





# DSTI/TIA/CSIR API Innovation Cluster Expression of Interest

## Process development for the production of APIs using modern manufacturing technologies

- TRANSLATIONAL DEVELOPMENT -

### **APIIC-EOI-01**

Release date: 23 September 2025

Closing date: 17:00 CAT, 31 October 2025







#### 1. Introduction

South Africa 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 at 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 the Department of Science, Technology and Innovation (DSTI) (Decadal Plan, White Paper on Science & Technology) and the Department of Trade, Industry and Competition (Industrial Policy Action Plan).

In response to this challenge, the <u>DSTI</u> and Technology Innovation Agency (<u>TIA</u>) have established an API Innovation Cluster (APIIC) to drive technology development and commercialisation of API manufacturing in South Africa. Hosted by the Council for Scientific and Industrial Research (<u>CSIR</u>), 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 Expression of Interest (EoI) 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-pilot scale (Technology Readiness Level, TRL6+).

#### 2. Description of the Opportunity

The APIIC has been capacitated with funding from DSTI/TIA to offer support to several HEIs, science councils and Enterprises specifically seeking to scale their proof-of-concept API (or advanced intermediate) production processes to hundred gram-kilogram scale (i.e. to move from TRL3 to TRL6+) and demonstrate synthetic improvements to enhance the competitiveness of the production process. These 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
- Utilisation of less hazardous and toxic materials.

Translational development projects of consideration for this EoI specifically include:

- Batch processes;
- · Continuous flow processes;
- Biocatalytic processes; and
- Any batch-flow-biocatalytic hybrid processes.

In terms of the APIs (and advanced intermediates where relevant), 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 antibacterials, anti-retrovirals, new anti-malarial drugs, etc.).

Note that this is **not** a call for project funding, but rather an expression of interest in receiving translational development support. Support provided by the APIIC will be undertaken through two implementing partners, namely the CSIR and Chemical Process Technologies (CPT) Pharma (through the API+ Laboratory). The CSIR will provide support through the open innovation FuturePHARMA facility that houses cutting-edge continuous flow equipment up to pilot scale, as well as through the R&D biocatalysis laboratories. The API+ Laboratory will provide batch-based support for the demonstration and translation of processes to kilo-lab scale.

#### Support offered will include:

- Utilisation of implementing partner infrastructure and skilled human resource support (scientists, technologists, process engineers) related to batch-flow-biocatalytic API production process development;
- Technology development, technology validation, scale-up support and techno-economic analysis;
- · Mentoring and training in modern manufacturing technologies; and
- Expert analytical support and method development (e.g. UPLC-MS, GC and NMR).

Applicant institutions will retain full ownership of all background intellectual property and non-disclosure agreements will be included with the implementing partner.







The following will not be covered under this Eol:

- Requests for infrastructure;
- · Requests for start-up costs;
- Requests for operational costs (salaries, rent, telephony and so forth);
- Efficacy studies or clinical trials;
- Equity holding or purchase rights; and
- · Accreditation of facilities.

#### 3. Eligibility

This is an open call for proposals from local researchers, universities, science councils, other public research organisations, and Enterprises for translational support, including:

- Any institution approved by the Minister of Science, Technology and Innovation for NRF funding;
- Locally registered not-for-profit research organisations whose primary purpose is to conduct research and/or product development. Such entities may be subject to due diligence before the award of funds; and
- Local enterprises registered with the Companies and Intellectual Property Commission (CIPC).
   Such entities may be subject to due diligence before the award of funds.

Applicants/PIs must be South African citizens or permanent residence holders. 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 and females are encouraged.

#### 4. Application Process and Timeline

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

- Are deemed non-responsive to the specific topics included in this Eol;
- Are received after the deadline for submission;
- Are incomplete, i.e. do not have all sections of the proposal template completed and all requested supporting documentation attached;
- Are from non-eligible organisations. Note that Enterprises not registered with the CIPC, or applications not accompanied by a BEE certificate or affidavit, will be excluded; and
- Applications are sent to any email address other than <a href="mailto:APIIC@csir.co.za">APIIC@csir.co.za</a>.







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.
- For enterprises, the B-BBEE certificate/affidavit and proof of CIPC registration.
- 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 SAST on 31 October 2025. Please use the following naming convention for attached documents: *Name of institution\_EoI*, *Name of institution\_CV\_Jane Smith*, *Name of institution\_CIPC registration* (where relevant), and *Name of institution\_B-BBEE certificate* (where relevant). Any applications received after this date and time will not be accepted.

The timelines for the application process are:

| Eol 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 submission process:

- 1. Internal APIIC members will screen the applications for responsiveness to all the specified administrative and procedural provisions required in the EoI, followed by a review of alignment of the proposed project to the implementing facilities' capabilities and available capacity.
- 2. Applications found to be responsive to the EoI and within the available capabilities and capacity of the implementation partners will then be engaged to provide detailed proof-of-concept information that will be used to assess the scientific and technical merit of the preliminary studies, market significance, status of IP and cost-benefit analysis to provide an overall funding decision for the proposal.

#### 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 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 overall scoring 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 EoI.

#### 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 EoI or any further invitations or communications.
- The APIIC reserves the right to amend or withdraw the EoI at any time.
- Successful awards may be subject to addressing reviewer comments and/or negotiation of the project plan.
- The APIIC may use text, video or other visual representations 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 EoI by email to Dr Jenny-Lee Panayides at <a href="mailto:APIIC@csir.co.za">APIIC@csir.co.za</a>.