ARC • LNR

Excellence in Research and Development

AGRICULTURAL RESEARCH COUNCIL

TECHNICAL SPECIFICATIONS

VACCINE PRODUCTION INFRASTRUCTURE USING SINGLE-USE BAGS FOR THE PREPARATION OF THE FOOT AND MOUTH DISEASE VACCINE AT ONDERSTEPOORT VETERINARY RESEARCH INSTITUTE OF THE AGRICULTURAL RESEARCH COUNCIL.

1. PART ONE

2. PART TWO

1. PART ONE

1.1 BACKROUND AND INTRODUCTION

The Agricultural Research Council (ARC) was established by the Agricultural Research Act, 1990 (Act no 86 of 1990, as amended) and is the principal agricultural research institution in South Africa. It is a schedule 3A public entity in terms of the Public Finance Management Act, (Act no 1 of 1999, as amended). In terms of the Act, the objectives of the ARC are to conduct research, technology development and technology transfer (dissemination) in order to,

- Promote agricultural and the industry;
- Contribute to a better quality of life; and
- Facilitate / ensure natural resource conservation.

The Onderstepoort Veterinary Research (OVR) institute, whose functions lies within the Animal Health business division of the ARC promotes animal health and welfare by providing an effective and efficient diagnostic service and producing vaccines against Foot and mouth and tick-borne diseases. OVR is also the collaborating centre for both the Office International des Epizooties (OIE) surveillance and control of animal diseases in Africa and the Food and Agriculture Organization (FAO) of the United Nations for the emergency preparedness for transboundary animal diseases for Africa.

The OVR intends to build, in the next five (5) years, a new vaccine production factory, which conforms to the current good manufacturing practices (cGMP), for the production of foot and mouth disease (FMD) and other transboundary animal diseases vaccines. However, until such time, they intend to produce the FMD vaccine in the existing (old) factory.

FMD is highly infectious viral disease of split (cloven) hooved animals including, cattle, sheep, goats and pigs. The disease has a high economic impact owing to the livestock and livestock products (meat, milk products, hides, etc.) trade embargoes imposed by the World Organisation for Animal Health (OIE), on a country experiencing an outbreak of the disease. Thus, the disease is registered as a controlled and compulsory notifiable disease in South Africa, under the Animal Diseases Act, Act No. 35 of 1984

and operations vaccine production, which involves virus proliferation, are conducted in biosafety level-3 (BSL-3) facilities.

This disease's vaccine production process consists of upstream processes, which include, buffers/ reagents preparation, mammalian cell based virus production as well as formulation and storage of starting, intermediate and finished product. Meanwhile, downstream processes include inactivation and clarification of the virus as well as concentration and purification of antigens for vaccine formulation. The existing production plant at OVR - in which the infrastructure this request for proposals calls for will be used - consists of separate/disconnected suites, in line with the basic OIE requirements for FMD vaccine manufacturing plants, namely:

1. Buffers/reagents preparation suite
2. Cells, virus and first inactivation suite
3. Second inactivation, concentration and purification suite and
4. Formulation and bottling suite

1.2 OBJECTIVES

The objective for this tender is to request proposals from prospective supplier(s), with the aim of selecting the most convincing upon feasibility evaluations, to:

i. Design, supply, delivery, installation and commissioning of a portable/single-use system, with a 200 litres working volume capacity, for the manufacturing of the foot and mouth disease (FMD) vaccine.

ii. Provide mobile, steam sterilisable single and double walled (jacketed) stainless steel mixing and formulation vessels.

1.3 SITE LOCATION:

GPS Location -25.650173° S, 28.187228°E

Physical address: 100 Old Soutpan Road, Onderstepoort, 0110

1.4 GUARANTEES

The service provider shall guarantee the installation, workmanship and materials being used for this project for a period of sixty (12) months. The guarantee will commence on the date of receipt of the total and complete installation, validation, and handover of the systems.

1.5 OCCUPATIONAL HEALTH AND SAFETY ACT, 1993 AS AMENDED

The installation of the work must be in accordance with the conditions as set out in the Occupational Health and Safety Act, 1993 (Act 85 of 1993) as amended.

