Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Operational Guidelines of the Scheme for Human Resource Development in Medical Device Sector

1. **Scheme in brief**:

In line with the Budget Announcement 23-24 that "dedicated multidisciplinary courses for medical devices will be supported in existing institutions to ensure availability of skilled manpower for futuristic medical technologies, high-end manufacturing and research", the scheme has been devised. The main objective of the scheme 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.

2. **Purpose of the Scheme:**

The scheme is expected to educate/ train around 5,400 students over a period of 3 years which will help in bridging the gap between industry and academia, provide skilled workforce to the industry and help in developing research & development ecosystem for medical device sector. The scheme aims to fulfill the objectives of the Medical Device Policy, which include reaching a $50 billion market size by 2030 and reducing India's dependence on imported high-end medical devices. The scheme aims to develop a specialized and skilled workforce tailored to the requirements of the medical device sector.

3. **Targeted Beneficiaries:**

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- 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. **Components of the scheme:**

The Scheme has the following two components:

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

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

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concerned.

4.2 **<u>Component B: Capacity development in Medical Devices - design, production and testing</u>**

Financial assistance will be provided to the Central Government Universities/ Institutes for running diploma, certificate and short- term training courses for existing workforce (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.

5. **KEY-TERMINOLOGY:**

5.1 Applicant: For Component A, eligible applicants would be Central Government Universities, /Autonomous Institutes/Institutes established by an Act of Parliament/ Institutes of National Importance offering Postgraduate (PG) courses in medical devices or inclined to run multi-disciplinary post-graduate courses in medical devices.

Applicants for Component B of the Scheme would be Central Government Universities/Institutes / recognized by statutory body for running diplomas, certificates and short-term training courses for students from multi-disciplinary background and existing workforce (technicians, regulators, faculty, etc.) of the medical device industry.

5.2 Application: Application is one 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.

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5.3 Application Approval Date: The date on which approval letter under the Scheme is issued by the PMA.

5.4 Application Window: Time period allowed for filing the applications.

5.5 "Medical device" has the meaning as defined under Medical Devices Rules, 2017 read with as defined under Section 3 of the Drugs and Cosmetics Act, 1940, as amended from time to time, and 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:
(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability
(iii) investigation, replacement or modification or support of the anatomy or of a physiological process
(iv) supporting or sustaining life
(v) disinfection of medical devices; and
(vi) control of conception.

5.6 Base Year: Financial Year 2023-24.

5.7 Duration of the Scheme: The duration of the scheme will be for a period of 3 years concurrent with the 15th Finance Commission from FY 2023-24 to FY 2025-26 (with financial outlay of scheme adjusted as per graduation of the last batch).

5.8 Financial Year: Financial Year begins on the 1st of April of a year and ends on 31st March of the following year.

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5.9 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).

5.10 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 providing secretarial, management and implementation support and to carry out other responsibilities as assigned by DoP within the framework of scheme and guidelines thereof.

5.11 Steering Committee (SC) - The Steering Committee with following composition would be constituted:

i	Secretary, Department of Pharmaceuticals	Chairperson
ii	Financial Advisor, Department of Pharmaceuticals	Member
iii	Joint Secretary (NIPER), Department of Pharmaceuticals	Member
v	Joint Secretary, (Medical Devices), Department of Pharmaceuticals	Member
vi	Joint Secretary, Department of Higher Education	Member
vii	Director/DS, Department of Pharmaceuticals	Convener

SC shall possess final authority concerning the approval of applications and any other matters pertaining to decision-making regarding the scheme. A quarterly review of the scheme will be done by the Steering Committee. The SC may revise ceilings under non- recurring and recurring heads as deemed appropriate during the tenure of the Scheme restricted to the SFC ceilings. However, the change, if any, in the ceilings, if required to be made, shall not result in exceeding the total financial outlay of the scheme. The SC will also be authorized to carry out any amendments in the Scheme and Guidelines

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thereof. The SC may hold stakeholder consultation as and when deemed necessary during the tenure of the Scheme.

5.12 Advisory Committee (AC)- A committee consisting of outside experts from institutes, industry, 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. The committee is expected to present suggestions, valuable perspectives, expert counsel, and furnish expert advice to the SC to make the final decision.

5.13 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.

5.14 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 from 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 investigator discontinues a scheme midway or does not follow the detailed technical programme as laid down and approved by the DoP. All raw data (in all forms) should be made available/accessible to DoP if needed.

