



Request for Proposal (RFP) for African vaccine manufacturing position paper

1. RFP Background & Objectives

Wellcome is a politically and financially independent global charitable foundation. It supports science to solve the urgent health challenges facing everyone. Wellcome supports discovery research into life, health and wellbeing, and is taking on three worldwide health challenges: mental health, climate and health and infectious diseases.

In 2021, Wellcome established the Infectious Disease Health Challenge, whose vision is a world in which escalating infectious diseases are under control in communities most affected. An analysis commissioned by Wellcome in 2019 highlighted issues across the vaccine development ecosystem, with vaccine manufacturing identified as a key barrier. Recognising that the global vaccine ecosystem does not optimally realise vaccines' potential to deliver health improvements, Wellcome aims to identify solutions that will improve the vaccine ecosystem.

Covid-19 has exposed Africa's lack of local production capacity, where supplies were slow to reach African countries and remain limited.

Given the clear gap in vaccine manufacturing and growing demand for vaccines in Africa, Wellcome would like to commission an analysis on how to build an enabling environment for the African continent to increase its end-to-end manufacture of vaccines and thereby:

- Ensure self-reliance for sustainable, secure supply of routine vaccines:
- Improve outbreak and emergency response; and
- Develop vaccine products that suit Africa-specific needs:

Previous analysis has mapped manufacturing capacity in Africa, with few facilities able to act at early stages in the vaccine manufacturing value chain, e.g. R&D and drug substance manufacturing. As political will and initiatives on the continent are gaining momentum, Wellcome would like to commission a focussed analysis, centred around Vaccine Manufacturers on the African continent with the following objectives:

Objective 1: To gain an understanding from the manufacturer's perspective of what the **barriers to vaccine development and manufacturing** on the African continent are.

Objective 2: To develop and prioritise a set of solutions, strategies and actions centred around vaccine manufacturers to increase the manufacture of vaccines in Africa to maximise **impact on the delivery of public health on the continent**.

Objective 3: To identify potential global stakeholders ideally positioned to play a role in the identified priority strategies and develop a **Plan of Action for Engagement**.

The **goals** of the report are:

1. To catalyse collaboration and action amongst global vaccine stakeholders to increase vaccine manufacture within Africa; and
2. To provide a Case Study which can be used by other similar Developing Country Vaccine Manufacturers.

To commission this report, Wellcome will partner with Biovac, a Public-Private Partnership and leading South African bio-pharmaceutical company based in Cape Town. Biovac's



mission and aspiration is to ensure that the country has the required domestic capacity to respond to both local and regional vaccine needs. As the only Southern African human vaccines manufacturer, Biovac recognises the need for a domestic manufacturer of vaccines to enable the Southern African region to respond to regional epidemics and vaccine-preventable diseases. The company is one of only three vaccine manufacturers in sub-Saharan Africa and in the last eight years, has successfully established modern manufacturing facilities able to produce vaccines (Vx) and sterile injectable (SI) products in vials and pre-filled syringes. In addition, the company has created strategic partnerships with key global manufacturers for the transfer of technology for critical paediatric vaccines to supply local Vx market

With the outbreak of Covid-19 in 2019, Biovac has become central to South Africa's response to the pandemic and has initiated the expansion of its capacity to respond to both the current and potential future vaccine needs, as well as to ensure the capability to respond to any future pandemics. Over the next five years, Biovac's capacity will be expanded to produce 100 million doses of vaccines annually. This strategy is aligned with the Africa CDC's Partnership for African Vaccines Manufacturing (PAVM) goal of achieving 60% local African production by 2040. The vaccine portfolio includes the Pfizer Covid-19 vaccine to be distributed across Africa as well as other African relevant vaccines. Biovac is also a consortium member of the World Health Organization (WHO) COVID mRNA vaccine technology transfer hub which, together with partners in South Africa - including a network of universities, as well as the Africa Centres for Disease Control and Prevention (CDC) - aims to scale up production and access to Covid-19 vaccines.

2. RFP Specification

This section sets out the specification of services for this RFP exercise. Suppliers should use this section to fully understand Wellcome's requirements and to inform their response.

We are interested in understanding what the barriers to vaccine development and manufacturing on the African continent are and what strategies and actions can be taken to increase the manufacture of vaccines.