1.6 ACCESS TO THE PRODUCTION FACILITY

Unauthorised persons will not be allowed in the facility during installations. Persons entering the facility will require prior clearance in line with biosecurity regulations of the facility. In addition, these persons will be under quarantine, i.e. not allowed to be in contact with cloven-hooved animals (cattle, sheep, goat sand pigs, as well as wild l animals) or areas where feed for such animals is sold or stored, at least five days after the last visit of the facility. Under no circumstances may any person be allowed to sleep or keep any possessions (material) on the installation site during the project period or thereafter unless prior arrangement is made.

1.7 DISTURBANCE

The service provider shall perform all work with as little noise and mess as possible and with the minimum disturbance for adjacent and existing buildings and their occupants.

The service provider shall take all the precautions to protect adjacent buildings from damage and he/she alone shall be held liable for any damage to persons or property because of insufficient precautions.

The service provider shall take the necessary steps to ensure that the workers do not walk around in existing buildings unless necessary for the activities.

NOTE:

After the issuing of the order, it shall be the service provider's duty to arrange for an inspection of the buildings, etc. and the adjacent sites in the presence of the Institute 's representative to identify any defects such as cracks, etc. in buildings, rainwater canals, kerb stones, etc. that may possibly be damaged during execution of this project.

Such defects shall be recorded to refute any allegations that they have been caused by the building operations under this project. If such defects are in fact present, the service provider shall record them and submit, this in writing to the representative before work commences.

If the service provider fails to inform the representative in writing, it shall be assumed that there are no such defect.

1.8 SITE-BRIEFING MEETINGS

A compulsory site-briefing meeting will be convened on 25 January 2022, wherein details of the current production facility will be discussed. Proposals from bidders who could not attend the site-briefing meeting will not be considered.

1.9 PROGRESS SCHEDULE

A provisional project plan proposal should be included as part of the bid that clearly indicates major deliverables and their associated times. Before any work shall commence the successful service provider shall submit a full detailed project plan in which all aspects of the project have been taken into consideration. Strict adherence to the provisions of this plan shall be required.

1.10 IMPLEMENTS, ETC.

The service provider shall supply and maintain all implements, for example, tools, etc. that may be required for the proper and timely execution of the work.

On completion of the project, the service provider shall remove at his/her own expense all implements belonging to him/her and leave the production site in a clean and orderly condition.

1.11 LOSS OF MATERIAL

The OVR shall not be held liable for any loss through theft, damage, etc. of materials. Therefore, the service provider shall take the necessary precautions for protection against such losses.

1.12 INJURIES

The OVR will not be held responsible for injuries to the services provider's personnel. As such, the service provider shall indemnify the OVR against any liability, loss, and/or death claim or lawsuit of any nature in accordance with the **Common Law or Acts of the Republic**, except where the injury arises because of actions undertaken by personnel of the OVR.

1.13 SPECIAL SAFETY EQUIPMENT

The service provider must supply all safety clothes and equipment as stipulated by law. The service provider will be responsible for all safety aspects as stipulated by industry.

PART 2

2.1. TECHNICAL SPECIFICATIONS

Specifications and quantities of infrastructure required are listed per production suite mentioned in the background and introduction (section 1.1)

