Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India

Operational Guidelines for the Scheme

"Strengthening of Medical Device Industry"

Central Sector Scheme under

Department of Pharmaceuticals

Dated the 08th November, 2024

CONTENT

CHAPTER-I:

1. Introduction to the Scheme

1.1 Background

Medical device is a sunrise industry in India, with double digit growth rate. Due to efforts of the government in the last decade in creating a suitable eco-system and incentivizing production of medical devices through PLI scheme, production of technology intensive medical devices such CT scan, MRI, C-arm etc. has started in India. However, the dependence on imports still continues to be about 70%. Moreover, to deepen our manufacturing capability along the value chains of different segments of medical devices, it is essential to incentivize domestic manufacturing of key components/raw materials/accessories etc., along with Medical Devices under the list of medical devices for which exemption from the instructions of Department of Expenditure for Global Tender Enquiry are available owing to lack of domestic manufacturing to meet the requirement of procurement of central government hospitals, by providing support to industry in form of grant for marginal investment. Another challenge faced by domestic medical device industry is high cost towards clinical investigations, which dissuades them from investing resources in R&D and manufacturing facilities, which can lead to newer product development, better safety and efficacy of devices, and enable access to markets abroad. As a nascent industry, the sector also requires support for awareness generation, knowledge sharing and promoting brand India. Availability of industry ready trained manpower is another constraint the industry faces.

To address these issues, after series of consultations and two Meditech Stackathons- a massive exercise involving about hundred manufacturers to identify industry issues and map value chains across eight medical device segments, the Department of Pharmaceuticals has formulated a scheme for strengthening of medical device industry. The scheme has five components, which are as follows –

(i) Common Facilities for Medical Device Clusters
(ii) Marginal Investment Scheme for Reducing Import Dependence
(iii) Capacity Building and Skill Development in Medical Device Sector
(iv) Medical Device Clinical Studies Support Scheme
(v) Medical Device Promotion Scheme

The scheme has an outlay of Rs. 500 crore and tenure of the Scheme is 3 years from Financial Year 2024-25 to FY 2026-27. In the next three years the scheme will provide the much needed thrust to address the unmet needs of the industry. The scheme is expected to have a multiplier effect in augmenting the domestic manufacturing capacities with significant reduction in imports, and promote - quality, human resource development, safety and efficacy of medical devices, and also enhance the depth of medical device value chains in the country.

Merger of existing Schemes

The following two sub-schemes were already approved in the Department of Pharmaceuticals (DoP) as part of scheme for 'Development of Pharmaceutical Industries:

(a) Assistance to Medical Device Clusters for Common Facilities
(b) Human Resource Development in Medical Device Sector

Now, the above schemes have become part of the single scheme – SMDI, with modification in the scheme guidelines and reduced financial outlay, as detailed in these guidelines.

1.2 Definitions

For purposes of this Scheme capitalized terms have the meanings set forth or referred to in this Section.

i. "**Animal Study**" means a pre-clinical study conducted on animal models to generate the clinical data related to a medical device for its safety, performance and effectiveness.
ii. "**Annual turnover":** Annual turnover, in reference to a business or company, is a financial metric that represents the total revenue generated by the company from its primary operations over a specific period of 12 months. It is commonly calculated on an annual basis and provides an indication of the company's sales performance and the scale of its business activities. The annual turnover figure includes all income generated from the sale of goods or services, excluding any taxes, discounts, or returns. It reflects the total value of all sales made during the specified period, regardless of whether the payment has been received or not.
iii. "**Articles of Association**" has the meaning set forth in Section 2(5) of the Companies Act, 2013.
iv. **"Application"** Application submitted by an applicant to the Project Management Agency (PMA) as per the Application form prescribed under these guidelines containing requisite information, along with supporting documents and application fee.
v. "**Application Window"** Time period allowed for filing the applications. The application window shall be opened based on notice issued by the department from time to time.
vi. "**Beneficiary**" means the entity(s) chosen, on an application approved by the SSC, to receive the benefits of the Scheme.
vii. "**Cluster development**" means a development of clusters containing the Medical Devices manufacturing units where the focus is concentrated in a selected area.
viii. "**Common facilities**" means all facilities intended for the shared use by the subscriber and will consist of creation of tangible "assets" as Common Facility Centers (CFCs). The same is further elaborated under Clause 10.7. The indicative list of common facilities is illustrative, and each cluster could have its own specific requirement based on the nature of units being set up and the products proposed to be manufactured.
ix. "**Committed Investment**" The amount of fresh investment which the applicant shall commit by declaration at the time of applying under the scheme.
x. "**Clinical Investigation**" means the systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness.
xi. "**Clinical Performance Evolution"** means the systematic performance study of a new in vitro diagnostic medical device on a specimen collected from human participants to assess its performance.
xii. "**Effluent treatment plant**" means a treatment plant exclusively established to treat the process waste of any kind generated by medical device industries according to the prevailing law, statutes, or rules.
xiii. "**Eligible Product**" Good manufactured in India and covered under one of the entries in the Annexure 1 of these guidelines or recommended by the Technical Committee from time to time.
xiv. **"Force Majeure**" Extraordinary events or circumstances beyond human control such as an event described as an act of God (like a natural calamity) or events such as war, strike, public health emergency, riots, crimes (but not including negligence or wrong- doing, predictable/ seasonal rain and any other events specifically excluded).

xv. **"Financial Year"** Financial Year begins on the 1st of April of a year and ends on 31st March of the following year.

xvi. "**Funding**" It is the financial assistance provided to each selected participant based on the laid down eligibility criteria.

xvii. "**Grant-in-Aid**" means any Grant issued by DoP as per Chapter-9 of GFR-2017.

xviii. "**Medical device"** means all devices, including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

a) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
b) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability
c) investigation, replacement or modification or support of the anatomy or of a physiological process
d) supporting or sustaining life
e) disinfection of medical devices; and
f) control of conception.

xix. "**Incentive**" means the financial benefit to be provided to the selected applicant based on fulfilling the criteria as mentioned herein the Scheme.

xx. "**Investigational Medical Device**" means medical device being assessed for clinical performance, effectiveness, or safety in a clinical investigation.

xxi. "**Logistic Center**" means a place within which all activities relating to transport and the distribution of medical devices- both international and national transit, are carried out by various operators on a commercial basis.

xxii. "**Medical devices testing laboratory**" has the meaning set forth in subsection (ze) of section 3 of Medical Devices Rules,2017.

xxiii. "**Micro, Small and Medium Enterprises**" has the meaning set forth in the Micro, Small and Medium Enterprises Development Act, 2006 [No. 27 of 2006].

xxiv. "**Memorandum of Association**" has the meaning set forth in Section 2(56) of the Companies Act, 2013.

xxv. "**New In-Vitro Diagnostic Medical Device**" means any medical device used for in vitro diagnosis that has not been approved for manufacture for sale or for import under Medical Devices Rules, 2017 and is being tested to establish its performance for relevant analyte or other parameter related thereto including details of technology and procedure required.

xxvi. **Performance Year** of the scheme is FY 2024-25 to FY 2026-27.

xxvii. "**Project Management Agency**" refers to the agency appointed by the DoP to act on its behalf for receipt and appraisal of applications, verification of eligibility and examination of disbursement claims through any method / document deemed appropriate and for managing the Schemes in accordance with these guidelines.

xxviii. "**Post-market clinical follow-up**" means a study carried out following marketing authorization intended to answer specific questions (uncertainties) relating to safety, clinical performance and/or effectiveness of a device when used in accordance with its labelling.

xxix. "**Research and Development Lab**" means a place used for experimentation aimed at the discovery of facts, or scientific development of new products, Medical Devices, technologies, or applications; but excludes industrial and manufacturing operations other than those required as part of research.

xxx. "**Scheme**" means the "**Scheme for Strengthening of Medical Device Industry (SMDI)**" Scheme of Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India.

xxxi. "**Scheme Steering Committee**" has the meaning as set forth in para 7.

xxxii. "**Special Purpose Vehicle**" means a legal entity registered under the Companies Act, 2013 or the Societies Registration Act, 1860 as amended from time to time

xxxiii. **"Technical Committee**" means a Technical Committee constituted by DoP to assist the Scheme Steering Committee (SSC) for discharge its function

xxxiv. **"Testing laboratory"** means a public or private laboratory that (i) offers or performs tests of medical devices, (ii) offers no service other than such tests, and (iii) is accredited by an accrediting body.

xxxv. **"Technology upgradation"** means any correction, improvement, modification or enhancements in the existing form of the technology with new features/releases that would have a substantial likelihood of achieving greater impacts.

xxxvi. **"Training Center"** means a place where people undergo skills training for work.

1.3 Objectives

Based on the requirements of the Medical Devices industry, the new Scheme for Strengthening of Medical Devices Industry has the following objectives: -

(I) Common Facilities for Medical Device Clusters: To strengthen existing infrastructure by providing financial assistance to medical device clusters for creating Common Infrastructure Facilities, boosting domestic manufacturing capacity and improving cluster quality. Further, to support any national or state level Government or Private institutions to establish or strengthen testing facilities for medical devices to support the arising needs of the Testing Laboratories for Medical Devices due to roll-out of licensing regime of the Medical Devices w.e.f 1.10.2022, ensuring availability of more testing facilities for evaluation of medical devices on behalf of the manufacturers, as mandated under the Medical Devices Rules, 2017.

(II) Marginal Investment Scheme for Reducing Import Dependence: Medical Device Industry needs specialized inputs /components in manufacturing of Medical Devices. These cannot be produced by the general industry and are often imported by medical device manufacturers. They can be incentivised through grant for manufacturing of essential/key components or upstream materials or accessories or closely related products used in manufacturing of medical devices. Presently in respect of 354 medical devices, exemption from the instructions of Department of Expenditure for Global Tender Enquiry (GTE) for tenders of value below Rs. 200 crore is available owing to lack of domestic manufacturing of these devices to meet the requirement of procurement of central government hospitals. Marginal Investment Support for manufacturing of these medical devices within the country would lead to reduction in import of these items.

(III) Capacity Building and Skill Development in Medical Device Sector: The main objective of this component is to fill up the gap existing in the education and research in medical devices sector and to ensure quality teaching, training and nurturing excellence in Medical Technology education for generating critical mass of trained human resource to meet the requirements of rapidly innovating multidisciplinary areas of Medical Technology and create R&D ecosystem for the sector.

(IV) Medical Device Clinical Studies Support Scheme: Support will be provided for conducting Clinical Investigations or Pre-Clinical animal studies for medical device or Clinical Performance Evaluation of new IVDs. This will promote manufacturing of quality products with better efficacy and

safety. It will also enhance credibility of domestic manufacturers to produce high quality products, opening up opportunities for them in markets outside the country.

(V) Medical Device Promotion Scheme: The scheme aims to promote Medical Device Industry by bringing industry leaders, academia and policy makers together to share their knowledge and experience for overall development of the sectors. Financial support will be provided to industry bodies/associations and educational institutions to conduct meetings/ seminars/ workshops/ events/ road-shows/expos etc. for which grant will be provided by the department. Also, support for manufacturer evaluation studies, creation of database, international study missions etc. will be provided for promotion and development of the medical device industry. Department may also directly incur expenditure on industry development activities.

1.4 Financial Outlay

The scheme finance will come from the Department of Pharmaceuticals' Budgetary Grants, with an overall limit of Rs. 500 crore. The component-wise financial outlay will be as follows: -

S. No.	Scheme for Strengthening of Medical Devices Industry	Component Outlay (Rs. in crore)	The performance year of the Scheme
1	Common Facilities for Medical Devices Clusters	110	2024-2025 to 2026-2027
2	Marginal Investment Scheme for Reducing Import Dependence	180	2024-2025 to 2026-2027
3	Capacity Building and Skill Development for Medical Devices	100	2024-2025 to 2026-2027
4	Medical Device Clinical Studies Support Scheme	100	2024-2025 to 2026-2027
5	Medical Device Promotion Scheme	10	2024-2025 to 2026-2027

1.5 Technical Committee (TC)

1.5.1 Technical Committee will be constituted by DoP to technically appraise proposals received under different components of the scheme, provide technical guidance and recommendations to the Scheme Steering Committee (SSC) in discharge of its functions. The TC may also give its comments on any technical matter referred by PMA/DoP. The composition of the committee is as given below.

i. One representative from Central Drugs Standard Control Organization (CDSCO)
ii. One representative expert from industry and academia each (sub-scheme concerned)
iii. One representative expert from ICMR, MSDE (sub-scheme concerned)
iv. Two representative experts having knowledge and experience in Process Development/ R&D/ Product Design/ Testing of Medical Devices/ Medical Devices Manufacturing etc. relevant institute (NIPER, IISc, IITs, Council of Scientific, Industrial Research (CSIR), National Council of Vocational Education and Training (NCVET) and in house faculty constituted to advise on development of course content, assess the infrastructure requirements and monitor progress of courses at the institutes or similar institutions (sub-scheme concerned)

1.6 Scheme Steering Committee (SSC)

1.6.1 The Department of Pharmaceuticals (DoP) will provide overall policy, coordination and management support for the implementation of the Scheme. The proposals under the scheme will be considered for approval by the Scheme Steering Committee (SSC), whose composition will be as follows: -

i. Secretary, DoP – Chairperson;
ii. Financial Adviser, DoP - Member;
iii. Joint Secretary (Medical Devices), DoP - Member;
iv. Drug Controller General of India - Member;
v. Representative of Ministry of MSME - Member;
vi. Representative of Ministry of MeitY – Member;
vii. Representative of Ministry of DPIIT – Member
viii. Representative of Ministry of SDE - Member;
ix. Representative of D/o Health and Family Welfare- Member;
x. Representative of ICMR- Member
xi. Director /Deputy Secretary (Medical Device), DoP – Convener;
xii. The SSC may co-opt representatives of any Pharma and Medical Devices Industry Associations, Financial Institutions/Program Management Consultant, R&D Institutions and Other Government/ Private sector expert organizations as members or special invitees as may be necessary from time to time.

