





DSTI/TIA/CSIR API Innovation Cluster Request for Applications

Process development for the production of APIs using modern manufacturing technologies

- PROOF-OF-CONCEPT STUDIES -

APIIC-RFA-01

Release date: 23 September 2025

Closing date: 17:00 Central African Time, 31 October 2025







1. Introduction

South African has a two-tier health system with a highly resourced private sector and a resource-stressed public system supporting 84% of the population. In recent years, the country has suffered from critical drug shortages and there are increasing reports of poor-quality medicine products and counterfeits entering the African market. Reliance on the importation of finished drugs or the active pharmaceutical ingredient (API) itself places the country with a security of supply risk, while also resulting in a significant trade deficit for the pharmaceutical sector. Within this context, there is an urgent need for the expansion of local manufacturing capacity to produce high quality and cost competitive medicines to support the South African and regional populations, while also mitigating disparities and achieving redress in the sector. As such, the local manufacture of APIs has become a key focus of the South African government, with inclusion in strategic national initiatives by both DSTI (Decadal Plan, White Paper on Science & Technology) and DTIC (Industrial Policy Action Plan).

In response to this challenge, the Department of Science, Technology and Innovation (DSTI) and Technology Innovation Agency (TIA) have established an API Innovation Cluster (APIIC) to drive technology development and commercialization of API manufacturing in South Africa. Hosted by the Council for Scientific and Industrial Research (CSIR), the APIIC will focus on aligning current capabilities residing at various Higher Educations Institutions (HEIs), science councils and commercial companies towards establishing a National Programme for the production of small molecule APIs using modern manufacturing technologies for **human health**, while also developing human capital in these scarce skill areas for industry uptake.

The goal of the current Request for Applications (RFA) is to make several awards to researchers who seek to develop and employ technologies to improve the manufacturing processes for drugs of need on the African continent by demonstrating synthesis of the selected small molecule APIs at laboratory scale (Technology Readiness Level, TRL3).

2. Description of Funding Opportunity

The APIIC is providing seed funding to support several projects specifically seeking to generate synthetic process improvements for APIs of need to develop technology competitiveness. The total number of awards will be based on the number of submissions, available budget and meritorious review of applications received. The duration of the awarded projects is dependent on the proposed scope of work and timeline, but as a guideline are expected in the range of 24 - 30 months.

Improvements to the API synthesis route may include:

- New routes that are an improvement over existing processes (for example through the inclusion of less reaction steps, improved yields, etc.)
- Alternative synthetic routes using strategically inexpensive starting materials or using an intermediate from an existing process,
- Telescoping stages for maximum efficiency to improve the robustness of the process and purification of process materials.
- Scalable and high-productivity processing for easier process scale-up,







- Offering high "atom economy", creating minimal waste or waste recycling via the application of green process design, or
- Utilization of less hazardous and toxic materials.

In terms of the APIs themselves, we are interested in receiving proposals where there is a **clear market need** for:

- Molecules on the South African essential medicines list whose patents may have expired, and
- Molecules of specific demand within South Africa or the broader African region (such as anti-bacterials, antiretrovirals, new anti-malarial drugs, etc.)

The following will not be covered under this RFA:

- Requests for large equipment (i.e. >R50k), and
- · Requests for consultation fees, etc.

3. Eligibility

This is an open call for proposals from researchers, HEIs, science councils and other public research organizations, including:

- Any institution approved by the Minister of Science, Technology and Innovation for NRF funding.
- Locally registered not-for-profit research organizations whose primary purpose is to conduct research and/or
 product development. Such entities should have at least one local university or science council collaborator and
 may be subject to due diligence before the award of funds.
- Local private sector partners can apply as sub-contractors on applications received from academic principal investigators (Pls) if the university is not able to conduct all of the research in-house.