2.1.1 BUFFERS/REAGENTS PREPARATION SUITE

ITEM	SPECIFICATIONS	QUANTITY
250 LITRES STAINLESS STEEL (WORKING VOLUME) STORAGE TANK WITH A LID	• Steam in place • 316L steel (inner wall in contact with product) • Surface finish with 0.6 micron internal RA electro polish and 1.2 micron external RA • Applicable for sterile applications and capacity for sterile liquid transfer • Sampling port • Glass window • Capacity for sterile harvesting (complete emptying) • Leak proofed	1
200 LITRES (WORKING VOLUME) SINGLE-USE BIOPHARMACEUTICAL STORAGE BAGS (MEDIUM STORAGE BAGS)	• Sterile • Non leachable and extractable material • Integrity tested • 0.2µm venting filter • Sampling port made of C-flex pharmaceutical grade tubbing • Transferring tubbing (preferable bio-weldable C-flex pharmaceutical grade tubbing, suitable for use with peristaltic pumps)	90
BAGS STORAGE AND TRANSPORTATION CARTS FOR STORAGE OF 200 LITRES SINGLE USE STORAGE BAGS.	• Bins, drums or carts on wheels • Wheels to withstand transfer to different production suites on smooth and rough concrete terrains • Suitable for sterile applications	4
STERILE LIQUID TRANSFER SYSTEM	• aseptic tube connections and disconnections • Transfer of liquid aseptically to various process vessels	1

BIOPHARMACEUTICAL TUBE CLAMPS	• Thin-walled tube clamps fit wall thicknesses 1/32" (0.79 mm) to 3/32" (2.38 mm) with a max OD of 1/2" (12.7 mm). • Tube clamps fit wall thicknesses 1/8" (3.2 mm) to 1/4" (6.4 mm) with a max OD of 1" (25.4 mm). • Large tube clamps fit wall thicknesses 1/8" (3.2 mm) to 1/4" (6.4 mm) with a max OD of 2.5" (63.5 mm).	30 30 30
DIRECT FILTRATION SYSTEM	• 8 - 10 µm Filter sheet pre-filtration application	10 boxes of x sheets per box
	• 0.45 µm reusable steam in place filters cartridge with free standing stainless steel filter domes/housing	20
	• 0.2 µm reusable steam in place filters cartridge with free standing stainless steel filter domes/housing	20
LIQUID TRANSFER TO NEXT PROCESS	• Peristaltic pump transfer media to next vessel • Pump speed 10/litre per minute	1
LOAD CELL WEIGHING SCALE	5-500 kg for in-process addition of reagents. To form part of the process control parameters	1

2.1.2 CELLS AND VIRUS INACTIVATION SUITE

ITEM	SPECIFICATIONS	QUANTITY

SINGLE-USE CELLS AND VIRUS CULTIVATION BAGS	• Sterile
	• Non leachable and extractable material, compatible for use with low concentrations of chloroform (0.3 % final concentration)
	• Integrity tested and testable by end-user.
	• Bag assembly with:
	  • 0.2µm venting filter and a condenser.
	  • Sampling port made of C-flex pharmaceutical grade tubbing and capacity for 10 sampling times during cultivation
	  • Transferring tubbing (preferable bio-weldable C-flex pharmaceutical grade tubbing, suitable for use with peristaltic pumps)
	  • Pt 100, pH and dissolved oxygen (DO) ports and probes
	  • Pressure sensor
	  • Agitation by pitched 3-blades marine impeller for culture agitation at various agitation speeds.
		45

	• Temperature control system inputs, capability for cooling and heating (0 – 40 °C). • Capacity for partial harvesting. Cells will be sedimented by gravitational forces for medium exchange before virus seeding • Inlets for in-process inoculations/additions • NB! pH will be controlled by gases and not chemically. • Gas supply (compressed air and carbon dioxide) tubing (head space and a ring sparger) and sparger as follows: • L shaped, under the lower impeller. • Micro pores of 5mm • Pores to provide enough gas flow to minimize levels of overlay air required and avoid formation of high levels of foam during sparging. • Biomass sensors (ideal not necessary) • Gas supply tubing for both head space and sparger to be fitted with sterile 0.2 µm air filters •	
CULTIVATION PROCESS CONTROL UNIT	The control unit must be easy-to-use touch screen for monitoring with actuators for the control of: • Temperature (Working temperatures of 0 – 40°C by the fermenter's Pt100 probe). • pH control by gases sparging: • Four gas rotameters with solenoid valves and mass flow controllers for gas flow control (carbon dioxide, compressed air and dissolved oxygen at 2 bar feed sources). • Gases mix option and capacity to select gas feed (by sparger or head space air inlet) • Dissolved Oxygen (DO) controllable between 45 - 100 % at 1 bar feed source, by sparging. • • Motor controlled and magnetically coupled agitator. • Agitation according to pre-determined tip-speeds (20-200 rpms) by marine impellers. • Sensors: pH, DO, foam level and Pt100 with cables connecting to the respective probes on the fermentation bag. • Biomass (cell density) monitoring will be ideal. • Overlay line for air over layer	1