1.7 Functions of the Scheme Steering Committee (SSC)

(i) To provide direction for effective implementation of the Scheme.
(ii) To evaluate & approve proposals under the scheme
(iii) To monitor the implementation of the scheme.
(iv) To amend operational guidelines within the overall financial outlay of the scheme
(v) Reallocation of funds from one component to another component within the overall approved outlay depending upon operational requirements.

1.8 Project Management Agency (PMA)

1.8.1 The scheme will be implemented by Project Management Agency (PMA) to be selected through open tender/nomination basis. PMA will be a bridge between the SSC and the beneficiary & would act as a catalyst in expeditious implementation of the projects in a systematic, professional and transparent manner.

1.8.2 The PMA will report directly to the SSC and shall have the following responsibilities:

a. PMA will be responsible for providing secretarial, management and implementation support and to carry out other responsibilities as assigned by DoP within the framework of scheme and guidelines thereof.
b. PMA will be responsible for receipt and appraisal of applications, verification of eligibility and examination of disbursement claims through any method/document deemed appropriate and or managing the above-mentioned in accordance with these guidelines.

c. Assist SSC in drafting and issuing Expression of Interest (EoI)/ Request for Proposal (RFP) and formulating criteria for evaluation to select the Projects from the Proposals received in response to RFP.
d. Devise the prescribed application formats and list the supporting documents as well as the appraisal methodology for approval of SSC/ DoP,
e. Preliminary examination of the proposals, and preparation of evaluation reports that will be placed before the SSC for final selection of proposals.
f. Sensitization of the Industry/potential beneficiaries on the Scheme and its benefits and also guiding them to apply for benefits under the scheme.
g. Preparing the Draft Agreement for selected beneficiaries for implementation of the scheme as per guidelines.
h. Developing an online portal to receive the applications and maintain the MIS and data of the applicants with all the details.
i. Assist the selected beneficiary in the selection of agencies/ experts for various services such as capacity building, business development, technical or engineering support, in developing suitable O&M framework for making the project more effective
j. Monitoring the approved projects through physical inspection, monitor implementation schedule based on Quarterly Review Report & submit monthly & quarterly review of the projects report to DoP/SSC for timely disbursement and utilization of the funds. PMA will also identify potential project delays and failures to meet deadlines, proposing corrective actions in their Monitoring Reports.

1.8.3 The Evaluation of the PMA shall be done on the basis of quality and timeliness of appraisal of new projects brought to DoP/SSC for final approval, monitoring for ensuring completion of the projects within the stipulated timelines mentioned in the approved DPR/Projects. If progress and performance of the PMA is not satisfactory, DoP/SSC reserve the right to remove the PMA at any time during the tenure of the scheme after serving a notice and considering its reply thereto.

1.9 Scheme Outcomes

(i) The NITI Aayog has developed an Output Outcome Monitoring Framework, on the basis of which performance will be monitored.
(ii) A mid-term review of the scheme would be conducted, for which the Department of Pharmaceuticals will engage the services of an approved independent agency. The review report would be submitted to the Scheme Steering Committee (SSC) for taking course correction / modification to the scheme /projects.
(iii) Stake holder consultations will be organized by DoP through PMA from time to time to obtain feedback on the effective implementation and need for modifications in the Scheme.

CHAPTER-II:

2. Common Facilities for Medical Devices Clusters Scheme

2.1 Assistance for Common Facilities (CF)

To strengthen the medical device clusters' capacity for their sustained growth by creating Common Infrastructure Facilities.

2.2 Assistance for Testing Facilities (TF)

To strengthen availability of more Medical Device Testing Laboratories in order to boost manufacturing of quality medical devices

2.1 Assistance for Common Facilities (CF)

2.1.1 Objective

To strengthen the Medical Device clusters' capacity for their sustained growth by creating "Common Infrastructure Facilities".

2.1.2 Intended Beneficiaries

i. Medical Devices manufacturing units in a cluster who have come together to form a Special Purpose Vehicle (SPV) to execute the project of developing common facility. There shall be a minimum of 5 Medical Device manufacturing units as members of SPV.
ii. Medical Devices clusters promoted by the State Governments: Such a Project Implementing Agency shall be legal entity under the Indian law with foresight of the State Governments. Such a cluster may be exempted from the requirement of formation of SPV & will be deemed to be an SPV for the purpose of this Scheme, provided separate accounts are maintained for the funds to be used for the projects assisted under Common Facilities for Medical Devices Clusters (CF-MDC) and an Executive Committee (EC) is set up for implementation of the project.

2.1.3 Eligibility Criterion for SPV

i. The SPV or the Executive Committee, as the case may be, will have representatives from cluster members, financial institutions, State and Central Government and R&D organization.
ii. Individual manufacturing unit cannot hold more than 50% in the SPV.
iii. Medical Devices enterprises shall hold at least 51% equity of the SPV
iv. The combined net worth of members of SPV shall be equivalent to total grant amount applied for and each SPV member must have a net worth of at least 1.5 times of their proposed equity contribution.
v. The SPV members shall be legally independent entities without any related-party relationship with each other as described under Accounting Standard (AS) 18 of the Companies (Accounting Standard) Rules, 2006.

2.1.4 Incentive under the scheme

The Department will assist in setting up of Common Facilitation Centres in the Medical Devices clusters. This scheme will provide the grant-in-aid component of Rs. 20 Crore or 70% of the total cost of purchase of equipment and machinery, for Central / State Government funded entities (50% in respect of private entities) for use in setting up of Common Facilities, whichever is less and Rs. 5 Crore or 70% for Central / State Government funded entities (50% in respect of private entities) for setting up of Testing Facilities, whichever is less.

2.1.5 Physical and Financial Outlay

Financial Year	Physical Target (no.)		Financial Outlay (Rs. in crore)		
	Common Facilities	Testing labs	Common Facilities	Testing labs	Total Grant-in-Aid
Year 1	0	0	0	0	0
Year 2	1-5	1-4	40	15	55
Year 3	6-10	5-8	40	15	55
Total	5-10	4-8	80	30	110

2.1.6 Modalities for utilization of incentive

i. The cost of project shall include cost of land, building, internal infrastructure, administrative and management support expenses including the salary of CEO, engineers, other experts and staff during the project implementation period (before commissioning), preliminary expenses, machinery & equipment, miscellaneous fixed assets and other support infrastructure such as water supply, electricity and margin money for working capital. However, *Grant-in-Aid from DoP will not be utilized towards land component of the project or construction of rest house, administrative buildings or any other building*, which in the opinion of SSC may be categorized as non-essential construction for the technical requirements of project.

ii. In case the SPV provides an existing land and building, the cost of the same will be decided on the basis of valuation report prepared by an approved agency of Central / State Government Departments / Financial Institutions (FIs) / Public Sector Banks and the cost of land and building may be taken towards contribution for the project.

iii. In case the SPV provides an existing land and building on lease separately, then the *minimum period of lease must be 30 years* for both land and Building. In case the SPV provides an existing land, building on the same land on lease, then the minimum period of lease for combined land and building must be 30 years.

iv. *Minimum of 30% or 50% of the approved project cost has to be contributed by the entity or SPV, as the case may be respectively* for the project & there will be no duplication of funding for the same component/ intervention. SPVs may dovetail funds from other sources as well for the project, provided there is no duplication of funding for the same component/ intervention. Resource raised through such dovetailing will be in addition to the 50% contribution of the SPV.

v. Assistance for Administrative and other management support of SPV during the project implementation period *shall not exceed 5 % of the Grant-in- aid*.

vi. Proportionate contribution by the SPV or the beneficiaries' share should be made upfront. Necessary infrastructure like land, access road, water and power supply, etc. must be in place or substantial progress should have been made in this regard before DoP assistance is released. Where bank finance is involved, written commitment of the bank concerned to release proportionate funds will also be necessary before release of DoP assistance.
vii. Escalation in the cost of project over and above the sanctioned amount, due to any reason will be borne by the SPV. The Central Government shall not accept any financial liability arising out of operation of any Common Facility.
viii. Project Implementing agency / SPV shall be responsible for obtaining all necessary statutory clearances in a timely manner.
ix. The Grants-in-Aid shall not be available to any individual production units, if any, owned by a member of the SPV.
x. The Common Facility may be utilized by the SPV members and also by other Medical Device units on 'user charges' basis to be decided by the SPV.
xi. User charges for services of Common Facility will be graded in such a manner that average charges will be lesser than prevailing market prices, as decided by the Governing Council of the SPV or the Executive Committee as the case may be. The SPV members would be given reasonable preference in user charges.

2.1.7 Eligible Activities

An indicative list of eligible activities, for the Common Infrastructure Facilities(CIF) for the MD clusters, under this Scheme are as under:

i. Research and Development Labs
ii. Designing and Testing Centre/ESDM/PCB/Sensors facility
iii. Biomaterial / Biocompatibility /Accelerated Aging testing Centre
iv. Medical grade moulding/milling/injection moulding/machining/tooling Centre
v. 3D designing and printing for medical grade products.
vi. Sterilization/ETO/Gamma Centre
vii. Animal Lab and Toxicity testing Centre
viii. Radiology Tube (Radiation)/Flat Panel Detectors/MRI Magnets/ Piezo electrical crystals/power electronics facility
ix. Solid waste management/ETP/STP/Electronic Waste management unit
x. Common Warehouse & Logistics
xi. Emergency Response Centre/Safety/Hazardous Operations Audit Centre
xii. Centre of Excellence/Technology Incubator/Training Centre
xiii. Facilities for rapid prototyping microfluidics based medical devices
xiv. Facilities for rapid prototyping of medical devices using biomaterial and tissue engineering.
xv. Electro-magnetic interference & Electro Magnetic Compatibility Centre

The above list of activities is indicative and other allied activities can be taken up on approval of SSC.

2.1.8 Project Proposal and its components

i. The project proposal must have technical recommendation from competent technical body (e.g. for ETP, the State Pollution Control Board may be the competent body and in case of Research Labs and Testing centers, NIPERs/IITs/CDL/ Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) /NIITs/ IISC/Certified MDTL Testing

Laboratories notified by CDSCO (MD-40) may be the competent authority to grant technical recommendations).

ii. In case of PMA / SSC are not satisfied with the technical recommendations, the PMA / SSC may ask the Entity/SPV to obtain technical recommendations from specific competent experts.

iii. Project proposal may have the following details:

a. Business Plan including processes of the cluster units like manufacturing process, Gap Analysis and proposed operations of the Common Facility such as technology, marketing, quality control, testing, purchase, outsourcing.
b. Final projections and financial viability report.
c. Identification of impediments and bottlenecks
d. Action Plan for enhancing competitiveness of the units of the cluster and positioning the cluster on a self-sustaining trajectory of growth. The proposal will have direct linkages between the impediments/bottlenecks identified and the measures recommended for improvement.
e. Implementation schedule for Action Plan to contain:
    1. Activity-wise time schedule
    2. Milestone for payments
    3. Expected date of Commissioning
    4. Delay and expected Risk
    5. Monitorable quantified targets for reporting on outcomes.

iv. The Indicative chapters that may be included in the DPR is mentioned in **Annexure-I**

2.1.9 Implementation Process & Timelines

i. PMA to invite project proposals for assistance under the scheme through newspaper /website, setting a cut-off date for receiving applications.

ii. Applicants to submit complete project proposal in prescribed format to PMA.

iii. PMA to scrutinize the project proposals and submit it appraisal report with recommendations to SSC within one month of the last day of receipt of application for considering grant of in-principle approval.

iv. In-principle approval will be granted to those applicants who submit a complete project proposal with technical recommendation and have availability of land.

v. Such *'in-principle'* approval will be valid for a period of 6 months from the date of approval. In case final approval is not accorded to the project within 6 months, in- principle approval will automatically lapse, unless it is specifically extended by the SSC.

vi. PMA may guide the applicants, who obtain the 1st stage approval, to fulfill all necessary conditions under the guidelines within 6 months.

vii. A project may be accorded final approval by the SSC, if the following conditions are fulfilled:

a. Establishment of project specific SPV;
b. Execution of shareholder's agreement and other related agreements between the SPV and its members;
c. Preparation of Project Proposal by SPV and its appraisal by PMA;
d. Procurement of requisite land by the SPV;
e. Establishment of project specific account with Scheduled Commercial Banks by the SPV. DoP would credit funds into this account;
f. Tying up of sources of funds for the balance amount.

viii. Projects to be completed *in 2 years*. However, SSC can grant an extension of 1 year for

delays due to reasons not within control of SPV.

ix. In case of any deviation from the approved project proposal or time line, approval of DoP must be sought for continuation of the project.

2.1.10 Selection Criteria

I. Preference in assistance will be given to project proposals by the SSC, based on category of projects.

II. Preference in assistance will be given to those proposals which will utilize leverage for scaling up production & financing of common cluster facility.

2.1.11 Schedule for release of Grant

i. The release of funds by the Department will be based on scrutiny by the PMA, approval by the Scheme Steering Committee (SSC) in the following manner: -

Instalment	Percentage of Funds	Remarks/Pre-requisite
1st	**25**	• Raising of minimum 25% of SPV contribution and deposit in the appropriate account. • Signing of Indemnity Bond on final approval of the project by SSC.
2nd	**25**	• Against the production of Bills • 75% utilization of 1st instalment • Proportionate expenditure incurred by the SPV.
3rd	**25**	• Against the production of Bills • 100% utilization of 1st instalment • 75% utilization of 2nd instalment • Proportionate expenditure incurred by the SPV.
4th	**25**	• 100% utilization of 2nd and 3rd instalment • SPV has mobilized and spent its 100% share in proportion to the first three grants.

ii. The SPV shall submit the Utilization Certificate (UC) in prescribed form, generated through PFMS portal, duly certified by CA and countersigned by Head of SPV for the amounts utilized in accordance with GFR-2017. Also, the expenditure details need to be uploaded in the CNA module of PFMS before processing the case for subsequent instalments. Accounts of SPV shall be subject to audit by the Comptroller & Auditor General of India.