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5.15 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-IV**.

6. ELIGIBILITY CRITERIA

Central Govt Institutes having facilities in either one or more disciplines identified in the focus areas of the scheme (Medical Devices) will be identified by the DoP & PMA, from various institutes all over the country.

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.

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

Support to up to 20 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 under this scheme in Medical Devices. 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

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to an Institute. The remaining 25% of the cost will have to be borne by the institute concerned.

6.1.1 Eligibility Criteria:

- 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.
- 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.
- Institutions will have flexibility to draw structure / content of course with mandatory inclusion of course component inputs shared by DoP as specified in **Annexure-V**.
- 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 I.**
- The selected institutions should incorporate the recommendations provided by DoP, as outlined in **Annexure-V**, Component A, into their coursework.
- Critical equipment for initiating the course. A suggested list of lab equipment necessary to initiate the course has been attached in **Annexure-III**.
- 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

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duplication of resources and for optimum utilization of the facilities available.

- The institute must provide clinical immersion (1-2 months) and apprenticeship (3-6 months) for the students.
- Shortlisted Institution should have adequate supporting staff like laboratory assistants/ attendants, LDC/UDC/Stenographer, Peon etc.
- Shortlisted Institute should meet Eligibility Criteria (such as Infrastructure etc.) as attached in **Annexure I**.
- 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.

6.1.2 Financial mechanism:

- 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.
- Grant of up to Rs. 15 Crore will be given to the institute to upgrade its infrastructural facilities as relevant/required for conducting the coursework while Rs 6 Crore for salary, wages and consumables.
- 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.
- Financial assistance would be for the upgradation of facilities for conducting coursework on Medical Devices for training.

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- 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.
- 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.
- Faculty support up to 3+1 years (Scheme Financial Outlay) will be provided as reimbursement basis at the universities/ institutes for running the multi-disciplinary courses in medical devices, with approval of the competent authority concerned subject to written commitment by the institute to sustain the faculty by their own resources before the end of the scheme. An undertaking to be submitted by Institution as per **Annexure IV**.

6.2 **Component B: <u>Capacity development in Medical Devices - design, production Quality testing and regulation</u>**

Support to up to 20 selected Central government institutions/ year [for 3 years] 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 up to 20 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 basis their evaluation criteria. Department of Pharmaceutical will provide financial support up to Rs. 10,000/month per Student for these Short-Term training courses.

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) will be provided on reimbursement basis to the trainee institute for the number of students enrolled.

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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).

6.2.1 Eligibility and Selection of Institutes:

- Institutes/ organizations imparting training must have necessary infrastructure facilities for training of about 20-30 candidates.
- Institute/organization must have strong industry linkages for training of candidates for hands on training and to provide a holistic learning experience.
- 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.
- 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.
- Availability of faculty and instructor: Qualified, trained faculty and instructor along with guest faculty from industry would be encouraged.
- 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.

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- The selected institutions will incorporate the suggested coursework as outlined in **Annexure-V.**
- Shortlisted Institute should meet Qualifying criteria mentioned in **Annexure II.**

6.2.2 Financial mechanism:

- 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.
- The amount will be reimbursed of the parent institute for disbursement to the fellow as per the prescribed norms and the parent institute will submit the utilization certificate under the GFRs for the expenditure incurred.
- 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.
- The institute shall submit the utilization report and audited statement of accounts carried out by the statutory body of the institute.

6.3 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.

6.4 Selection of the applicants:

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- Selection of the applicants in each component will be governed by the parameters given in **Annexure I & II.**
- All eligible applicants shall be ranked based on marks obtained in the evaluation criteria as given in **Annexure I & II.**
- 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 industry recruitment rate will be ranked higher.
- Number of applicants to be selected: **Component A: 20/ Component B: 20**

7. <u>Call for Application:</u>

- The applicant is required to submit the call for application as per the form prescribed in **Annexure VI** to the PMA.
- The Scheme shall 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 is considered as application under scrutiny after the closure of application window.
- An applicant needs to submit the application in the format as at **Annexure VI**.
- 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 15 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.

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- In case, on the above-mentioned examination, an application is found to be incomplete, PMA shall inform the applicant accordingly within 15 working days of receipt of the application. An applicant must complete an incomplete application within 15 days of such communication from PMA, failing which the application will be closed under intimation to the applicant.