	• pH & DO calibration through the process control unit. • Overpressure safety shutdown • Data logging: • Fermenter must be operated from controller at fermenter and (free-standing computer (PC) desirable) • Free-standing PC which is compatible with the specialized software used to control and monitor fermenter from PC • Specialized software package to data logging, control and monitor fermenter from PC Software must be compatible with Microsoft windows 10 and upgradable if new software become available	
LIQUID TRANSFER TO NEXT PROCESS	• Peristaltic pump transfer media to next vessel Pump speed 10/litre per minute	1
LOAD CELL WEIGHING SCALE	5-500 kg for in-process addition of reagents. To form part of the process control parameters	1

2.1.3 INACTIVATION, CONCENTRATION AND PURIFICATION SUITE

ITEM	SPECIFICATIONS	QUANTITY

SINGLE-USE CELLS AND VIRUS CULTIVATION BAGS	• Sterile
	• Non leachable and extractable material, compatible for use with low concentrations of chloroform (0.3 % final concentration)
	• Integrity tested and testable by end-user.
	• Bag assembly with:
	  • 0.2µm venting filter and a condenser.
	  • Sampling port made of C-flex pharmaceutical grade tubbing and capacity for 10 sampling times during cultivation
	  • Transferring tubbing (preferable bio-weldable C-flex pharmaceutical grade tubbing, suitable for use with peristaltic pumps)
	  • Pt 100 and pH ports probes
	  • Pressure sensor
	  • Motor controlled and magnetically coupled agitator.
	  • Agitation by pitched 3-blades marine impeller for culture agitation at various agitation speeds.
	  • Temperature control system inputs, capability for cooling and heating (0 – 10 °C).
	  • Capacity for complete liquid transfer
	• NB! pH will be controlled chemically.
		45

CULTIVATION PROCESS CONTROL UNIT	The control unit must be easy-to-use touch screen for monitoring with actuators for the control of: • Temperature (Working temperatures of 0 – 40°C by the fermenter's Pt100 probe). • pH control by chemicals: • Minimum of two fixed speed pumps for controlled liquid additions. • • Motor controlled and magnetically coupled agitator. Agitation according to pre-determined tip-speeds (20-200 rpms) • Sensors: pH, foam level and Pt100 with cables connecting to the respective probes on the fermentation bag. • pH calibration through the process control unit. • Overpressure safety shutdown • Data logging: • Fermenter must be operated from controller at fermenter and (free-standing computer (PC) desirable) • Free-standing PC which is compatible with the specialized software used to control and monitor fermenter from PC • Specialized software package to data logging, control and monitor fermenter from PC • Software must be compatible with Microsoft windows 10 and upgradable if new software become available		1
LIQUID TRANSFER TO NEXT PROCESS	• Peristaltic pump transfer media to next vessel Pump speed 10/litre per minute		1
LOAD CELL WEIGHING SCALE	5-500 kg for in-process addition of reagents. To form part of the process control parameters		1
ANTIGEN CLARIFICATION	Direct flow Filtration system	Tripod stands with inlet and outlet ports for serial connection of 0.8 and 0.45 µm filters cartridges/capsules (steam sterilisable). NB! Chloroform (CHCl3) compatible filter medium	1
	Transfer to next process	• Peristaltic pump transfer media to next vessel • Pump speed 10 liter per minute	1