2.1.12 Maintenance and ownership of assets

i. SPV shall be responsible for O&M of assets created under the scheme by way of collecting user charges from the members/users;

ii. SPV shall ensure that the services of the facilities created under the scheme are extended to the cluster in general, in addition to the member enterprises;

iii. The Assets acquired by the SPV out of government assistance shall not be disposed,

encumbered or utilized for the purposes other than for which the funds have been released.

iv. A register of permanent and semi-permanent assets acquired wholly or mainly out of the funds provided by Government of India should be maintained as per GFR.

v. If for any reason SPV is liquidated, Government of India shall have the first right to recover the grant funds provided by it. The assets created with such grant funds and any unutilized fund shall be vested with the Central Government. The Memorandum of Association & Articles of Association of the SPV with the Government shall incorporate this provision.

2.1.13 Expected Benefits

i. Improvement in quality standards of medical devices
ii. Improvement in regulatory compliance specified for medical device
iii. Increased availability of trained personnel for Medical Devices clusters
iv. Increased competitiveness of Medical Devices units in the cluster
v. Reduction in the manufacturing cost of Medical Devices

2.1.14 Monitoring

I. The PMA shall carry out regular monitoring of the implementation of the scheme and each project approved thereunder. The PMA shall prepare Monitoring Reports in the frequency and format as decided by the SSC and assist the SSC and DoP in monitoring the Scheme.

II. PMA will provide full access to scheme monitoring portal to the Department of Pharmaceuticals for monitoring purpose and shall monitor approved projects through physical inspection, implementation schedule based on Program Evaluation and Review Technique (PERT)/ Critical Path Method (CPM)/ Gantt Chart and submit monthly & quarterly reports of review of the projects to DoP/SSC for timely disbursement and utilization of the funds.

III. PMA shall identify potential delays and failure of projects to meet deadlines and propose corrective action as part of the Monitoring reports.

2.2 Assistance for Testing Facilities (TF)

2.2.1 Objective

To strengthen availability of more Medical Device Testing Laboratories in order to boost manufacturing of quality medical devices.

2.2.2 Intended Beneficiaries and Eligibility Criteria

i. Central/ State Government or Private institutions interested to establish or strengthen testing facilities for medical devices to test Class A, B, C and D medical devices including In-vitro diagnostic medical devices under MDR, 2017.
ii. Such legal entity under the Indian law will open a separate account for the funds to be utilized for the projects assisted under the sub-scheme.

2.2.3 Incentive under the scheme

For Testing Facilities (TF) of Medical Device (MD) products, the limit of support will be 70% of the approved Testing Facilities project cost or Rs. 5 cr., whichever is less in case of state government funded entities and 50% of the approved Testing Facilities project cost or Rs. 5 cr., whichever is less, in case of Private Institution, as per the approval of SSC. Any expenditure above the prescribed limit shall be borne by the selected applicant.

2.2.4 Physical and Financial Outlay

Year	Physical Target (In No.)	Financial Outlay (Rs. in Crores)
	Testing labs	Testing labs
Year 1	0	0
Year 2	1-4	15
Year 3	5-8	15
Total	4-8	30

2.2.5 Modalities for utilization of incentive

i. The cost of project shall include cost of land, building, internal infrastructure, administrative and management support expenses including the salary of Manager, Lab Technicians, Medical Device Officers and other experts and staff during the project implementation period (before commissioning), preliminary expenses, machinery & equipment, miscellaneous fixed assets and other support infrastructure such as water supply, electricity and margin money for working capital. However, *Grant-in-Aid from DoP will not be utilized towards land and building components of the project or construction of rest house, administrative buildings or any other building*, which in the opinion of SSC may be categorized as non-essential construction for the technical requirements of project.
ii. In case, the Central/State Government or private Institution provides an existing land and building, the cost of the same will be decided on the basis of valuation report prepared by an approved agency of Central / State Government Departments / Financial Institutions (FIs) / Public Sector Banks and the cost of land and building may be taken towards contribution for the project.

iii. In case, the Central/State Government or private Institution provides an existing land and building on lease separately, then the *minimum period of lease must be 30 years* for both land and Building. In case the National or State Government or private Institution provides an existing land, building on the same land on lease, then the minimum period of lease for combined land and building must be 30 years.

iv. *Minimum of 50% of the approved project cost has to be contributed by private Institution* for the project & there is to be no duplication of funding for the same component/ intervention*. For the* Central/State Government *Institution, Minimum of 30% of the approved project cost has to be contributed.* The Central/State Government or private Institution may dovetail funds from other sources as well for the project, provided there is no duplication of funding for the same component/ intervention. Resource raised through such dovetailing will be in addition to the 50% contribution of the Institution.

v. Assistance for Administrative and other management support of the Institution during the project implementation period *shall not exceed 5 % of the Grant-in- aid*.

vi. Proportionate contribution by the Central/State Government or Private Institution's share should be made upfront. Necessary infrastructure like land, access road, water and power supply, etc. must be in place or substantial progress should have been made in this regard before DoP assistance is released. Where bank finance is involved, written commitment of the bank concerned to release proportionate funds will also be necessary before release of DoP assistance.

vii. Escalation in the cost of project over and above the sanctioned amount, due to any reason will be borne by the Central/State Government or Private Institution. The Central Government shall not accept any financial liability arising out of operation of the testing facility.

viii. Central/State Government or Private Institution shall be responsible for obtaining all necessary statutory clearances in a timely manner.

ix. User charges for services of Testing facilities will be graded in such a manner that average charges will be lesser than prevailing market prices.

x. The Testing Facility may be utilized by the respective National or State Government or Private Institution on 'user charges' basis as decided by it.

2.2.6 Eligible Activities: An indicative list of eligible activities, for the testing facilities for the MD clusters, under this Scheme are as under:

i. Component Testing Centre for ESDM/PCB/Sensors facility
ii. Electro-magnetic interference & Electro Magnetic Compatibility testing lab
iii. Biomaterial / Biocompatibility /Accelerated Aging testing lab
iv. Electronic and Electrical measuring, calibration and testing center
v. AERB and NABL Certified X-ray Radiation testing lab
vi. Other Medical Devices testing lab etc.

2.2.7 Project Proposal and its components

i. The project proposal must have technical recommendation from competent technical body (e.g. CDSCO/ National Institute of Biologicals (NIB)/ National Accreditation Board for Testing and Calibration Laboratories (NABL), NIPERs/ IITs, Council of Scientific and Industrial Research (CSIR), Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) etc. may be the competent authority to grant technical recommendations). In case of PMA / SSC not being satisfied with the technical recommendations, the PMA / SSC may ask the SPV to obtain technical recommendations from specific competent experts.

ii. Project proposal may include have the following details:

a. Details about the Medical Devices testing Facilities;
b. Benefit/Objective/ Salient features of the Medical Devices Testing Facilities
c. Premises showing location and area of the different sections;
d. Qualification, experience of technical staff employed for testing and the person in-charge of testing;
e. List of equipment with specifications and their utilisation procedure;
f. Classes of medical Devices and list / type of tests that are proposed to be performed in the facility along with the Procedure of testing going to be followed; This should contain the Standards of Medical Devices – BIS or ISO or the respective Standards.
g. Tests and the purpose of the testing should also be furnished.
h. Type of support provided by Medical Devices Testing Facilities to manufacturer and Medical Devices Industry.
i. PERT/Critical Path Method (CPM)/ Gantt Chart for completing the Medical Devices Testing Facilities;
j. Action Plan for getting MD-40 issued by the CDSCO to get notified as MDTL under MDR-2017.
k. Action Plan for getting accreditation certificate issued by National Accreditation Body for Testing and Calibration Laboratories or any other similar body as may be notified by the Central Government.
l. Details of Fees to be charged for Medical Devices product testing from users.
m. Operation & Maintenance plan of the Medical Devices Testing Facilities
n. Action plan for enhancing competitiveness of Medical Devices Testing Facilities and positioning the Medical Devices Industry on a self-sustaining trajectory of growth. The proposal will have direct linkages between the impediments/bottlenecks identified and the measures recommended for improvement.
o. Implementation schedule to contain:

I. Activity-wise time schedule
II. Milestone for payments
III. Expected date of Commissioning
IV. Delay and expected Risk
V. Monitorable quantified targets for reporting on outcomes

2.2.8 Implementation Process & Timeline

i. PMA to invite project proposals for assistance under the scheme through newspaper / website, setting a cut-off date for receiving applications.
ii. PMA will handhold applicants to get registered and notified as a Medical Device Testing Laboratory to carry out testing or evaluation of a medical device on behalf of a manufacturer. Application will be made to the Central Licensing Authority accompanied with a fee through online portal of the Central Government as per the mandate under Medical Device Rules, 2017 and as per further amendments from time to time.
iii. PMA to scrutinize the project proposals and submit it appraisal report with recommendations to SSC within one month of last day of receipt of application for considering grant of in-principle approval.
iv. In-principle approval will be granted to those applicants who submit a complete project proposal with technical recommendation and have availability of land.

v. Such in-principle approval will be valid for a period of 6 months from the date of approval. In case final approval is not accorded to the project within 6 months, in-principle approval will automatically lapse, unless it is specifically extended by the SSC.

vi. PMA will guide the applicants, who obtain the 1st stage approval, to fulfill all necessary conditions in the guidelines within 6 months.

vii. A project will be accorded final approval by the SSC if the following conditions are fulfilled:

a. Registration of Institution;
b. Business Plan including processes, final projections and financial viability report and identification of impediments and bottlenecks
c. Execution of shareholder's agreement and other related agreements between the Institutions or Entrepreneurs in case of partnership, collaboration etc.;
d. Preparation of Project Proposal by Institutions or Entrepreneurs and its appraisal by PMA;
e. Procurement of requisite land by the Institutions or Entrepreneurs;
f. Establishment of project specific account with Scheduled Commercial Banks by the Institutions or Entrepreneurs. DoP would credit funds into this account;
g. Tying up of sources of funds for the balance amount.
h. Project Specific bank account shall be opened by Institutions or Entrepreneurs

viii. Projects to be completed in 2 years from the date of final approval of SSC. However, SSC can grant an extension of 6 months for delays due to reasons not in control of the applicant.

ix. In case of any deviation from the approved project proposal or time line, approval of DoP must be sought for continuation of project.

2.2.9 Selection Criteria

The selection of beneficiary will be based on appraisal by the PMA and recommendations of the technical Committee. Decision of the SSC will be final.

2.2.10 Schedule for release of Grant

(i) The release of funds by the Department will be based on scrutiny by the PMA and approval by the Scheme Steering Committee in the following manner:-

Installment	Percentage of Funds	Remarks/Pre-requisites
1st	**25**	• Raising of minimum 25% of SPV contribution and deposit in the appropriate account. • Signing of Indemnity Bond on final approval of the project by SSC.
2nd	**25**	• Against the production of Bills • 75% utilization of 1st instalment • Proportionate expenditure incurred by the applicant.

3rd	**25**	• Against the production of Bills • 100% utilization of 1st instalment • 75% utilization of 2nd instalment • Proportionate expenditure incurred by the applicant.
4th	**25**	• 100% utilization of 2nd and 3rd instalment • The Institution has mobilized and spent its 100% share in proportion of the first three grants. • Submission of Accreditation certification from NABL/AERB and Notified as Medical Device Testing Laboratory by Central Licencing Authority(CDSCO)

(ii) The Institution(s) or organization shall submit the Utilization Certificate (UC) in prescribed form (GFR-12A), generated through PFMS portal, duly certified by CA and countersigned by Head of Institution(s) or organization for the amounts utilized in accordance with GFR-2017. Also, the expenditure details need to be uploaded in the CNA module of PFMS before processing the case for subsequent instalments. Accounts of SPV shall be subject to audit by the Comptroller & Auditor General of India.

2.2.11 Maintenance and Ownership of Assets

i. Institution(s) or organization shall be responsible for O&M of assets created under the scheme by way of collecting user charges from the members/users;
ii. Institution(s) or organization shall ensure that the services of the facilities created under the scheme are extended to the cluster in general;
iii. The Assets acquired by the Institution(s) or organization out of government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.
iv. A register of permanent and semi-permanent assets acquired wholly or mainly out of the funds provided by Government of India should be maintained as per GFR.
v. If for any reason Institution(s) or organization is liquidated, Government of India will have the first right to recover the grant funds provided by it. The assets created with such grant funds and any unutilized fund shall be vested with the Central Government. The Memorandum of Association & Articles of Association of the Institution(s) or organization shall incorporate this provision.

2.2.12 Monitoring

(i) The PMA shall carry out regular monitoring of the implementation of the scheme and each project approved thereunder. The PMA shall prepare Monitoring Reports in the frequency and format as decided by the SSC and assist the SSC and DoP in monitoring the Scheme.

(ii) PMA will provide full access to scheme monitoring portal to the Department of Pharmaceuticals for monitoring purpose and shall monitor approved projects through physical inspection, implementation schedule based on Program Evaluation and Review Technique (PERT)/ Critical Path Method (CPM)/ Gantt Chart and submit monthly & quarterly reports of review of the projects to DoP/SSC for timely disbursement and utilization of the funds.

(iii) PMA shall identify potential delays and failure of projects to meet deadlines and propose corrective action as part of the Monitoring reports.

CHAPTER-III:

3. Marginal Investment Scheme for Reducing Import Dependence Scheme

3.1 Objective

To promote domestic production of key components, raw materials and accessories used in manufacturing of medical devices, including in-vitro diagnostic devices, in order to reduce dependence of Indian medical device manufacturers on imported key components and raw materials and increase the depth of our value chains.

3.2 Intended Beneficiaries

Central/ State Government Organizations, Companies/LLPs registered in India, Special Purpose Vehicle (SPV) registered under Companies Act or Societies Registration Act to manufacture key components / raw materials / accessories used in manufacturing of finished medical devices including *in-vitro* diagnostic medical devices.

