?**

Ans: The main objective is to provide financial assistance to institutions to run diploma, certificate, and short-term training courses. This will equip the existing workforce and students with the skills required in the medical device sector, making them compatible with the needs of the industry.

**Q2. Who is the target audience for the Component B courses?**

Ans: The courses are aimed at existing workers in the medical device industry (like technicians and regulators) and students from various backgrounds like pharmacology, engineering, and medical fields who want to work in the medical device industry.

**Q3. What kind of financial assistance is provided under Component B?**

Ans: Financial support is provided to the training institute on a reimbursement basis and is based on the number of students enrolled, with Rs. 25,000 per student per month for diploma courses and Rs. 10,000 per student per month for certificate and skill development training programs.

**Q4. What are the eligibility criteria for institutions offering courses under Component B?**

Ans: Institutions must have the necessary infrastructure to train 20-30 candidates and must have strong industry linkages for practical training. A proven track record of organizing successful courses, especially in the pharma-MedTech sector, is preferred. Courses should align with the National Education Policy 2020, the National Credit Framework and be affiliated with a relevant awarding body.

**Q5. What areas of study should the courses cover?**

Ans: Courses should include topics like medical device testing and design, manufacturing processes, quality assurance, medical device regulations, and IP regulations. All courses should be affiliated with an awarding body approved by the National Council of Vocational Education and Training (NCVET).

**Q6. Can I apply for financial assistance under Component A of the Capacity Building and Skill Development in Medical Device Sector Scheme?"**

Ans: No, you cannot apply for Component A at this time. The applications for Component A, which supports postgraduate courses, are currently closed. The scheme is only open for applications for Component B, which supports diploma, certificate, and short-term training courses.