



science & innovation

Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA



SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

MEDICAL DEVICE AND DIAGNOSTIC INNOVATION CLUSTER



Request for Applications (RFA):

Localization of Medical Device Manufacture

SAMRC-RFA-GIPD-02-2021

Release Date: 15 April 2021

Closing Date: 14 May 2021

1. Introduction

The mission of the South African Medical Research Council (SAMRC) is to improve the nation's health and quality of life by conducting and funding relevant and responsive health research, development, innovation and research translation. The SAMRC is the largest local funder of health research in Southern Africa and supports high quality research, innovation and capacity development through a variety of grant programs and strategic partnerships.

The SAMRC hosts the Medical Device and Diagnostic Innovation Cluster (MeDDIC) under its Global Health Innovation Accelerator (GHIA) Program. MeDDIC is a national initiative created to exploit a high concentration of skills, expertise, infrastructure and companies across South Africa within the medical devices field. The initiative, supported by the Technology Innovation Agency (TIA) and the Department of Science and Innovation (DSI), is aimed at stimulating and intensifying technology innovation within the sector as well as encouraging an integrated ecosystem in support of increasing the competitiveness of the industry.

The cluster model advocates for the participation of both public and private entities, such as but not limited to the DSI, the Department of Trade Industry and Competition (the dtic), National Treasury, the National and Provincial Departments of Health, Industry Associations (South Africa Medical Device Industry Association (SAMEDI) and the Medical Device Manufacturers Association of South Africa (MDMSA)), the Industrial Development Corporation (IDC), science councils and the higher education institutions. The cluster will also seek partnerships with international organizations, where appropriate. The intention is for an integrated ecosystem to be created by the cluster that can collectively address major challenges faced by the sector to achieve the common goal of a sustainable and competitive South African medical device industry.

2. Funding Opportunity Description

One of the key goals of MeDDIC is to increase the competitiveness of the local medical devices manufacturing sector and to increase the local content of medical devices utilized in the country. Together with pharmaceuticals, medical devices are the 5th largest contributor to South Africa's trade deficit. South Africa's domestic medical diagnostic and device industry imports 90% of the products by value with an increasing trade deficit in excess of R14.8 billion per annum. However, the sector has potential for reducing the trade deficit as well as increasing employment and improving healthcare, if the necessary processes and structures are put in place to encourage growth of the sector (BMI Research, 2017).

To address the medical devices trade imbalance, MeDDIC is seeking to fund opportunities for increasing the local content of existing medical devices by localizing the manufacture of either key components of or complete medical devices. The RFA is specifically aimed at medical devices already in the public sector market in South Africa that are either fully or substantially imported. As such, new medical devices in development will not be considered for funding unless they can directly replace an imported or largely imported device already in use in the public healthcare sector in the country. One such example of an identified need is for the manufacture of components of the ventilator patient circuits, especially the CPAP masks.

For this RFA preference will be given to proposals that:

- Bring together all the required expertise and capability to manufacture the medical devices of interest or key components thereof
- Address a technology and/or manufacturing capability currently limited or not available in the country
- Aim to deliver a registered product ready for manufacture within a maximum of 12-18 months

- Will result in products or components that are rapidly scalable in terms of manufacture and deployment
- Will result in products or components that are competitively priced

Budgets submitted in response to this RFA should not exceed R800,000 (excluding VAT) over 12-18 months. Given the limited funds available for this RFA, it is expected that the budgets in the applications will be substantially subsidized through co-funding, contributions from the applicant organization and/or leveraging / repurposing of existing resources, i.e. the projects will not be funded at full cost. In addition, the focus will be on funding direct development costs and the budgets should not include any major infrastructure costs. Eligible activities may include, for example, product refinement, product testing, manufacturing process development, development of technical and manufacturing files, and regulatory approvals. Proposals must, however, outline all necessary steps towards development, testing, and scaling of components or devices. They must also provide clear market data and motivation to justify the investment and indicate how the project will result in reducing the reliance on imports.

3. Eligibility

This is an open call for proposals from researchers or product developers based at South African companies, universities, science councils (including the SAMRC) and other organisations. Organizations eligible to apply include:

- South African private/ for-profit small and medium enterprises involved in developing and manufacturing medical devices, diagnostics and/or components thereof
- Any institution approved by the Minister of Higher Education Science and Technology for National Research Foundation funding
- Locally registered not-for profit research organisations whose primary purpose is to conduct research and/or product development

Note that, while universities, science councils and other research organisations are eligible to apply if they are addressing part of the product and/or process development aspects, applications from these organizations must include a commercial manufacturing partner as a co-applicant.