3.3 Eligibility Criteria

a) Medical devices/in-vitro diagnostic manufacturers having manufacturing facility and/or intending to produce key components, input materials, accessories, which may reduce import dependence and enhance the depth of domestic value chains

b) Manufacturers of critical raw materials such as polymer, glass, metal, textile, paper, etc., having manufacturing facility and/or intending to manufacture medical grade raw materials or components or accessories for use in manufacturing of medical devices/ in-vitro diagnostic applications.

c) Manufacturers or importers who intend to manufacture any medical device or in-vitro diagnostic equipment that is on the GTE list and whose manufacture would lead to reduced import dependence.

3.4 Incentive under the scheme

3.4.1 The selected applicant will be incentivised through one-time capital subsidy on re-imbursement basis for manufacturing key components/ raw material/ finished devices/ accessories to reduce import dependence as per the table below: -

S. No	Turnover of the company	Eligible incentive
1	Up to 250 crore	20% of investment in the project or 10 crore whichever is less.
2	250 crore to 1,000 crore	15% of investment in the project or 10 crore whichever is less.
3	Above 1,000 crore	10% of investment in the project or 10 crore whichever is less.

3.4.2 Central/State Government Organizations will be supported with a grant of 20% of the investment in the eligible project or 10 crore, whichever is less.

3.5 Physical and Financial Outlay

Financial Year	Physical Target (no.)	Financial Outlay (Rs. in Crore)
	Facilities for key components, raw materials or accessories used in the manufacturing of medical devices	Grant-in-Aid
Year 1	0	0
Year 2	15	90
Year 3	15	90
Total	30	180

3.6 Modalities for computation of incentive

a) The total cost of project may include cost of land, building, internal infrastructure, machinery & equipment, miscellaneous fixed assets and related utilities such as water supply, electricity, steam etc. *However, subsidy or grant from DoP will be computed strictly on the basis of fixed investment excluding land costs.*
b) Escalation in the cost of project over and above the sanctioned amount, due to any reason, will be borne by the Central/ State Government or Private Institution or the Manufacturer. The department shall not accept any financial liability arising out of operations.
c) The Central/ State Government or Private Institution or the Manufacturer shall be responsible for obtaining all necessary statutory clearances in a timely manner.

3.7 Eligible Activities:

An indicative list of key components, raw materials, accessories used for manufacturing of medical devices/in-vitro diagnostics is given at **Annexure-II.** The SSC will be empowered to include additional items and/or revise the list as per exigencies from time to time and/or approve additional items beyond the list, if recommended by the technical committee after scrutiny of the applications received in this regard.

3.8 Project Proposal and its components

Project proposal may include, but not limited to have the following details: -

a. Details about the proposed manufacturing facility.
b. Benefit/Objective/ Salient features and rationale to justify how the produced key component, raw material, and accessories will reduce import dependence.
c. Premises showing location and area of the different sections.
d. List/segment of medical devices/in-vitro diagnostics for which the key components/raw materials/accessories are proposed to be manufactured.
e. Market size of the key components and other materials/ accessories used in manufacturing of finished medical devices.
f. PERT/CPM/ Gantt Chart for completing the manufacturing facility.
g. Action Plan for getting statutory approvals for the manufacturing facilities.
h. Details of expected increase in Domestic Value Addition in the finished medical device.

i. Operation & Maintenance plan of the project.
j. Action Plan for making the project self-sustaining.
k. The impediments/bottlenecks identified and the measures recommended for improvement.
l. Implementation schedule to contain:

I. Activity-wise time schedule
II. Milestone for payments
III. Expected date of Commissioning
IV. Delay and expected Risk
V. Monitorable quantified targets for reporting outcomes

3.9 Implementation Process & Timeline

i. PMA to invite project proposals through newspaper/website and set a cut-off date for receiving applications.
ii. PMA shall handhold applicants to get application registered for manufacturing key components, raw materials, accessories used in manufacturing of finished medical devices to reduce import dependence.
iii. PMA to scrutinize the proposals and submit its appraisal report with recommendations to the Technical Committee within one month for in-principle approval by SSC.
iv. In-principle approval will be valid for a period of 6 months from the date of approval. In case final approval is not accorded to the project within 6 months, in-principle approval will automatically lapse, unless it is specifically extended by the SSC.
v. A project may be accorded final approval by the SSC if the following conditions are fulfilled:
- Business plan including processes, final projections and financial viability report, identification of impediments and bottlenecks
- Execution of agreement and other related agreements between Institutions or entrepreneurs in case of partnership, collaboration etc.;
- Procurement of requisite land by the applicant;
vi. Project Specific bank account shall be opened by the applicant.
vii. Projects to be completed in 2 years from the date of final approval of SSC. However, SSC can grant extension for one year for delays due to reasons not in control of the manufacturer.
viii. In case of any deviation from the approved project proposal or time line, approval of DoP must be sought for continuation of the project.
ix. PMA shall be allowed to inspect the manufacturing facility if required and the applicant shall make the required documents/ assets available to the PMA or its authorized agency for purpose of verification.
x. Applicant may be required to furnish an undertaking as decided by the SSC.

3.10 Selection Criteria

i. Preference in assistance will be given to project proposals by SSC based on appraisal of project proposals by the PMA and TC.
ii. Preference will be given to those proposals which will lead to substantial reduction in import dependence and contribute to more domestic value addition.

3.11 Schedule for release of grant/subsidy

The release of funds by the Department will be based on scrutiny by the PMA, recommendation of Technical Committee, and approval by the Scheme Steering Committee

Disbursement	Remarks/Pre-requisites
10-20% of the project cost or Rs.10 crore whichever is less on re-imbursement basis.	1. After full completion of the project and commissioning of the product. 2. Submission of certificate from Chartered Engineer empaneled by the PMA verifying the plant and machinery installed. 3. Submission of Certificate from Statutory Auditor empaneled by the PMA for Investment made under eligible heads by the applicant in the manufacturing facility and First Sales Invoice. 4. Verification report by the PMA.

3.12 Maintenance and Ownership of Assets

i. The Central/ State Government or Private Institution or the Manufacturer shall be responsible for O&M of assets created under the scheme.

ii. The Assets acquired by the Institution(s) or organization out of government assistance shall not be disposed of, encumbered or utilized for purposes other than for which the funds have been released.

iii. If for any reason, Institution(s) or organization is liquidated during the implementation of the project, Government of India will have the first right to recover the grant funds provided by it.

3.13 Monitoring

3.13.1 The PMA shall carry-out regular monitoring of the implementation of the scheme and each project approved thereunder. The PMA shall prepare Monitoring Reports in the frequency and format as decided by the SSC and assist the SSC and DoP in monitoring the Scheme.

3.13.2 PMA will provide full access to scheme monitoring portal to the Department of Pharmaceuticals and shall monitor approved projects through physical inspection, implementation schedule based on Program Evaluation and Review Technique (PERT)/ Critical Path Method (CPM)/ Gantt Chart and submit monthly & quarterly reports of the projects to DoP/SSC for timely disbursement and utilization of funds.

3.13.3 PMA shall identify potential delays and failure of projects to meet deadlines and propose corrective action as part of the monitoring process.

CHAPTER-IV

4. Capacity Building and Skill Development in Medical Device Sector Scheme

4.1 Objective

The main objective of the component is to fill the gap existing in the education and research in medical devices sector and to ensure quality teaching, training and nurturing excellence in Medical Technology education for generating critical mass of trained human resource to meet the requirements of rapidly innovating multidisciplinary areas of Medical Technology and create R&D ecosystem for the sector.

4.2 Intended Beneficiaries and Eligibility Criteria

- Govt. universities/ institutes offering Postgraduate/PG Diploma/ Graduate/ Diploma/ Certificate courses in medical devices.
- Students willing to work in the medical device sector.
- Existing work force(regulators/technicians) already working in medical device sector.

4.3 Components of the scheme:

The Scheme has the following two components:

4.3.1 Component A: Support for running post graduate courses (MS/MTech/ PG-Diploma) in Medical Devices in existing institutes.

Financial assistance will be provided to Center Government Universities/Institutes for running multi-disciplinary post-graduate courses in medical device with objective of building infrastructure for education and research in medical devices and developing skilled workforce adaptable to changing requirements of Medical Device sector. These would be advanced level courses designed to train the students in multidisciplinary areas of MedTech. The teaching courses would be supported in the areas of Life Sciences and Biotechnology covering broader areas of basic sciences, medical, engineering, pharmacology, and allied areas with focus on specialized and new/emerging areas of medical devices which need to be incorporated as electives and core courses for imparting quality education and hands on training in Medical Technology. The Course curriculum would be approved by the relevant competent authority for the University/ Institute as per guidelines laid out in National Education Policy, 2020 (NEP- 2020) and National Credit Framework and in accordance with the expertise of core/collaborating faculty.

Admission of the students will be made through competitive examination open to students from medical, engineering, IT and Pharmaceutical backgrounds. Department of Pharmaceutical will provide up to 75% of the cost of the course or Rs 21 Cr., whichever is lower, on reimbursement basis. The remaining 25% of the cost will have to be borne by the institute concerned.

4.3.2 Component B: Capacity development in Medical Devices - design, production and testing

Financial assistance will be provided to the Central/State Government Universities/Institutes and Private Institutions (approved by NCVET) for running diploma, certificate and short- term training courses for existing workforce (clinical technicians, regulators) of medical device industry, students from pharmacology, engineering, technology and medical background willing to work in

medical device industry to equip them for the medical device sector and make them compatible with the requirements of the industry on reimbursement basis. Financial support based on the number of students (Rs. 25,000/student/month for diploma and Rs 10,000/student/month for certificate/ skill development training programs) will be provided to the trainee institute for the number of students enrolled.

4.4 Base Year: Financial Year 2023-24.

4.5 Annual Utilization Certificate - The release of grants-in-aid on reimbursement basis and the terms and conditions thereof including submission of utilization certificates shall be subject to the provisions of General Financial Rules.

- Each year a simple statement of accounts giving the funds received and expenditure incurred by 31st March needs to be submitted for release of the first instalment for the next year duly signed by the Accounts Officer of the Institute/ PMA.
- An audited statement would be essential for release of the next instalment of the annual grant from the second year onwards.

4.6 Final Settlement of the Accounts- The final settlement of the Accounts, which will be done only after the receipt of the following:

- Final audited statement of expenditure
- Final utilization certificate
- List of equipment procured for the project along with their cost, date of purchase, and suggestions for disposal.

The grant paid by the DoP shall be refunded by the institution as and when the programme is discontinued midway or the detailed conditions as laid down and approved by the DoP are not followed. All raw data (in all forms) should be made available/accessible to DoP, if needed.

4.7 Integrity Compliance: Integrity compliance refers to the systematic and conscientious efforts taken by individuals, organizations, or entities to ensure that their actions, decisions, and operations are conducted in a manner that upholds high ethical standards, honesty, transparency, and legality. It involves implementing policies, processes, and controls to prevent and detect any behaviours or practices that could compromise integrity, such as corruption, fraud, conflicts of interest, and other unethical conduct. Integrity compliance aims to create a culture of integrity within an organization and maintain the trust of stakeholders while also ensuring compliance with relevant laws and regulations. An undertaking to be submitted by both PMA & Institute as described in **Annexure-III.**

4.8 Eligibility criteria

Central Govt. Institutes having facilities in either one or more disciplines identified under the focus areas of the scheme (Medical Devices) by the DoP & PMA.

The applicant institutions will be selected based on their Proposals for financial assistance for Postgraduate (MSc/MTech/ PG Diploma) and Certification/Training courses submitted in the prescribed format, highlighting the learning outcomes against each course-curriculum, core or optional, and the practical-hands-on- exposure given to the students on pre- defined objective criteria to assess their eligibility.

4.8.1 Component A: <u>Support for running post graduate courses (MS/MTech/ PG-Diploma) in Medical Devices in existing institutes</u>

Support to up to 4-8 selected Central Government institutions/ year [for 3 batches] for running PG coursework for Students [batch size of 30] selected by the Institution through their approved admission process. Department of Pharmaceutical will provide up to 75% of the cost of the course or Rs 21 Cr., whichever is lower, on reimbursement basis. Out of which, up to Rs. 15 Cr as non-recurring expenses for infrastructure/Lab Equipment & machinery and Rs. 6 Cr as recurring expenses for salary, wages, and consumables etc. will be provided to an Institute. The remaining 25% of the cost will have to be borne by the institute concerned.

4.8.1 Eligibility Criteria:

4.8.1.1 Government University/Institution should have in house faculty members or may hire Professor of Practice/ Industry Expert faculty necessary for running the course for proposed teaching program in Medical Technology for a batch strength of 20-30 students/year.

4.8.1.2 The institute must also have teaching facilities for other inter-related courses, viz., medical science, manufacturing, medical electronics, mechanical/electrical engineering, bioengineering, Information Technology, Pharmacology, IP and departments imparting education in allied areas at the premise or in collaboration with other institutes.

4.8.1.3 Institutions will have flexibility to draw structure / content of course with mandatory inclusion of course component inputs shared by DoP as specified in **Annexure-IV.**

4.8.1.4 It will be ensured that course curriculum is approved by the relevant competent authority for the University/ Institute and in accordance with the expertise of the core/collaborating faculty and Course curriculum should be in line with National Education Policy, 2020 (NEP 2020) and credits for course should be as per National Credit Framework (NCrF) with mandatory component as mentioned in **Annexure-V**

4.8.1.5 The selected institutions should incorporate the recommendations provided by DoP, as outlined in **Annexure-VI** into their coursework.

4.8.1.6 Critical equipment for initiating the course. A suggested list of lab equipment necessary to initiate the course has been attached in **Annexure-VI**

4.8.1.7 The Institute must provide the laboratory experience at the premises or in collaboration with other institutions. Students should be directed to common instrumentation facilities, wherever feasible, to prevent duplication of resources and for optimum utilization of the facilities available.

4.8.1.8 The institute must provide clinical immersion (1-2 months) and apprenticeship (3-6 months) for the students.

4.8.1.9 Shortlisted Institution should have adequate supporting staff like laboratory assistants/ attendants, LDC/UDC/Stenographer, Peon etc.