Applicants/PIs must be South African citizens or permanent residence holders. Where the applicant has an emerging track record in process development, it is encouraged that applications include an established co-investigator that may be able to provide access to existing facilities and strong mentorship. While there is no limit on the number of applications submitted per institution, applicants may only submit one application as PI but may be involved in more than one application if listed as a co-investigator. **Applicants from previously disadvantaged institutions**, **as well as female candidates**, **are encouraged to apply**.

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 topics 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 template completed and all requested supporting documentation attached.







- Are from non-eligible organizations.
- Applications sent to any email address other than <u>APIIC@csir.co.za</u>.

All applications must be submitted using the APIIC proposal template available. The submission **must** include the following:

- The fully completed proposal template signed by the relevant authority at the institution and the PI in pdf format.
- CV of the principal investigator.

The full set of application documents must be emailed to Dr Jenny-Lee Panayides (<u>APIIC@csir.co.za</u>) by 17:00 South African time on 31 October 2025. Please use the following naming convention for attached documents: Name of institution_RFA and Name of institution_CV_Jane Smith. Any applications received after this date and time will not be accepted.

The timelines for the application process are:

RFA release date	23 September 2025
Application due date	31 October 2025
Peer review of applications	October-November 2025
Internal approvals	November 2025
Notification of awards	December 2025

5. Review and Evaluation of Proposals

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

- 1. Internal APIIC members will screen the applications for responsiveness to all the specified administrative and procedural provisions required in the RFA.
- 2. National and international peer review to assess the scientific merit (and other review criteria as specified below) of applications found to be responsive to the RFA.

Peer review

Each responsive and complete application received by the due date will be reviewed by local and international reviewers who are experts in the RFA priority areas. Reviewers will consider each of the review criteria below in determining scientific and technical merit and provide and overall score for the proposal.

Significance

Does the proposal fit well within the objectives and scientific remit set out in the RFA? Is the technology improvement measurable and scalable? Is the chosen API of importance to (South) Africa? What is the market size? What is the IP status of the molecule? Is the molecule on the priority drug list?







Investigator(s) and research team

Are the PIs, collaborators, and other researchers well suited to and qualified to undertake the project? Do they have international scientific standing in the field, including publications and citations? Is the PI experienced in the area?

Environment

Will the scientific environment in which the research will be conducted contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the proposed project? Will the project benefit from unique features of the scientific environment, existing research programmes, collaborative arrangements, or other resources?

Methodology and approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are the milestones and deliverables clearly thought through and articulated? Are potential problems, alternative strategies, and benchmarks for success presented? Has any preliminary work been done to inform the design and feasibility of the study? Are the plans feasible, with a realistic timeline? Is there credible supporting data on which the study is based (applicants must supply this). Are all of the necessary components for product development in place and/or available to the investigators?

Funding

Budgets should be detailed, reasonable and realistic. Is there any co-funding that can be leveraged for the projects?

6. Selection of Awardees

The award of grants emanating from this call will be determined by the APIIC Steering Committee taking into account the results of the peer review process, as well as national strategic imperatives which may also consider additional factors, such as geographical and institutional diversity and transformation in making its final determinations.

Based on the scientific merit of the applications and/or budget limitations, the APIIC 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 APIIC may seek to verify any information provided by applicants through independent research or by third parties approved by the APIIC.
- The APIIC assumes no responsibility for costs incurred in responding to this RFA or any further invitations or communications.
- The APIIC 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 the project plan and budget.







- Grants will be paid to the institution where the principal investigator is employed, as set out in a funding agreement to be concluded between the parties.
- No grant funds will be paid over until proof of the necessary ethics and regulatory approvals for the project have been provided to the APIIC. Should the investigators fail to obtain the necessary approvals within a reasonable period of time, the APIIC reserves the right to withdraw the award.
- The APIIC may use text, video or other visual representation submitted by successful applicants on the CSIR website or on materials for publicity and/or public awareness.

8. Contact Details

Please direct any requests for information and questions/queries on this RFA by email to Dr Jenny-Lee Panayides at APIIC@csir.co.za.