Entities that have not previously received grant funding from the SAMRC will be subject to due diligence before the award of funds.

Foreign entities are **not** eligible to apply for funding through this RFA.

In addition to the above, applicants / project leaders must be South African citizens or permanent residence holders. While there is no limit to the number of applications submitted per organization, primary applicants/project leaders may only submit one application each as the primary applicant/project leader.

4. Application Process and Timeline

It is critical that applicants follow the instructions in this RFA. **Applications will not be processed further or considered for funding if they:**

- Are deemed non-responsive to the specific topic included in this RFA
- Are received after the deadline for submission

- Are incomplete, i.e. do not have **all** sections of the proposal and budget templates completed and all requested supporting documents attached
- Are from non-eligible organizations

All applications must be submitted using the SAMRC Proposal and Budget templates available on the SAMRC website (<https://www.samrc.ac.za/funding/request-for-applications>). The length of the application should not exceed 15 single-spaced A4 pages, excluding annexures, using Arial 11 font. The submission must include the following:

- The fully completed Proposal Template signed by the relevant authority at the institution/company and the primary applicant/project leader – the proposal may be submitted as a Word document with a separate scanned pdf with signatures or a converted pdf document with signatures
- The fully completed Budget Template in Excel

The full set of application documents must be emailed to meddic@mrc.ac.za by **5 pm SA time on Friday 14 May 2021**. Any applications received after this date and time will not be accepted.

The timelines for the application process are shown in Table 1.

Table 1 Application timelines:

RFA Release Date	15 April 2021
Application Due Date	14 May 2021, 5pm SAST
Peer Review of Applications	May 2021
Internal Approvals	June 2021
Notification of Awards	June 2021

For more information on the SAMRC’s General Terms and Conditions of Funding please go to <https://www.samrc.ac.za/funding/samrcfunding>.

5. Review and Evaluation of Proposals

There will be a two-step review and evaluation process:

1. Internal SAMRC screening for responsiveness to all the specified administrative and procedural provisions required in the RFA.
2. National and international peer review to assess the technical merit and commercial feasibility (and other review criteria as specified below) of applications found to be responsive to the RFA.

5.1 Internal screening

All applications will be screened by the SAMRC for completeness and responsiveness to the RFA and its administrative requirements/provisions. If the application is found to be incomplete or unresponsive to the provisions and priority area described in the RFA, or was submitted after the deadline, the application will not be processed further.

5.2 Peer review

Each responsive and complete application received by the due date will be reviewed by an expert review panel, taking into account at least the following criteria:

- Technical feasibility and likelihood of success
- Timeframe to completion of approved product
- Compatibility with existing infrastructure
- Scalability, portability and cost
- Competitiveness of the resulting product/component(s)
- Impact on the trade imbalance
- Existing capacity for development and manufacture
- Track record of the organization/team
- Budget

6. Selection of Awardees

The award of grants emanating from this call will be determined by a committee including representatives from the SAMRC, DSI, TIA and DTIC, and the SAMRC's Executive Management Committee, taking into account the recommendations of the peer review panel. The selection committee and EMC may also consider additional factors, such as geographical and institutional diversity and transformation in making its final determinations. Based on the merit of the applications and/or budget limitations, the SAMRC may award fewer or more grants than expected and may elect not to allocate all of the available funds to awards from this RFA.

7. Important Information

- The SAMRC may seek to verify any information provided by applicant's through independent research or by third parties approved by the SAMRC.
- The SAMRC assumes no responsibility for costs incurred in responding to this RFA or any further invitations or communications.
- The SAMRC reserves the right to amend or withdraw the RFA at any time.
- Successful awards may be subject to addressing reviewer comments and/or negotiation of project plans and budget.
- Grants will be paid to the institution/organization where the primary applicant or project leader is employed, as set out in a funding agreement to be concluded between the parties.

8. Contact Details

Please direct any requests for information and questions/queries on this RFA **by email** to Dr Michelle Mulder michelle.mulder@mrc.ac.za