4.8.1.10 Shortlisted Institute should meet Eligibility Criteria (such as Infrastructure etc.) as attached in **Annexure-V.**

4.8.1.11 Admission of the students will be made by the individual institutes, as per the standard process adopted by them to admit graduate students from medical, engineering, IT and pharmaceutical background etc. Selection procedure should ensure the selection of diverse cohort of students.

4.8.2 Financial mechanism:

4.8.2.1 Financial support up to 75% of the cost of the course or Rs 21 Cr., whichever is lower, will be

given to existing central government institutions on reimbursement basis, having the necessary infrastructure (building, space, lab etc.) and faculty to start the course. Support for non- recurring expenditure (for upgradation of the existing infrastructure and lab equipment) and for recurring expenditure (consumables, contingency, salary & wages, etc.) will be provided for running the courses. The remaining 25% of the cost is to be borne by the Institution itself.

4.8.2.2 Grant of up to Rs. 15 Crore for non-recurring expenses will be given to the institute to upgrade its infrastructural facilities as relevant/required for conducting the coursework, while up to Rs 6 Crore for recurring expenses such as salary, wages and consumables etc., as considered necessary by the PMA/SSC.

4.8.2.3 The quantum of the amount of grant will depend on the quantum of facilities to be upgraded / newly established as identified by the PMA and Steering Committee.

4.8.2.4 Financial assistance would be for the upgradation of facilities for conducting coursework on Medical Devices for training.

4.8.2.5 The grant will be released (as reimbursement) to the Head/Director of the institute, utilization certificate will be furnished by the institute to DoP & PMA.

4.8.2.6 The Institute will maintain a separate account of the funds received under the scheme and will furnish the audited statement of accounts, carried out by 'statutory audit body' of the institute.

4.8.2.7 Faculty support up to 2+1 years (Scheme Financial Outlay) will be provided as reimbursement basis to the universities/ institutes for running multi-disciplinary courses in medical devices, with approval of the competent authority concerned subject to written commitment by the institute to sustain the faculty through their own resources before the end of the scheme. An undertaking will be submitted by the Institution as per **Annexure-III.**

4.9 Component B: Capacity development in Medical Devices - design, production Quality testing and regulation

Support to selected Central/State Government Universities/institutions and Private Institutions (approved by NCVET) to provide Diploma to Students/ trainees/ existing workforce [batch size of 20] selected by the Institution through their examinations under this scheme in Medical Devices. Department of Pharmaceutical will provide financial support as reimbursement basis up to Rs. 25,000/month per Student for diploma.

Support to selected Central Government institutions/ year [for 3 years] to provide Short-Term training courses of 6 months to trainees/ existing workforce [batch size of 20 for 6 months I.e., 40/year] selected by Institution on the basis of their evaluation criteria. Department of Pharmaceutical will provide financial support up to Rs. 10,000/month per Student for these Short-Term training courses.

7 to 15 selected institutions will be provided financial support based on the number of students (Rs. 25,000/month for diploma and Rs 10,000/student for certificate/ skill development training programs) on reimbursement basis to the trainee institute for the number of students enrolled.

Some of these short-term courses can be offered in various formats, such as Hybrid mode or as online MOOCs etc. as well as through evening/weekend batches allowing individuals to conveniently manage the coursework alongside their current job without the need to leave their present employment. All the Diploma, Certificate/ Short Term Skill Development Courses should be as per NEP 2020 guidelines, aligned to NCrF and must be affiliated with the awarding body

approved by approved by National Council of Vocational Education and Training (NCVET).

4.9.1 Eligibility and Selection of Institutes

4.9.1.1 Institutes/ organizations imparting training must have necessary infrastructure facilities for training of about 20-30 candidates.

4.9.1.2 Institute/organization must have strong industry linkages for training of candidates for hands on training and to provide a holistic learning experience.

4.9.1.3 Expertise and Experience: Institutes with proven track records of organizing successful diploma /certificate / Graduate/ PG courses in the past 5 years, especially related to pharma-MedTech sector would be given preference.

4.9.1.4 Curriculum and Course Offerings: Courses that cover topics such as medical device testing & design, manufacturing processes, quality assurance, medical device regulation, IP regulations etc. Each course offered under this Scheme should be affiliated with relevant awarding body approved by NCVET and must be compliant to NEP 2020 guidelines and National Credit Framework.

4.9.1.5 Availability of faculty and instructor: Qualified, trained faculty and instructor along with guest faculty from industry would be encouraged.

4.9.1.6 Industry Partnerships and Collaboration: Number of MoU signed with industry in past 5 years, number of trainings done with industry, post training recruitment rate, etc.

4.9.1.7 The selected institutions will incorporate the suggested coursework as outlined in **Annexure-IV.**

4.9.1.8 Shortlisted Institute should meet Qualifying criteria mentioned in **Annexure-VII.**

4.9.2 Financial mechanism:

4.9.2.1 Financial support based on the number of students Rs. 25,000/month for diploma and Rs 10,000/month for certificate/ skill development training programs will be provided to the trainee institute for the number of students enrolled.

4.9.2.2 The amount will be reimbursed to the parent institute for the expenditure incurred by the institute in running the course. SSC may decide on the cost components which may be admissible towards reimbursement and may also stipulate conditions for running the course, such as maximum fees that may be charged from the trainees. The parent institute will submit utilization certificate under the GFRs for the expenditure incurred.

4.9.2.3 The amount released under the scheme will be kept in a separate account by the institute concerned and a separate account of expenditure will be maintained.

4.9.2.4 The institute shall submit the utilization report and audited statement of accounts carried out by the statutory body of the institute.

4.10 Support can be withdrawn from Universities/Institutions under following conditions-

- If the total number of students admitted in a particular academic session is less than 50% of its intake.
- If the core faculty strength is less than applicable student teacher ratio
- Any administrative difficulties in running programme
- Delay in implementation of the program.
- Unable to impart quality teaching and training to students based on their feedback to DoP.

4.11 Selection of the applicants:

- Selection of the applicants in each component will be governed by the parameters given in **Annexure- V & VII**
- All eligible applicants shall be ranked based on marks obtained in the evaluation criteria as given in **Annexure - V & VII**
- The applicant securing highest marks shall be ranked 1, followed by applicant securing second highest marks and so on.
- The selection of the applicants shall be in the order of their ranks.
- If two or more applicants have the same score, the applicant having higher marks in respect for academic criteria will be ranked higher for component A. As regard Component B, the institutes with higher industry recruitment rate will be ranked higher.
- Number of applicants to be selected: **Component A: 4-8/ Component B: 7-15**

4.12 Physical and Financial Outlay

Financial Year	Physical Target (no.)		Financial Outlay (Rs. in crore)		
	Component - A	Component - B	Component - A	Component - B	Total Grant-in-Aid
Year 1	0	1-7	0	0	0
Year 2	1-4	1-7	42	8	50
Year 3	5-8	8-15	42	8	50
Total	4-8	7-15	84	16	100

4.13 Call for Application:

- The applicant is required to submit the application as per the form prescribed in **Annexure-VIII** to the PMA.
- The Scheme will be open for applications during the Application Window which is 30 days twice in a year **(No application shall be accepted after the end of the Application Window.)**
- A period of 30-40 days will be considered as application under scrutiny after the closure of application window.
- An applicant needs to submit the application in the format as at **Annexure-VIII.**
- On the receipt of an application in the prescribed format, PMA will conduct an examination as per the checklist. The aforesaid examination shall be completed within 30 working days from the date of the receipt of the application or any subsequent submission of the revised application if the original application was returned as incomplete earlier. Thereafter, the PMA shall issue an acknowledgement of receipt of the application. This acknowledgement shall not be construed as approval of the Scheme.
- In case, on the above-mentioned examination, an application is found to be incomplete, PMA shall inform the applicant accordingly within 30 working days of receipt of the application. An applicant must complete an incomplete application within 30 days of such communication from PMA, failing which the application will be closed under intimation to the applicant.

4.14 Approval and disbursement of funding under the Scheme

- An application, complete in all aspects, will have to be submitted before the due date.

Acknowledgement will be issued by PMA after initial scrutiny of the application.

- The eligible applicants will be appraised on an ongoing basis and considered for approval, based on predefined selection criteria. PMA may seek advice from the Advisory Committee for technical assistance on same.
- The funding shall be released to the selected participants under the scheme who meet the required criteria on reimbursement basis.
- Timely disbursals of funding by the PMA will be monitored by DoP and reviewed by the Steering Committee, subject to budgetary allocations.
- The funding will be provided as defined in scheme guidelines in respect of a maximum period of 2+1 years from the date of approval.
- The progress in approval of applications and disbursal of funding shall be monitored on an on-going basis against the monitoring framework to be specified in the guidelines.
- The PMA shall recommend two (02) waitlisted applicants, if available, along with selected applicants for each target segment.
- All the applications will be finalized within 60 days from the date of closure of the application window.
- After receiving approval from the DoP, the PMA will issue a letter to the selected applicant within 5 working days, communicating approval under the Scheme. The approval letter shall clearly mention the following:

    i. Name of Applicant
    ii. Course(s) Selected
    iii. Funding Allocated

- The selected applicant shall submit, within two weeks of the date of issuance of approval letter by the PMA, the details of No lien account on bank's printed letter head as per **Annexure-IX.**
- The aforesaid approval letter shall not be construed as a guarantee for disbursement of incentive as the same will be dependent upon verification of eligibility after submission of disbursal claim and other criteria defined in these guidelines.
- If the selected applicant is found to be ineligible at any stage, or if it has not compiled with notifications, orders, guidelines etc., of the Scheme, or declines the offer of the approval under the Scheme at any stage, for any reason, the offer letter issued shall stand cancelled. In such case, the offer shall be extended to the waitlisted applicant for the period remaining.
- For claiming incentive under the Scheme, applicants will be required to submit claims for disbursement of incentive to the PMA. Applicants must ensure that the claims are complete in all respects and are accompanied by all the documents required as per prescribed format and made available on the online portal.
- An applicant may submit a claim for disbursement of incentive on an annual basis. Claims for any period shall be made only once, unless withdrawn, and no subsequent part claims shall be allowed for the said period.
- Claims for disbursement of incentive shall be filed along with supporting documents within one month of the closure of the given financial year. If the claim is found to be in order, same shall be released after submission of final audited account and UC.
- The PMA shall examine and verify eligibility and assess incentive payable to an applicant based on the method laid down in these guidelines and the approval letter issued to the applicant.
- The PMA may seek the advice of the Advisory committee for technical assistance. PMA will

have the right to verify any document(s) in relation to the claim for incentives, including but not limited to Statutory Auditor or Independent Chartered Accountant certificates, whichever is applicable, and returns furnished to various Ministries / Departments/ Agencies.

- The PMA will have the right to carry out physical inspection of an applicant's institute through site visit, if and when directed by SSC.
- In case of any doubt with respect to determining eligibility and incentive amount due, or any other matter in discharge of its duties and responsibilities, the PMA may refer such matter to DoP for clarification and the decision of DoP shall be final in this regard
- The PMA shall process claim for disbursement of incentive within 60 days from the date of receipt of such claim and make appropriate recommendations to SSC.
- SSC will consider claims for disbursement of incentive, as examined and recommended by the PMA:

a. PMA will maintain a separate Bank Account for receipt of funds from DoP related to the incentives and make disbursements of incentive amount to the applicants upon approval of the claim by DoP. All interest earned on this account shall accrue to the Consolidated Fund of India.

b. PMA shall disburse the incentive through direct transfer (via PFMS) after approval of the claim and completion of all pre-disbursal formalities by the applicant.

- DoP shall make budgetary provisions for disbursal of incentives under the Scheme. The PMA will submit budgetary requirements to DoP as a consolidated amount on quarterly basis.
- The PMA shall furnish applicant wise statement of all claims received, processed and approved and all incentives, disbursed and pending, to DoP on quarterly basis.

4.15 Monitoring and Evalution

The work and progress of the scheme will be evaluated periodically by the PMA and the Department of Pharmaceuticals.

4.16 Project Administration

As regard administration of the scheme, a Project Management Agency (PMA) will be appointed by the Department of Pharmaceuticals. No regular posts need to be created at the PMA specifically for the purpose.

4.17 Implementing Agency

The scheme will be implemented by DoP, which will exercise overall managerial control. The funds for implementation of the scheme in respect of approved projects /proposals will be released by DoP.

4.18 Terms and Conditions:

The general and specific category-wise terms and conditions of the Scheme are as per **Annexure III to X.**

4.19 Role of PMA

The scheme shall be implemented and monitored through a Project Management Agency (PMA)

which will be responsible for providing secretarial, management and implementation support and to carry out other responsibilities as assigned by DoP within the framework of scheme and guidelines thereof. The PMA, on behalf of DoP, will be responsible for receipt and appraisal of applications, verification of eligibility and examination of disbursement claims through any method / document deemed appropriate and or managing the above-mentioned in accordance with these guidelines.

The PMA shall be responsible, *inter alia*, for:

4.19.1 Development and maintenance of dashboard for:

COMPONENT A

- Enrollment of students, completing coursework and being successfully placed.
- Number of Faculty available in the institution for the course.
- Course Design – Elective and compulsory subjects.
- Record of Students Any startup / entrepreneurship idea incubated or formulated.
- Placement Report of Students.
- Feedback Evaluation on Coursework Component for posterity.

COMPONENT B

- Enrollment of the students and their completing coursework
- Record of professionals trained on Quarterly / Yearly basis
- Record of professionals absorbed in Industry and Salary Increments, if any
- Feedback Evaluation on Coursework Component for posterity

4.19.2 Industrial Training Output Monitoring

- Regularly review the scheme's objectives and make necessary adjustments based on feedback and changing needs.
- Incorporate new technologies and advancements in medical technology to keep the training up to date

4.19.3 Track Enrollment and Participation Rates

- Monitor the number of students and professionals enrolling in the program.
- Track participation rates to ensure a sufficient pool of candidates are benefitting from the scheme.