We would therefore like to commission a report based on a literature review/landscape analysis and interviews with experts. The experts should be currently involved in vaccine manufacturing on the African continent.

We are interested in developing and prioritising a set of solutions, strategies and actions centred around vaccine manufacturers which will increase the manufacture of vaccines in Africa to maximise impact on the delivery of public health on the continent. We would like to identify potential global stakeholders ideally positioned to play a role in the identified priority strategies and develop a Plan of Action for Engagement.

Part 1: Literature/Landscape Analysis

The study should include a comprehensive analysis of published and grey literature, studies and websites to investigate how an increase in vaccine production in Africa could be triggered. This will include the PAVM Framework for Action (2022) .

The study should be supplemented by targeted primary research (online questionnaires and/or interviews) directed to specified organizations and African countries, aimed at determining their perspectives on improving the capacity for vaccine manufacturing



implementation in Africa and key opportunities for African manufacturers. This will provide evidence and the basis for an analysis of the critical factors required to create an enabling environment. An analysis of how other low and middle income countries not based in Africa, have achieved sustainable vaccine manufacturing could be incorporated into the study.

The anticipated outcome would be a comprehensive overview and analysis of the current challenges of concern for African manufacturers: main directions, issues, barriers, constraints and opportunities etc., relating to increasing vaccine manufacture on the continent. Potential strategies and actions relevant for implementation by Manufacturers in the African context should be identified and mapped to the outcome from the Landscape Analysis.

It would be useful to gather information directly from those currently involved in vaccine manufacturing on the African continent.

Part 2: Review and Gap Analysis of African vaccine manufacturing strategy

Development of a more comprehensive and sustainable vaccine manufacturing industry in Africa requires active intervention in order to establish a conducive business environment. This component of the study therefore requires review of the current African Manufacturing Landscape, paying particular attention to the upstream aspects of the value chain, within the context of the Landscape Analysis and the conclusions reached in Part 1.

Recent activities in Africa need to be assessed in light of more recent events in the African vaccines ecosystem post the beginning of the Covid-19 pandemic and to ensure harmonisation with the PAVM Framework for Action (2022) and Pharmaceutical Manufacturing Plan for Africa (PMPA). The study should hence include a Gap Analysis identifying potential areas which are (1) not currently being addressed and/or (2) which require modification.

Part 3: Development of a Plan of Action

The analysis conducted in this Part should identify preferred options and provide detailed recommendations of the strategies and associated actions for the establishment of sustainable vaccine manufacturing capacity in response to the gaps identified.

With consideration of the Strategic and Action Plan, the study should conclude with an outline of the potential role to be all global stakeholders, including Wellcome Trust, considering the alignment of these stakeholders with the recommend strategies and actions.

Part 4. Early actions

It would be valuable if the report could identify the key activities likely to achieve early wins, even if a stepping stone to a longer term solution. Of interest value would be the identification of specific places and/or interventions where Wellcome and Biovac could assist and have impact.

Proposed methodology

As part of your response, we are interested in your proposed methodology, particularly:

- Methodology for literature search
- Selection of interviewees and suggested interview process



-Approach for analysis, including quantitative approach

-Proposed changes or additions to the categories outlined above

Please see Section 4 for further details of the requirements for your response.

Scope

We are interested in the vaccine development process including mass manufacturing for distribution, and access and uptake post the beginning of the Covid-19 pandemic

Out of scope: The study will exclude any policy development or specific strategies which will require government intervention.

Deliverables

OUTPUT 1 – A final report of the analysis that will be published on the Wellcome website. The intended audience will be vaccine manufacturers, vaccine developers, researchers, regulators, and funders, but the report should also include an executive summary accessible to a non-expert audience. Suppliers should include in their response to this RFP how they will create an informative, accessible and clear (including graphics) final report.

OUTPUT 2 – Slide deck summarising report findings including graphics and high-level summary.

