





SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

Medical Device and Diagnostic Innovation Cluster



Request for Expressions of Interest (REoI)

Medical Device and Diagnostic Host Companies for Regulatory Internships

SAMRC-REOI-GIPD-01-2025

Release Date: 9 September 2025

Closing Date: 22 September 2025

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 supports high quality research, innovation and capacity development through a variety of grant and innovation 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, supported by the Technology Innovation Agency (TIA) and the Department of Science, Technology and Innovation (DSTI), aimed at stimulating and intensifying technology innovation within the medical devices and diagnostics sector as well as encouraging an integrated ecosystem that collectively addresses major challenges faced by the sector to achieve the common goal of a sustainable and competitive South African medical device industry.

One of the challenges identified in the medical devices and diagnostics sector in South Africa is the shortage of skills and experience in addressing regulatory requirements within companies. Medical device companies are faced with the requirement to achieve ISO13485 certification in order to qualify for an establishment license from SAHPRA as well as the registration of products in various jurisdictions, including obtaining CE marks. Navigating these requirements necessitates in depth knowledge of the processes, documentation, systems and facility requirements, much of which can only be gained by working towards these in a real-world situation. In response, MEDDIC is piloting an internship program that involves the placing of science graduates in medical device companies, science councils and academic units that have established, or are in the process of establishing, certification for their manufacturing facilities and/or medical device products. The intention is to provide hands-on training to graduates in a company environment (or industrial unit in academia) in meeting regulatory requirements for medical devices and diagnostics and thereby to increase the skills base in industry.

2. Internship Opportunity Description

MEDDIC/GHIA is seeking small, medium and micro enterprises (SMMEs) and product development units in science councils and universities in South Africa who develop and manufacture medical devices and/or diagnostics and/or provide support for regulatory compliance and are willing to host and train one or more interns for a period of 6 months. The internship must include participation in the processes and activities for establishing and/or maintaining facility and/or product certification or registration. The intention is for the interns to gain exposure to a workplace environment and training and practical experience in regulatory compliance and for the host organisations to gain additional human resource capacity to undertake the detailed activities towards certification and/or maintenance thereof.

The ultimate goals of the program are:

- To create a pipeline of skilled individuals with scientific / technical degrees that have hands-on experience in achieving and maintaining regulatory compliance in the medical devices industry;
- To increase the marketability of science graduates and facilitate their uptake in industry; and
- To capacitate medical device companies to address their regulatory requirements in-house.

For this REoI, preference will be given to companies and academic units that:

 Are developing and manufacturing medical devices or diagnostics or provide support for regulatory compliance for medical devices or diagnostics;

- Have proven expertise and capability to develop, test and register a medical device or diagnostic;
- Have or are in the process of acquiring ISO13485 certification;
- Have or are in the process of registering medical devices or diagnostics in one or more jurisdictions;
- Are willing to host an intern on a full-time basis for 6 months;
- Demonstrate a commitment to either absorb the individual into the company or to find an appropriate placement for them after completion of the internship.

Host organisations will be expected to provide a workspace and all on-site utilities required for the intern to undertake the work as well as hands-on training in regulatory compliance. Host organisations will also be expected to set out a workplan/internship structure for the intern and provide a mid-term and final report on the work allocated and completed by the intern and the outcomes and impact thereof. The SAMRC, through MEDDIC/GHIA will cover a monthly stipend for the interns for a period of 6 months. The SAMRC will work with the host organisations to identify additional formal regulatory training for the interns in the form of short courses, as needed.

3. Eligibility

This is an open national, competitive call for expressions of interest from South African SMMEs, science councils and higher education institutions involved in developing and manufacturing medical devices, diagnostics and/or major components thereof and/or providing support for regulatory compliance for medical devices or diagnostics. Entities will be subject to due diligence before notification of award to host interns. Foreign entities are <u>not</u> eligible to apply for this internship opportunity.

4. REol Process

All Expressions of Interest must be submitted online using the following link Meddic-Reol by 5 pm SA time on 22 September 2025. Any Eols received after this date and time and Eols submitted via email will not be accepted. Submissions must include the following details in the online form:

- Summary of the company/academic unit, its stage of maturity, products, and involvement in product development and/or regulatory support
- Status of ISO13485 certification and product registration
- Indication of intended activities of the intern over the 6 months
- Resources and training to be provided to the intern
- Potential for absorption and/or external placement of the intern after the 6 months

Expressions of Interest will not be considered if they:

- Are incomplete (all sections of the online submission must be completed in full)
- Are not in the medical device or diagnostic field
- Are received after the deadline for submission
- Do not meet the requirements set out in the Internship Opportunity Description section above
- Are from non-eligible organisations

5. Selection of Host Companies/ Organisations

Companies and institutions submitting expressions of interest will be screened for eligibility and suitability and commitment to host interns and to provide the necessary regulatory exposure and training. Additional factors, such as geographical and institutional diversity and transformation /

BBBEE, may be considered in making a final selection of host organisations. The number of internships awarded will be based on the selections from this REoI and availability of funding.

6. Important Information

- The SAMRC may seek to verify any information provided by applicants through independent research or by third parties approved by the SAMRC.
- The SAMRC assumes no responsibility for costs incurred in responding to this REoI or any further invitations or communications.
- The SAMRC reserves the right to amend or withdraw the REoI at any time and to make no awards.
- Successful hosts may be subject to further due diligence or information requests.
- The interns will be paid directly by the SAMRC as set out in an internship agreement to be concluded between the parties.
- The SAMRC reserves the right to withdraw the intern if the information provided by the host company was incorrect or if a situation arises that requires intervention.
- The SAMRC may use text, video or other visual representation submitted by the host company
 / organisation on the SAMRC website or on SAMRC materials for publicity and/or public
 awareness.

7. Compliance with POPIA

As of the 1st of July 2021, the new Protection of Personal Information Act (POPIA) came into full effect. The law is designed to protect how all juristic persons use, store and process data. You can read the full details on the act here: https://popia.co.za/.

The SAMRC as a responsible statutory science council complies with POPIA. The SAMRC will receive personal information through the expressions of interest submitted to the SAMRC in response to this REoI. The personal information requested on the submission template is necessary for the SAMRC to fully evaluate the submission for potential selection. This information may be shared with external reviewers, as well as the SAMRC management for the purposes of processing the submissions. The SAMRC will process this personal information strictly in accordance with POPIA. The SAMRC undertakes specifically to process the personal information on the basis that (a) it was provided voluntarily and (b) the information will be processed only as far may be necessary and within the limitation and ambit of the purpose of evaluating the submission for suitability to host interns (i.e., the purpose with which the personal information was received). The SAMRC confirms that it is lawfully processing the information since the purpose of processing is to support capacity development which the SAMRC is mandated to do in terms of Section 4 of the SAMRC Act 58 of 1991, thus the SAMRC is fulfilling its legislated and lawful mandate, and strategic objectives as provided for in the SAMRC Act.

By submitting your EoI to the SAMRC you acknowledge and agree to the use of your personal information as outlined above. Should you not approve of such use of your personal information then please refrain from submitting an expression of interest.

8. Contact Details

Please direct any requests for information and questions/queries on this REoI by email as follows:

Attn: Ms Grace Baloyi

Grants Innovation and Product Development (GIPD), SAMRC

email: meddic@samrc.ac.za