4.19.4 Retention Rate and Completion Rates

- Monitor the retention rate of enrolled candidates throughout the training period.
- Track the completion rate of students successfully finishing the training program

4.19.5 Feedback from Trainees

- Conduct regular surveys to gather feedback from trainees about the quality and relevance

of the training.
- Use the feedback to make improvements and address any concerns.

4.19.6 Employment and Placement Rates

- Track the rate of successful employment and placement of trainees after completing the training.
- Assess the scheme's impact on enhancing employability and career opportunities for the participants.

4.19.7 Employer Feedback

- Gather feedback from employers who hire graduates of the training program.
- Evaluate their satisfaction with the skills and knowledge of the trainees.

4.19.8 Skill Enhancement and Knowledge Upliftment

- Evaluate the skill enhancement and knowledge upliftment of trainees through pre and post-training assessments.
- Analyze how the training has helped in filling knowledge gaps and improving practical skills.

4.19.9 Follow-up with Alumni

- Establish a follow-up system to track the progress of alumni in their careers.
- Measure their success and contribution to the medical technology field after completing the training.

4.19.10 Gender Inclusivity

- Monitor the representation of both genders in the training program.
- Assess efforts to ensure gender inclusivity and equal opportunities for all.

4.19.11 Long-term Outcomes

Monitor the long-term impact of the scheme on the medical technology sector, including advancements and innovations contributed by the trained professionals.

4.19.12 Comparison with Industry Standards

- Benchmark the training program against industry standards and best practices in medical technology education.
- Identify areas for improvement to align with international standards.

4.19.13 Public Awareness and Outreach

- Assess the effectiveness of public awareness and outreach campaigns to promote the scheme among potential candidates.
- Measure the scheme's visibility and its impact on attracting eligible participants

4.19.14 Application Monitoring

- Preparing operating procedures for processing, scrutiny, appraisal, verification, etc., as per procedure/established practice and getting them approved from DoP.
- Receiving and processing of applications against the qualification and evaluation criteria for the purpose of selection of participants.
- Inspection of the institute if required by the SSC

4.19.15 Departmental Support

- Placing the appraisal reports of shortlisted participants before the DoP for its concurrence.
- Preparation of agenda papers for meetings and providing secretarial assistance to DoP for the same.
- Periodic submission of data at various stages of the scheme to DoP which includes compilation of data on cumulative progress done by selected applicants.
- Providing all necessary documents and information as may be required for the conduct of mid-term and end-of-term evaluation of the scheme. Providing utilization certificates in the prescribed format wherever applicable from applicants.
- A dynamic dashboard/registry of all outgoing candidates exiting through the post-graduate/diploma/certificate programs along with their skill sets and other details will be maintained

4.20 Completion of documentary formalities and issuance of approval letter to all selected institutes. Outcome of the scheme will be evaluated based on number of the manpower educated/ trained, number of manpower hired in the industry, number of start-ups created, number of IPs filed, etc.

CHAPTER-V

5. Medical Device Clinical Studies Support Scheme

5.1 Objective

To support the medical device industry by fostering development of devices supported by clinical evidence and generation of clinical data that demonstrates the safety and efficacy of the devices manufactured in India. This will promote manufacturing of quality products with better efficacy and safety. It will also enhance credibility of domestic manufacturers to produce high quality products, opening up opportunities for them in markets outside the country.

5.2 Intended Beneficiaries

(i) Medical device manufacturers, having manufacturing facility in India, intending to generate pre-clinical data by means of animal studies to demonstrate safety and performance of an investigational medical device in animal models.
(ii) Medical device manufacturers, having manufacturing facility in India, intending to conduct clinical investigation on human subjects to generate clinical evidence to demonstrate safety and performance of an investigational medical device.
(iii) Medical device manufacturers, having manufacturing facility in India, intending to conduct Post Market Clinical Follow-up (PMCF) studies on human subjects to generate clinical evidence to demonstrate safety and performance of a medical device.
(iv) In-vitro diagnostics manufacturers, having manufacturing facility in India, intending to conduct clinical performance evaluation on clinical samples to generate clinical evidence to demonstrate clinical performance of a new in-vitro diagnostic medical device.
(v) Institutes of national importance like NIPERs, IISER, IITs, AIIMS, IISc, etc., and other reputed Central Institutes or Laboratories involved in design and development, or in pre-clinical evaluation, or in the clinical investigation or clinical performance evaluation of medical devices or IVDs.

5.3 Eligibility Criteria

(i) Medical device manufacturers, having manufacturing facility in India, involved in design and development of an investigational medical device are eligible to apply to conduct animal studies as part of pre-clinical study. Applicant should be holding a test licence issued under the provisions of the Medical Devices Rules, 2017.

OR

(ii) Medical device or in-vitro diagnostic manufacturers, having manufacturing facility in India, involved in design, development and manufacturing of an investigational medical device or a new in-vitro diagnostic medical device, are eligible to apply to conduct clinical investigation or clinical performance evaluation, as the case may be. Applicant should be holding permission to conduct clinical investigation or clinical performance evaluation issued under the provisions of the Medical Devices Rules 2017.

OR

(iii) Medical device manufacturers, having manufacturing facility in India, involved in manufacturing of class C and class D medical devices are eligible to apply to conduct Post Market Clinical Follow-up studies. Applicant should be holding permission to conduct such study, as per regulatory norms, if any.

OR

(iv) Institutes of national importance like NIPERs, IISER, IITs, AIIMS, IISC etc. and other reputed Central Institutes or Laboratories may conduct the clinical investigation / clinical performance evaluation themselves or through any Clinical Research Organization approved by the Regulatory Authority. The Startups working in the Incubation Centres under these Institutes may also apply through these institutes.

5.4 Incentive under the scheme

The department will provide financial support in conducting clinical investigation/clinical performance evaluation/Post Market Follow-up Study/animal studies to the eligible applicants as referred to in clause 5.3, in the form of grant on re-imbursement basis as per the following criteria:

- Pre-Clinical Studies - Rs. 2.0 crore or 25% of the expenditure incurred, whichever is less;
- Clinical Investigations – Rs. 5.0 crore or 25% of the expenditure incurred, whichever is less;
- Post Market Clinical Follow-up – Rs. 1 crore or 25% of the expenditure incurred, whichever is less;
- Performance Evaluation of new IVDs – Rs. 1 crore or 25% of the expenditure incurred, whichever is less;

5.5 Terms for disbursement of incentive

i. The cost of project should include cost of conducting single or multi sites clinical investigation/PMCF. Expenditure incurred for subject enrolment, principal investigator fee, etc. may be claimed for re-imbursement. *The expenditure incurred for manufacturing the devices/new IVD samples used during study will not be eligible for re-imbursement.*

ii. Escalation in the cost of project over and above the sanctioned amount, due to any reason will be borne by the applicant. The department will not accept any financial liability arising due to delay in conducting/completion of clinical studies covered under these guidelines.

iii. The applicant shall be responsible for obtaining all necessary statutory clearances in a timely manner.

iv. The incentive under the scheme shall be disbursed on reimbursement basis on submission of statutory auditor certificate for the expenditure incurred during study and proof of publication of clinical study results. In case where applicant is an Institute of national importance like NIPERs, IISER, IITs, AIIMS, IISc, etc., or any other reputed Central Institute or Laboratory, the expenditure incurred shall be certified by their respective finance/account wing.

v. Mere approval of the proposal by the Scheme Steering Committee for consideration of the support does not guarantee disbursement of grant to the applicant. Disbursement of the grant will be subject to fulfilment of conditions under which approval is granted and its verification by the Project Management Agency up to the satisfaction of the SSC.

vi. The applicant will be required to sign undertaking/agreement as may be approved by the SSC.

vii. The applicant shall make available all records which may be sought by PMA for purpose of verification, allow PMA access to facilities which have been used in the study and individuals/authorities who may have been involved in the project.

viii. Re-imbursement of expenditure incurred will be restricted to Clinical Studies conducted within India.

5.6 Eligible Activities

A list of eligible activities, under this Scheme is as under:

i. Clinical investigation of an investigational medical device.
ii. Clinical performance evaluation of the new in-vitro diagnostic medical devices.
iii. Conduct of animal studies as part of pre-clinical activity for investigational medical devices.
iv. Conduct of Post Market Clinical Follow-up studies for the devices approved under provisions of Medical Devices Rules 2017.

5.7 Project Proposal and its components

Project proposal should have the following details:

a. Detailed process of conducting Clinical Investigations or Pre-Clinical animal studies for medical device or Clinical Performance Evaluation of new IVDs.
b. Expected gains from the clinical investigation / clinical performance evaluation.
c. Complete cost estimates for the proposed study and other activities till rolling out of the project.
d. Expected number of patients who will be benefitted in the study.
e. Expected overseas regulatory approvals for market authorization of the product with the help of clinical data generated from the study.
f. Approved Protocol by CDSCO for conducting clinical investigation/clinical performance evaluation/PMCF study.
g. Permission to conduct clinical investigation/clinical performance evaluation/PMCF study issued under provisions of Medical Devices Rules 2017.
h. Identification of impediments and bottlenecks.
i. Implementation schedule in the Action Plan to contain:

    1. Activity-wise time schedule
    2. Milestone for payments
    3. Expected date of Commissioning
    4. Delay and expected Risk
    5. Monitorable quantified targets for reporting outcomes.

5.8 Implementation Process & Timelines

i. Eligible applicants should submit complete proposal for conducting Clinical Investigations/PMCF or Pre-Clinical animal studies for medical device or Clinical Performance Evaluation of new IVDs
ii. PMA will scrutinize the proposals and submit its appraisal report with recommendations to the Technical Committee constituted for the evaluation of the proposals within one month.
iii. PMA shall submit the proposals, complete in all aspects, along with the recommendation of the Technical Committee to SSC for final approval.

iv. Approved clinical investigations/animal studies/clinical performance evaluation, shall be completed within 3 years or as per the approved timeline by the CDSCO. However, SSC can grant an extension of 1 year for delays due to reasons not in control of applicants.

v. In case of any deviation from the approved project proposal or time line, approval of DoP must be sought for consideration of financial support to the project.

vi. Financial support for clinical studies under this scheme may also be obtained along with support from Indian Clinical Trial and Education Network (In-TENT) initiatives of the ICMR. However, any duplication of financial support for the same purpose should be avoided.

5.9 Selection Criteria

I. Project proposals will be considered by SSC based on category of medical devices/new IVDs for which clinical studies are being conducted.

II. Preference in assistance will be given to those proposals which involve conduct of clinical investigation for investigational medical devices or for clinical performance evaluation for new in-vitro diagnostic medical devices or where the medical device under study is intended to be used for rare diseases, national health priorities and reducing dependence on import of high end medical devices.

5.10 Physical and Financial Outlay

Year	Physical Target (no.)	Financial Outlay (Rs. in crore)
	Support to pre-clinical studies, clinical investigation for medical device and clinical performance evaluation for in-vitro diagnostic medical device	Grant-in-aid
Year 1	0	0
Year 2	20-30	50
Year 3	30-60	50
Total	30-60	100

5.11 Schedule for release of Grant

The release of funds by the Department will be based on scrutiny and verification by the PMA with approval of the Scheme Steering Committee (SSC) in the following manner: -

Grant-in-Aid disbursement on reimbursement basis	**Pre-requisites**
• Performance Evaluation of new IVDs – Rs. 1 crore or 25% of the expenditure incurred, whichever is less; • Pre-Clinical Studies - Rs. 2 crore or 25% of the expenditure incurred, whichever is less;	• Final approval of the project by SSC. • Verification of the records and documents by the PMA. • The expenditure incurred on new studies taken up after the date of approval by the SSC will only be considered. • Submission of Certificate from Statutory Auditor along with supporting documents such as receipts in respect of total

• Clinical Investigations – Rs. 5 crore or 25% of the expenditure incurred, whichever is less; • Post Market Clinical Follow-up – Rs. 1 crore or 25% of the expenditure incurred, whichever is less;	expenditure incurred by the applicants for conducting Clinical Investigations or Pre-Clinical animal studies for medical device or Post Market Clinical Follow-up or Clinical Performance Evaluation of new IVDs. • Publication of the clinical data of Clinical Investigation/Post Market Clinical Follow-up/ Clinical Performance Evaluation. • Any other condition laid down by the SSC at the time of approval of the proposal.

5.12 Maintenance and ownership of assets/data

i. The assets/data acquired by the applicant out of government assistance shall not be encumbered or utilized for purposes other than for which the funds have been released.
ii. The clinical data generated through the study shall be maintained by the applicant for a minimum of 20 years and such data shall be made available to any Government agency as and when asked.

5.13 Expected Benefits

i. Improvement in quality standards of medical devices.
ii. Improvement in regulatory compliance specified for medical device
iii. Increase in export of Medical Devices based on Clinical Investigations or Pre-Clinical animal studies for medical device or Post Market Clinical Follow-up Clinical Performance Evaluation of new IVDs
iv. Promotion of domestic Contract Development and Manufacturing Organizations (CDMOs) industry.

5.14 Monitoring

i. The PMA/DoP shall carry out regular monitoring of the implementation of the scheme and each project approved thereunder. The PMA shall prepare Monitoring Reports in the frequency and format as decided by the SSC and assist the SSC and DoP in monitoring the Scheme.
ii. PMA will provide full access to the scheme monitoring portal to Department of Pharmaceuticals and shall monitor approved projects through physical inspection, implementation schedule based on Critical Path Method / Gantt Chart and submit monthly & quarterly reports.
iii. PMA shall identify potential delays and failure of projects to meet deadlines and propose corrective action as part of the monitoring process.

CHAPTER-VI

6. Medical Device Promotion Scheme

6.1 Objective

The scheme has two main objectives. The first objective is to promote Medical Device Industry by bringing industry leaders, academia and policy makers together to share their knowledge and experience for overall development of the sectors. The other objective of the scheme is to facilitate growth and development of the sectors through conducting studies, organizing awareness programs, creation of databases and promotion of industry.