Deliverables timetable (please note that these dates may be subject to change):

	Deliverable	Deadline
1	Contract start date	w/c 25.07.22
2	Inception meeting	w/c 25.07.22
3	Presentation/“inception report” from Supplier to Wellcome with detailed plans	w/c 08.08.22
4	First draft of report (for comments from Wellcome)	w/c 10.10.22
5	Slide deck and presentation to Wellcome	w/c 31.10.22
6	Final report	w/c 28.11.22
	Wellcome sign-off Publication of final report	w/c 12.12.22

3. RFP Timetable

#	Activity	Responsibility	Date
1	RFP issue to Suppliers	WT	w/c 06.06.22
2	Submission of expression of interest to RFP via the following form	Supplier	17:00 on 17.06.22
3	Submission of Supplier Q&A to Wellcome contact	Supplier	17.06.22
4	Return of Supplier Q&A to Suppliers	WT	21.06.22



5	Submission of RFP Response and TPSRA2 form	Supplier	17:00 on 01.07.22
6	RFP Evaluation Period	WT	04.07.22 to 08.07.22
7	Supplier Presentations	WT or Supplier	11.07.22 to 12.07.22
8	Notification of Contract Award	WT	15.07.22
9	Contract Negotiation	WT & Supplier	18.07.22 to 22.07.22
10	Contract Start Date	WT & Supplier	25.07.22

4. Response Format

The following headers support the timetable by providing further detail of the key steps.

Expression of Interest

Suppliers are asked to submit a short expression of interest via this [form](#).

Supplier Q&A

Prior to the submission of your RFP response, Suppliers are provided the opportunity to submit any questions they have about the exercise by the timeframe set out in the RFP Timetable above. All questions will be collated, anonymised, answered and returned to all Suppliers who have submitted an expression of interest in the RFP process.

RFP Proposal

Suppliers are required to submit proposals which respond to the following sections;

RFP Questions

This section requests responses from Suppliers on specific questions in relation to this RFP exercise.

#	Question	Max pages
Team		
1	A brief overview of your organisation, including your track record and expertise relevant to analysis of the type outlined in this RFP. Please also include a brief description of who would be involved in the project team, their qualifications/experience and their main responsibilities.	1
2	What makes you best placed to fulfil Wellcome's requirements set out in this RFP?	1
Approach		
3	Your proposed approach to this work, including the proposed: <ul style="list-style-type: none"> Methodology 	6



	<ul style="list-style-type: none"> • Timeframes • Management plan, including role of team members • Plan for engagement with Wellcome during contract • Plan for production of final report, including copy editing, formatting and graphics • Diversity and inclusion planning (how you will ensure that: the literature reviewed, and interviews conducted will be inclusive to different groups of people and locations; your methodology does not introduce bias). 	
4	Case studies of where you have successfully provided similar services to those described in this RFP	1
5	Highlight any risks you foresee in meeting the RFP requirements and any mitigation you will undertake (both related and not related to Covid-19)	1
Costs		
6	Cost proposal detailing and justifying the proposed costs to meet our requirements including breakdown as necessary	1
Other		
7	Provide details of any existing restrictions that may impact your ability to meet Wellcome's requirements. These should include (but not be limited to): <ul style="list-style-type: none"> • Conflicts of interest with other clients • Conflicts of interest with internal Wellcome staff • Restrictions on your licence to operate in certain jurisdictions 	1

Proposals will be assessed against the following criteria:

Methodology	<i>Quality:</i> Is the proposed methodology aligned with our objectives? <i>Utility:</i> Will the proposed methodology deliver the desired, credible, and useful results?
Team and experience	<i>Skills and Experience:</i> Does the applicant/s have the relevant skills, experience, and contextual understanding to deliver this work?
Delivery and outputs	<i>Delivery plan:</i> Is the proposed delivery plan appropriate and achievable? <i>Feasibility:</i> How feasible is the delivery plan? Are there significant risks associated with the proposed timelines, and how well are they mitigated?
Budget	<i>Value for Money:</i> Is the proposed work within budget and good value for money?

Contract Feedback

This section allows Suppliers to provide specific feedback to the contractual agreement which will be used should their proposal be successful. Contract feedback is to be incorporated into your proposal as an annex and in the following format;

Clause #	Issue	Proposed Solution/Comment



Suppliers submitting proposals as a registered company should review the following Terms and Conditions [document](#).

Individuals submitting proposals as a sole trader (not registered) should review this [document](#).