8. <u>Approval and disbursement of funding under the Scheme:</u>

- 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 3+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:

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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 VII**.
- 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.

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- The PMA may seek the advice of the Advisory committee for technical assistance. 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 SC.
- 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 SC.
- SC 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, an applicant and product wise statement of all claims received, processed and approved and all incentives, disbursed and pending, to DoP on quarterly basis.

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9. MONITORING AND EVALUTION:

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

10. 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 be created at the PMA specifically for the purpose.

11. 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.

12. TERMS AND CONDITIONS:

The general and specific category-wise terms and conditions of the Scheme are as per **Annexure I-VIII**.

13. ROLE OF PMA:

The scheme shall be implemented and monitored through a Project Management Agency (PMA) as defined in para 5.10 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:

13.1 Development and maintenance of dashboard for:

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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

13.2 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.

13.3 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.

13.4 Retention Rate and Completion Rates

- Monitor the retention rate of enrolled candidates throughout the training period.

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- Track the completion rate of students successfully finishing the training program

13.5] 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.

13.6 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.

13.7 Employer Feedback

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

13.8 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

13.9] 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.

13.10 Gender Inclusivity

- Monitor the representation of both genders in the training program.

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- Assess efforts to ensure gender inclusivity and equal opportunities for all.

13.11 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.

13.12 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.

13.13 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.

13.14 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 SC

13.15 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.

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- 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

13.16 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.

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Annexure I

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		

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(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		
(E) 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		

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	/attendants, LDC/UDC/Stenographer, Peon etc. g. Research papers/Joint Research Publication and citation • NRF Ranking No. of Technology: Developed/Perfected/Transferred/Commercialized • Entrepreneurship Education and Training: Status of Incubator		
(F) Linkage Developed with Industry for Skill Training (Summer/Winter Training) as per standards of Sector Skill Councils		**15**	
8.	Skill Training Modules aligned with coursework		
9.	Existing **Industrial Partnership** and Practical Training (Industrial visit, Workshop, Industrial Training Output Monitoring)		
10	**Expert Engagements** • Guest lectures by Industry Experts • International faculty		
(G) Placement Strategy for Students enrolled in Medical Device and similar field		**10**	
11.	Placement Support for industrial placements		
12.	Strategy for Engagement of Student in Higher Studies (PhD and Post Doctoral):		
13.	Facility for Training and Hand holding Support for Entrepreneurship		
14.	Career Counselling		
(H) Any Other		**20**	
15.	Past Workshops (of medical device and similar area) • Hands on training		

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	• Workshops • Industry expert talks		
TOTAL		**100**	

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Annexure II

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-	20

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	30 students with facility of in-house and on- spot training for the trainee.	
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**

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Annexure-III

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

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Annexure-IV

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]

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Annexure-V

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

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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

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Annexure-VI

Department of Pharmaceuticals
Ministry of Chemical and Fertilizers
Government of India

CALL FOR PROPOSAL FOR STARTING HUMAN RESOURCE DEVELOPMENT 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.

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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.** The Institute Nodal Officer will submit the consolidated proposal on or before **30th XX, 2023** to **Dr. XX Email: YY**, Department of Pharmaceutical's, Ministry of Chemicals and Fertilizers, ADDRESS. Please also visit the DoP website https://pharmaceuticals.gov.in/ for complete information and format for submission of proposal under link 'Latest Announcements'.

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		

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	• Faculty employed to different courses		
3.	Detail of course proposed Course Structure		
4.	Details of Infrastructure in the institute (Faculty/ Research facility Equipement/ Other supporting staff and basic infrastructure- Classroom/ Auditorium etc		
5.	Detail **of** past MoU signed with the industry/academic institution		
6	NIRF Ranking		
7.	Internship offered during course and clinical immersion.		
8.	Details of faculty and other facilities		
9.	Course Structure		
10.	Details of Research ecosystem (Past patents filled, patents approved)		

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

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ANNEXURE VII

DETAILS OF NO LIEN ACCOUNT

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

Ref No.:
Dated:

Subject: No Lien account opened in favour of M/s ---------- for Course titled "----------" under HRD 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 HRD 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.

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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 VIII

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 HRD Scheme for Pharmaceuticals notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- **XX-NIPER dated XX/XX/XX** in Part-I, Section 1 of the Gazette of India (Extraordinary) to Department of Pharmaceuticals (DoP), Government of India 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

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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 behavior.

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

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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

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