6.2 Intended Beneficiaries

The medical devices industry in India will be the beneficiary of this scheme. Grants will be provided to any of the following: -

a. Recognized Industry associations and bodies.
b. Organizations/Firms with track record in conducting studies/survey etc. in medical devices and related sectors.
c. Government/quasi-government agencies with relevant experience.
d. Department may also directly incur expenditure on industry development activities.

6.3 Eligible Activities

(i) Preparation of study reports on topics of importance for Indian Medical Device industry.
(ii) Support to Medical Devices Organizations and Bodies to organize seminars, conferences, conventions, workshop & exhibitions (all such sessions individually referred to herein as the "**Event**").
(iii) Non-financial Logo support for Medical Devices events.
(iv) Creation of Database for the medical device sector.
(v) Organizing Mega events like annual India Medical Devices meet/ Medtech Expo and participating in other national or international events.
(vi) Organize events for promotion and development of Medical Device Industry
(vii) Support Bodies under the department such as Export Promotion Council for Medical Devices in their activities

6.4 Preparation of study/survey reports on topics of importance for Indian Medical Device Industry / Creation of Database for the medical device sector

This will include conducting studies/surveys & preparation of reports/database etc. by professional agencies of repute. The applications shall be invited through PMA on topics of importance for Medical Device industry as given to them by DoP. PMA will scrutinize the applications and submit its recommendation to SSC for approval and release of grant by the department will be as per following norms:

(i) The study/survey reports will be done through firms empanelled with NITI AAYOG or equivalent organizations (Ministries/Departments of Government of India), recognized industry associations, non-profit companies/ organizations, Private companies of repute and Government agencies.

(ii) DoP may implement this component through agencies selected on nomination basis. However, such agencies will be Government Autonomous bodies, PSUs or Government academic institutions.

6.5 Release of grants for preparation of study/survey reports

The applications shall be invited by PMA through an open and competitive bid, unless it is decided to nominate an agency as per para 19.4(ii) above. The PMA will scrutinize the applications and submit its recommendation to SSC for approval. If the grant is approved, it would be released in three instalments by the department as per following norms: -

(i) 30% will be issued along with sanction order after executing surety bond in the prescribed format.
(ii) 30% grant will be released on submission of the draft report along with executive summary. If required, presentations need to be arranged before the Department before this instalment is released.
(iii) Final instalment of 40% will be released on submission of the final report and its acceptance there on (10 hard copies and soft copies).
(iv) Any study report funded by the Government under the Scheme will be the property of the Department of Pharmaceuticals. This will be suitably acknowledged and shall not be used for any commercial purpose by the organization conducting study/ survey.

6.6 Support to Medical Device Associations / Bodies to organize seminars, conferences, workshop & exhibitions etc. in the form of grant in Aid

This will include organization of seminars, workshops, conferences, conventions, exhibitions, investor's meet, trainings, knowledge improvement programs/activities etc. on issues/subjects relevant to Development of Medical Devices sectors.

6.7 Organizations eligible for Grant

a. Government agencies such as academic institutions and autonomous bodies/ PSUs under the Department in Medical Device and related sector.
b. National/ State level Industries Associations in Medical Device and related sector.
c. Bodies under the department such as Export Promotion Council for Medical Devices
d. Any specialized organization having demonstrated expertise in the field in which proposed event is to be organized.

6.8 Implementation process

Eligible organizations seeking financial assistance shall apply at least 60 days prior to the proposed event on online portal. Preliminary proposals giving details of the proposed event, topic/theme of the knowledge dissemination event, likely speakers and participants and other details such as venue, likely date etc. will be required to be submitted. PMA will scrutinize the applications received on online portal and submit its recommendation to SSC for approval and release of grant by the Department. Grant-in-Aid under this component may be given upto Rs. 10 lakhs for a single event.

6.9 Physical Target and Financial Outlay

Financial Year	Physical Target (no.)	Financial Outlay (Rs. in crore)
Year 1	1-8	2
Year 2	9-15	4
Year 3	16-23	4
Total	15-23	10

6.10 Organize of seminars, conferences, workshop & exhibitions on the Initiative/Subject suggested by the Department

(i) For program being organized by Government Departments/ Institutions/ Agencies and for program organized by autonomous bodies, private agencies, industry associations, private institution, bodies under the department on the initiative/subject suggested by the Department full funding (100%) may be provided subject to realistic assessment of income and expenditure for the event and availability of budget

(ii) For activities organized by autonomous bodies, private agencies, industry associations, on their own initiative and having relevance to the mandate of the Department, assistance may be provided for not more than 75% of the cost of the event, with the concurrence of IFD.

(iii) For mega events, viz., India Medical Expo and other international events organized jointly by Department of Pharmaceuticals, the grant-in-aid will be worked out based on the estimates furnished and the parameters like expenditure incurred in the past by organizers etc. with the concurrence of IFD.

6.11 General conditions for availing Grant/Assistance.

(i) The grantee institutions would comply with the provisions of GFR 2017 as applicable and would comply with the instructions regarding EAT (Expenditure, Advance, Transfer) module of PFMS (Public Financial Management System) as issued by Ministry of Finance from time to time.

(ii) In case of conferences/workshops etc., the organization should agree to the participation of at least two Technical/Administrative officer(s) from Department of Pharmaceuticals free of charge as full delegates.

(iii) Department's fund will not be used for providing boarding/lodging, travel of speakers and delegates, any expenditure of recurring nature, and grant would not be released to an event manager.

(iv) All organizations receiving assistance under the Scheme will submit Utilization Certificate in GFR 12A format by 30th June of the subsequent financial year.

6.12 Terms and conditions for payments

The Grant-in-Aid will be released on submission of the following information /documents to PMA-

(i) Confirmed date of the event/programme.

(ii) Disclosure of sources of funding.

(iii) Confirmation from the organizers that no Utilization Certificate is pending in respect of previous grant(s), if any, availed from this Department.

(iv) Organizations receiving Grant for this component will be required to submit a report within two months after organization of the event on following lines: -

(a) Proceedings of the event.
(b) Copies/cutting of advertisements/publicity done.
(c) List of participants.
(d) List of resource persons with topics/presentation by them.
(e) Suggestions/Queries of participants, if any.
(f) Outcome of the event/recommendations for various stakeholders.
(g) Performance-cum-Achievement Report.
(h) Follow up action taken/to be taken.
(i) Details of actual expenditure and income earned (from all sources) after the event duly certified by Charted Accountant.
(j) Utilization Certificate in the prescribed proforma duly signed by the Head of the Organization.

6.13 Logo Support

Request for Logo Support of the DoP, inauguration /delivery of keynote Address by the Minister/MOS/Secretary /other senior Officers of DOP, Co-sponsorship by DOP without financial commitment, participation by officers of the Department as delegates should be specifically mentioned in the proposal clearly indicating profile of the organizations, performance of the past event, salient features of the current event, details of participants, list of speakers and other relevant information. Organizations will be permitted to use the Logo of the Department for display on publicity material as well as during the event with the prior approval of the Department. The Organization will have to ensure that while displaying the Logo of the Department of Pharmaceuticals, all the provisions of the Notification G.S.R. 643 (E) dated 4th October, 2007 of the M/o Home Affairs regulating the use of the State Emblemof India and time-to-time guidelines and conditions in this regard are strictly adhered-to. The organization would be expected to submit a report within two months of the event, outlining the proceedings, list of participants, recommendations, if any.

6.14 Creation of Database, MIS and IT Enabled systems for Medical Devices sector to enable informed policy decisions and program formulation

Under this component grant will be provided to the Government Organizations / agencies with proven expertise for creation of data base, MIS and /or IT enabled systems for the medical device sector. Funds will be transferred to select implementing agency either in form of Grant-In-Aid or budgetary allocation as the case may be. Suitable mechanism for selection of agency, monitoring and reporting of progress will be developed by PMA in consultation with Department of Pharmaceuticals under the supervision and guidance of SSC.

6.15 Organize any activity not covered under above components

Under this component Grant-in-Aid may be given to eligible organizations for organizing any industry facilitation and support measures, help desk, Advisory Forum and Development Committee meetings, etc. and any other activity, which may be decided with the approval of Secretary, Department of Pharmaceuticals in consultation with Financial Advisor of the Department.

Awards may also be given to encourage Startups, Innovators, Industry and similar entities for excellence in Medical devices sector in manufacturing, research, innovation, academic etc.

6.16 Expected benefits

The objective is to bring awareness about the policies and schemes of the Government and promote Medical Device Industry within the country as well as outside. Events supported under the scheme will bring industry leaders, academia and policy makers together to share their knowledge and experience for overall development of the sector. Also identifying problems/issues faced by the industry and possible solutions by way of workshops, seminars etc. Further, the studies and other activities are aimed at creating knowledge base about the sector The impact of these awareness, consultative and knowledge building initiates may not be directly linked to any physical output. Providing financial assistance to agencies will lead to promotion of investment & growth of medical device sector and will benefit the Meditech industry.

6.17 Monitoring

The PMA will monitor the implementation of the scheme component and ensure that study /survey reports are to the satisfaction of Department of Pharmaceuticals. Department will directly monitor that beneficiaries getting grant in aid under this scheme component achieve the desired results and comply the norms under the guidelines, along with the financial rules.

**** ***** ****

Annexure-I

Indicative chapters that may be included in the Detailed Project Report (DPR) to apply under the sub-scheme of Common Facilities for Medical Devices Clusters

S. No.	Contents
1.0	SPV Details with Checklist (minimum of 5 Medical Devices units, Medical Devices enterprises shall hold at least 51% equity of the SPV.)
2.0	Introduction
3.0	States: Diagnostic Study
3.1	Demographic Profile
3.2	Existing Infrastructure
3.3	Enterprise Profile
3.4	Market Characteristics
3.5	Raw Material Sourcing
3.6	Product Mix
3.7	Industry Analysis
3.8	Weak Supply of Raw Material (based on Project)
3.9	Slow Growth in Market (based on Project)
4.0	Need Assessment
4.1	Quality Assurance and Standardization
4.2	Availability of Raw Material (based on Project)
4.3	Access to Technology (based on Project)
4.4	Access to Market (based on Project)
4.5	Human Resource (based on Project)
4.6	Access to Funds (based on Project)
4.7	Description of Project (based on Project)
4.8	Project Rationale (based on Project)
4.9	Location of the Project (based on Project)
4.10	Management Details
5.0	Potential Entrepreneurs
5.1	Member Activity Description

Sl. No.	Contents
6.0	SWOT Analysis Of The Project
7.0	Proposed Project Components
7.1	Common Facility (based on Project)
7.2	Research and Development with Pilot Plant (based on Project)
7.3	Common Logistic Centers (based on Project)
8.0	Development of Project (based on Project)
8.1	Phase wise progress plan
9.0	Project Financials (based on Project)
9.1	Land Availability, Requirements & Proposed Utilization (based on Project)
9.2	Utilities Requirement Estimates (based on Project)
9.3	Details of Building and Estimates (based on Project)
9.4	Details of Land Development Expenditure (based on Project)
9.5	Details of Machinery, Equipment and Estimate (based on Project)
9.6	Details of Preliminary Expenses (based on Project)
9.7	Details of Pre-operative Expenses (based on Project)
9.8	Quality Control Testing Laboratory (based on Project)
9.9	R&D Centers (based on Project)
9.10	Clean Room & HVAC (based on Project)
9.11	Common Logistic Centre (based on Project)
9.12	Utility (based on Project)
9.13	Common Effluent Treatment Plants (CETPs) (based on Project)
9.14	Other necessary common Facilities requirement of the project (based on Project)
9.15	Details of Expenditure of Administrative (shall not exceed 5 % of the Grant-in-aid) (based on Project)
9.16	Cost Paid for Land (based on Project)
9.17	Means of Finance (based on Project)
9.19	Description of fund Raising (based on Project)
10.0	Financial Appraisal of Project (based on Project)
10.1	Appraisal framework and objectives (based on Project)

Annexure-II

Indicative list of Key Components/ Raw Material /Accessories

1. Sensors or sensor modules used in diagnostic equipment
2. Embedded system software / Standalone software used in/for medical devices
3. Closure and containers for capital equipment
4. Syringe Dispensing Pump/ peristaltic pumps
5. Turbine system/compressor pump for ventilators
6. Optical Filters for diagnostic / IVD equipment
7. Electrodes (Na+, K+, cl+, Ca+, pH+, Ref)
8. Antigen/Antibodies for detection of various Analytes
9. Microwell plates
10. Detectors for medical imaging equipment except flat panel detector
11. Primers and Probes for IVD Kits
12. Nitrocellulose (NC) membrane used in Lateral Flow IVDs
13. Haemodialysis membranes
14. Polymer Tubing components for disposable medical devices
15. Metal Tubing Components for implants
16. Acrylic Blanks/sheets for Intraocular Lenses
17. Speech Processors for hearing aids/hearing implants
18. UHMWPE Raw material (sheet/bar)
19. Stainless steel/Carbon steel and Titanium alloys materials used as raw material in medical devices manufacturing
20. Medical grade packaging material
21. Medical grade polymer granules/powders

Note: This is an indicative list, an applicant may apply for any other key component / raw material /accessory, however, the application will be reviewed by the Technical Committee for eligibility of the component/ raw material / accessory.

Annexure-III

Undertaking from the Institute

We, [**Institute Name**], hereby undertake the following conditions for availing the Scheme Financial Support on reimbursement basis to hire faculty to run the multi-disciplinary courses in medical devices for a duration of up to 4 years:

- We understand that the financial support will be subject to compliance with the guidelines and regulations set forth by the scheme's governing authorities.
- Regular progress reports and updates will be submitted to the concerned authorities to demonstrate the effective utilization of the financial outlay and the successful implementation of the courses.
- We commit to sustaining the faculty appointed for the multi- disciplinary courses by utilizing our own resources before the end of the scheme's duration.
- In the event of any changes or deviations from the proposed plan, we will promptly inform the competent authority and seek their approval.

[We hereby agree to abide by the above-stated conditions and acknowledge that an undertaking, as above will be submitted to the competent authority to formalize our commitment.]