Individuals submitting proposals through their own personal services company please highlight this to the Wellcome contact immediately (see point 7 below).

Information Governance

Wellcome's Data Protection Compliance

Under [GDPR/Data Protection law](#), Wellcome must keep a record of all personal information it is processing (i.e. collecting, using and sharing). This record will be made available to the Information Commissioner's Office upon request.

This is Wellcome's record of data processing activities which meets GDPR article 30 requirements.

Suppliers are asked to complete the [TPSRA2](#) assessment before the RFP proposal submission deadline for Wellcome to assess how you handle data.

5. About Wellcome

Wellcome supports science to solve the urgent health challenges facing everyone. We support discovery research into life, health and wellbeing, and we're taking on three worldwide health challenges: mental health, global heating and infectious diseases. Find out more about Wellcome and our work at: wellcome.org.

6. Non-Disclosure and Confidentiality

Prospective Suppliers should be aware that inappropriate publicity could have a serious effect upon Wellcome's business. The information contained within this document or subsequently made available to prospective suppliers is deemed confidential and must not be disclosed without the prior written consent of Wellcome unless required by law.

7. Prospective Suppliers Personnel - IR35 and Off Payroll Working Rules

Before the RFP response deadline, Prospective Suppliers must make the Wellcome Contact aware if they are intending to submit a proposal where the services will be provided by any individuals who are engaged by the Prospective Supplier via an intermediary i.e.

- Where the Prospective Supplier is an individual contracting through their own personal services company; or
- The Prospective Supplier is providing individuals engaged through intermediaries, for the purposes of the IR35 off-payroll working rules.



8. Independent Proposal

By submission of a proposal, prospective Suppliers warrant that the prices in the proposal have been arrived at independently, without consultation, communication, agreement or understanding for the purpose of restricting competition, as to any matter relating to such prices, with any other potential supplier or with any competitor.

9. Funding

For the avoidance of doubt, the output of this RFP exercise will be funded as a **Contract** and not as a Grant.

10. Costs Incurred by Prospective Suppliers

It should be noted that this document relates to a Request for Proposal only and not a firm commitment from Wellcome to enter into a contractual agreement. In addition, Wellcome will not be held responsible for any costs associated with the production of a response to this Request for Proposal.

11. Sustainability

Wellcome is committed to procuring sustainable, ethical and responsibly sourced materials, goods and services. This means Wellcome seeks to purchase goods and services that minimise negative and enhance positive impacts on the environment and society locally, regionally and globally. To ensure Wellcome's business is conducted ethically and sustainably, we expect our suppliers, and their supply chains, to adhere to these principles in a responsible manner.

12. Disability Confident

The Wellcome Trust is proud to be a Disability Confident Employer (DC Level 2) and we encourage all our partners and suppliers to do the same. More information about this can be found on the government website [Disability Confident employer scheme and guidance - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/guidance/disability-confident-employer-scheme-and-guidance). Disability Confident is creating a movement of change, encouraging employers to think differently about disability and take action to improve how they recruit, retain and develop disabled people.

13. Accessibility

Wellcome is committed to ensuring that our RFP exercises are accessible to everyone. If you have a disability or a chronic health condition, we can offer adjustments to the response format e.g. submitting your response in an alternate format. For support during the RFP exercise, contact the Wellcome Contact.

If, within the proposed outputs of this RFP exercise, specific adjustments are required by you or your team which incur additional cost then outline them clearly within your commercial



response. Wellcome is committed to evaluating all proposals fairly and will ensure any proposed adjustment costs sit outside the commercial evaluation.

14. Diversity & Inclusion

Embracing [diversity and inclusion](#) is fundamental to delivering our mission to improve health, and we are committed to cultivating a fair and healthy environment for the people who work here and those we work with. As we learn more about barriers that disadvantage certain groups from progressing in our workplace, we will remove them.

Wellcome takes diversity and inclusion seriously, and we want to partner with suppliers who share our commitment. We may ask you questions related to D&I as part of our RFP processes.

15. Wellcome Contact Details

The single point of contact within this RFP exercise for all communications is as indicated below;

Name: Alyce O'Connor
Role: Procurement Officer
Email: RFP@Wellcome.org