Authorized Signatory:

[Name]
[Designation]
[Institute Name]

[Date]

Annexure-IV

Selected Institute to incorporate the following areas in their coursework

The following areas may be covered in medical device courses:

For Component A (PG Course):

Mandatory Foundational Courses:

1. Regulatory and quality compliances in medical devices
2. Foundation of human biology for medical devices

A minimum of 4 Foundational Courses selected from the following options (1-6) must be incorporated:

i. Mathematical modelling in medical device perspective (CAD/CAM etc)
ii. Materials in biomedical devices/engineering
iii. Basics in biosensors and bioelectronics
iv. Basics in design aspect of medical devices
v. IoT and machine learning in medical devices
vi. Cell and Molecular biology and bioinformatics in medical device perspective

Indicative list of specialization courses which can be included in the program:

i. Designing and prototyping of Medical Devices
ii. Advance Biomaterials
iii. Advanced fabrication approaches in medical devices
iv. Clinical translation of medical device
v. Medical imaging
vi. Tissue engineered medical device.
vii. Biomechanics
viii. Artificial organs
ix. Mathematical modelling and biological system controls in medical devices
x. In vitro diagnostics: principle and instrumentations
xi. Pre-clinical models (in vitro and in vivo)
xii. Additive manufacturing
xiii. Fluidics in medical devices
xiv. Bioelectricity
xv. Medical imaging
xvi. Bio-nanotechnology
xvii. Diagnostics and IVDs
xviii. Regenerative medicine
xix. Artificial intelligence in medical device
xx. Medical instrumentation

It is expected that a program will offer six foundational courses and two courses for any of the specialization areas.

For Component B (certificate course)

Broad areas of Certificate Course should cover these themes only:

i. Testing of medical device (safety and standards)
ii. Design aspect of medical device
iii. Medical Device regulation
iv. Additive manufacturing (3D printing)
v. Electronics assembly for biomedical machining
vi. Production machining
vii. Quality assurance for manufacturing
viii. Maintenance of robotics machinery
ix. Analytical skills of calibration and validation
x. Compound assembly
xi. Fluidics in biomedical devices

Annexure V

Parameters for Evaluation of Proposals Received for DoP Support under PG Program in Medical Devices

[Component A] Name of the University/Institute:

Name of PG Course Proposed:

Name of Program Coordinator/Representative:

S. No.	Criteria	Weightage (Total 100 Marks)	Remarks of TF
(A) Faculty		**20**	
1.	University/Institution should have a course relevant faculty (either by teaching experience or qualification) dedicated for the proposed teaching program in Medical Devices.		
(B) Course Curriculum		**10**	
2.	Syllabus should be in accordance with the model course curriculum inputs shared by DoP and in accordance with NEP 2020.		
3.	**Learning Outcome:** (a) Hands on training and skill set proposed to be provided (b) Existing Industrial Partnership and Practical Training (Industrial visit, Workshop, Industrial Training Output Monitoring) (c) Entrepreneurship Skills proposed to be Imparted		
(C) Collaboration		**5**	
4.	Existing Collaboration, if any, with **education/ research** institute for Medical Device courses • Academic collaboration • Research collaboration		
5.	**Student Exchange** • Existing Program • Existing academic exchange collaboration • Industrial training program		
(D) Research Ecosystem in Medical Devices and similar area		**20**	

6.	• Areas of Research & Development to be specified. • Existing Patents (Filed/Granted/Commercialized) • Research infrastructure a. Laboratories (at least 2 in number) for practical to accommodate minimum 20-30 students at a time. b. Lecture halls/rooms (at least 2 in numbers) for theory classes with the capacity of 20-30 students at a time. c. One storeroom and one library room in the Department. d. One Room for Head of the Department/Coordinator and 4 Rooms for other core faculty members e. One seminar/conference room. f. Supporting staff like laboratory assistants/attandants, LDC/UDC/Stenographer, Peon etc. g. Research papers/Joint Research Publication and citation h. NRF Ranking No. of Technology: Developed/Perfected/Transferred/Commercialized i. Entrepreurship Education and Training : Status of Incubator		
(E) Linkage Developed with Industry for Skill Training (Summer/Winter Training) as per standards of Sector Skill Councils		**15**	
7.	Skill Training Modules aligned with coursework		
8.	Existing **Industrial Partnership** and Practical Training (Industrial visit, Workshop, Industrial Training Output Monitoring)		
9.	**Expert Engagements** • Guest lectures by Industry Experts • International faculty		
(F) Placement Strategy for Students enrolled in Medical Device and similar field		**10**	
10.	Placement Support for industrial placements		
11.	Strategy for Engagement of Student in Higher Studies (PhD and Post Doctoral):		
12.	Facility for Training and Hand holding Support for Entrepreneurship		
13.	Career Counselling		
(G) Any Other		**20**	

14.	Past Workshops (of medical device and similar area) • Hands on training • Workshops • Industry expert talks		
	TOTAL	**100**	

Annexure-VI

Tentative List of Basic Instruments Required for initiating Medical Devices Course and Testing Laboratory

1. **Computational facility-** Computers (routine and high-end)/software (CAD/CAM etc)/servers/projectors/classroom aided materials/etc.
2. **Biosensor and Bioelectronic lab-** Material synthesis (basic stirrers/ovens/furnace),FTIR/electrochemical analyser/multimeter/power supplies/precision hand tools/soldering iron tools/oscilloscope/function generator/analog circuit-based generator/etc.
3. **Material fabrication facility-**weighing balance/magnetic stirrer/electrospinning/solvent baths/3d-printer/lathe machine/injection moulding/plasma coater/lyophilizer/polymer extruder/FE-SEM/SEM/TEM/AFM/UTM/contact angle/rheometer/ etc.
4. **Cell and molecular biology lab-** Cell culture lab (CO2 incubator/laminar flow/microscope/centrifuge/refrigerated centrifuge/water bath/electrophoretic unit/RT-PCR machine/transfer blot/nano drop/UV visible spectrophotometer/multimode reader/incubators/etc.

Annexure-VII

Parameters for Evaluation of Proposals Received for DoP Support under Diploma/ Short-Term Training in Medical Devices [Component B]

Name of the University/Institute:

Name of Diploma/ Training Course Proposed: Name of Program Coordinator/Representative:

S. No	Eligibility Criteria	Weightage
1	**Academic Need** • Certified faculty – Trained and Certified by relevant awarding body (approved by NCVET) • Existing diploma, certificate and short- term training courses. • Existing Training courses in IPR, regulatory affairs, and medical devices or any similar fields if any. • To initiate Courses in Following Areas [Regulatory/Pharmacology/IPR/Quality Control and Assurance/ Good Practices (GMP, GCP, etc.Medical Instrumentation, Maintenance and Repair]	15
2	**Existing Infrastructure** o Advanced Technology in Medical Device and similar arena o Safety and Necessary equipment o Availability of functional lab, library, classroom for training of 20-30 students with facility of in-house and on- spot training for the trainee	20
3	**Placement** • Previous track record of placement • Placement Cell in Institution for support • Career Counselling	15
4	**Earlier training program** • Quality training • Workshops / Hands on Experience • Support & Resources	15
5	**Proximity to Medical Device industrial area for Industrial Visit and Inhouse-Training**	10
6	**Customized training according to Industrial demand/ market Demand** • Training based on market demand. • Entrepreneurship Skills and start up ecosystem developed. • Industrial Training Output Monitoring	10
7	**Existing Collaboration** • Industrial partnership (particularly with medical device industry/hospitals) • Industrial expert talks • Industry academic collaboration • Hand's on Training • MoU's with stakeholders in Industry/Academic/Government	15
	Total	**100**

Annexure-VIII

Department of Pharmaceuticals Ministry of Chemical and Fertilizers Government of India

CALL FOR PROPOSAL FOR STARTING CAPACITY BUILDING AND SKILL DEVELOPMENT IN MEDICAL DEVICE SECTOR SCHEME IN MED-TECH PROGRAMME IN PARTNERSHIP WITH DEPARTMENT OF PHARMACEUTICALS

The Department of Pharmaceuticals, Ministry of Chemical and Fertilizers is seeking proposals from Indian Institutions for establishment of Training Centers under DoP Human Resource Development Programme in Medical Technology.

Programme Activities: The Department of Pharmaceuticals will provide support for following components under DoP Human Resource Development Programme in Medical Technology:

i. Students' Training Programme
ii. Technician Training Programme
iii. Refresher Course/Faculty Training Programme
iv. Entrepreneurship Development Training Programme
v. Medical Technology Finishing School Programme

Training Centre: Facilities in universities/institutes could be suitably modified and strengthened to act as a Training Centre. This center will be expected to impart quality skill training and enhance the job opportunities in the Medical Device sector.

Who can apply?

- Central University, Central autonomous Institute, Central Training Institute, Research Institute, with proven track record of conducting teaching/ training programmes in Medical Technology and related areas.
- The programme implementing University, Training Institute, Research Institute and State Councils/Organization should have requisite networking and linkages with other academic and research institutions to take advantage of existing expertise.

How to Apply?

Interested institutions/agencies/organizations should submit the proposal in prescribed format to PMA appointed by DoP within 30 days. Also visit the DoP website https://pharmaceuticals.gov.in/ for complete information and format for submission of proposal.

Checklist for preliminary assessment of Institute

S. No.	Parameter	Data as per Applicant	Comments from PMA
1	Name of applicant		
2	Application submission date		
3	Details of the applicant: • Type of Institute (Autonomous/Independent/Deemed to be University) • Student already enrolled • Recruitment Rate • Faculty employed to different courses		
4	Detail of course proposed		
5	Course Structure		
6	Details of Infrastructure in the institute (Faculty/ Research facility Equipment/ Other supporting staff an d basic infrastructure- Classroom/		
7	Auditorium etc.		
8	Detail of past MoU signed with the		
9	industry/academic institution		
10	NIRF Ranking		

PMA is authorized to make physical inspection and examine the document and as when required as per direction of SSC.

Annexure-IX

DETAILS OF NO LIEN ACCOUNT

(To be furnished on bank's printed letter head)

Ref. No. and Date:

Subject: No Lien account opened in favour of M/s _____for Course titled "_____" under Capacity Building and Skill Development in Medical Device Sector scheme.

Sir/ Madam,

At the request of M/s---------- , we have to advise you that we have opened a separate no lien account bearing No in our books for the purpose of crediting the
financial assistance aggregating to Rs. ---------- (Rupees ---------- only) sanctioned by you which may be availed of by the Institute under Capacity Building and Skill Development in Medical Device Sector Scheme for Course entitled "----------" and the Course cost component put in by the Institute amounts to Rs. ---------- (Rupees only).

We confirm that the said total sum of Rs. ---------- (Rupees ---------- lakhs only), as and when received by us either in part or in full, will be credited by us to the said no lien account and that we will not exercise or claim any right of set off or lien on any balance lying to the credit of the said account.

It is confirmed that we had not taken any other undertaking from the account holder contrary to the certificate issued hereto.

We further confirm that we shall furnish to the PMA/ Department of Pharmaceuticals, as and when required by it, a certified true copy of the No Lien Account.

Yours faithfully,
Chief Manager (Name & Seal of the Bank)

ANNEXURE-X

Proforma for Integrity compliance of Scheme

(To be signed by full time Director/ Registrar / Head of Institute, Head of PMA depicting the designation and submitted on official stationery of the applicant along- with the authorization to do so)

FORMAT-A

1. Whereas, the applicant namely (Director/ Registrar / Head of Institute, Head of PMA) has submitted an application under Capacity Building and Skill Development in Medical Device Sector Scheme for Pharmaceuticals, Government of India released on 8.11.2024 by Department of Pharmaceuticals (DoP) seeking application pertaining to running Postgraduate Coursework in Medical Devices.
2. Now, therefore, the applicant including its officers / representatives commits and undertakes that he / she will take all measures necessary to prevent corruption. He / She commits to observe the following principles during his / her association / engagement with DoP or its agencies or its consultants engaged with the process of appraisal and verification of application for the approval of application and disbursement of incentives:

a. The Selected applicant/PMA will not directly or through any other person or firm, offer, promise or give to any of the DoP's officer(s) or consultant or agency representative (appraisal or / and verification agency appointed by DoP to handle the application) involved in the process of dealing with application or to any third person any material or other benefit which he / she is not legally entitled to in order to obtain in exchange any advantage of any kind whatsoever before or during or after the process of the application for grant of approval or disbursement of incentives under Scheme.

b. The Selected applicant/ PMA will not commit any offence under the relevant IPC / PC Act; Further, the applicant will not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the DoP.

c. The Selected applicant shall disclose the name and address of the duly authorized Agents

d. Representatives who will be dealing with DoP or its agencies and the remuneration of these agents or representatives shall not include any hidden amount or component to get the work done in undue manner or causing inducement of whatsoever nature whether in cash or kind to influence the normal process or practice of work.

e. The Selected applicant/PMA will disclose any and all payments he / she has made, is committed to or intends to make to agents, brokers or any other

intermediaries, other than regular employees or officials of the applicant, in connection with the grant of approval or / and disbursement of incentives.

f. The Selected applicant/PMA will not offer any illicit gratification to obtain an unfair advantage.

g. The Selected applicant/PMA will not collude with other parties to impair transparency and fairness.

h. The Selected applicant/PMA will not give any advantage to anyone in exchange for unprofessional behaviour.

3. The Selected applicant/PMA declares that no pervious transgressions occurred in the last 3 years with any other Company in any country conforming to the anti-corruption approach or with any other Public Sector Enterprises / Central or State Government or its any instrumentality in India.

4. The Selected applicant/PMA agrees that if it is found that the applicant has made any incorrect statement on this subject, the application will be closed or rejected and DoP reserves the right to initiate legal action of whatsoever nature. In case if DoP has disbursed the incentives under scheme, the amount disbursed to applicant be recoverable along with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually besides blacklisting of the applicant and initiation of legal action of whatsoever nature at the discretion of DoP.

The contents of the above undertaking have been gone through and after understanding the same is being executed / given on……day of ..... (month / year)

Signature (Name & designation with address)

Director/Head