2.1.4 FORMULATION AND FILLING SUITE

ITEM	SPECIFICATIONS	QUANTITY
250 LITRES STAINLESS STEEL MIXING TANK WITH A LID	Steam in place Double wall (jacketed) tank • 316L steel Sterile for inner wall (in contact with product) • and 304 for outer wall (not in contact medium) • Surface finish with 0.6 micron internal RA electro polish and 1.2 micron external RA • Applicable for sterile applications and capacity for sterile liquid transfer • Sampling, pH and temperature ports • Allow for fitment of air venting filter • Supply pH and temperature (Pt100) probes with applicable cables to connect them to tanks' process control unit. • Peeping glass window • Inlet for process additions/inoculations • Leak proofed • Capacity for sterile harvesting (complete emptying) • Motor operated agitator with pitched marine impeller blades (round edges)	1
500 LITRES STAINLESS STEEL MIXING TANK WITH A LID	Steam in place Double wall (jacketed) tank • 316L steel Sterile for inner wall (in contact with product) • and 304 for outer wall (not in contact medium) • Surface finish with 0.6 micron internal RA electro polish and 1.2 micron external RA. • Applicable for sterile applications and capacity for sterile liquid transfer • Sampling pH and temperature ports • Allow for fitment of air venting filter • Supply pH and temperature (Pt100) probes with applicable cables to connect them to tanks' process control unit. • Peeping glass window • Inlet for process additions/inoculations • Capacity for sterile harvesting (complete emptying) • Motor operated agitator with pitched marine impeller blades (round edges)	1
Formulation process control unit	The control unit must be easy-to-use and; • Have capacity to connect two mixing tanks at the same time • Have a screen that displays: • Process pH, agitation speeds and temperature	1
Liquid transfer to	• Peristaltic pump transfer media to next vessel Pump speed 10 litre per minute	1

next process			
Load cell weighing scale	5-500 kg for in-process addition of reagents. To form part of the process control parameters		1
Filtration	Direct flow Filtration system	• Tripod stands with inlet and outlet ports for serial connection of 0.45 and 0.2 µm filters cartridges (steam sterilisable).	2
	FILTERS	• Steam sterilisable 0.45 and 0.2 µm filters suitable for oil adjuvants	45 each

2.1.5 SYSTEM COMPATABILITY

No	Description
2.1.5.1	State power requirement a 220-240 V single phase or 380 v 3 phase
2.1.5.2	Normal compressed air, carbon dioxide at 2 bar from source
2.1.5.3	2 bar Medical grade oxygen available
2.1.5.4	Normal municipality water supply between 2 and 4 bar
2.1.5.5	2 bar carbon dioxide available

2.1.6 AFTER SALES AND TECHNICAL SUPPORT

No	Description
2.1.6.1	Software upgrades and data extraction must be permissible
2.1.6.2	Training for relevant production personnel shall be provided by the bidder on site at the TAD facility

2.2. SPECIAL CONDITIONS & ADMINISTRATIVE REQUIREMENTS OF TENDER

NO	SPECIAL CONDITIONS & ADMINISTRATIVE REQUIREMENTS	COMPLY (YES / NO)
2.2.1	The vaccine production system will be required to be fully installed and operational within **6 months** after appointment.	
2.2.2	The successful bidder shall submit, within ten (10) working days from award of the tender, the complete safety file for review of the ARC-OVR Occupational Health and Safety Officer. A valid, current Certificate of Occupational Injuries and Diseases Act (COIDA) must be attached to the proposal.	
2.2.3	Any damages to the Campuses' equipment due to the negligence of the service provider will be repaired or replaced by the service provider at his/her own cost.	
2.2.4	All equipment supplied as per specification must comply with bio-pharmaceutical standards and legislation, Good Manufacturing Practices (GMP), Pharmaceutical Inspection Co-operation Scheme (PIC/S) and/or American/ European Pharmacopoeia guidelines.	
2.2.5	All the work done and the material used must comply with the requirement of the Occupational Health and Safety Act, National building regulation, South African National Standard and any other relevant legislation.	
2.2.6	The bidder shall be responsible to obtain the necessary measurements for all work to be conducted as part of this document. ARC shall not be liable for any incorrect measurements obtained.	
2.2.7	All installed units and equipment as per specification must be guaranteed for a minimum period of 12 months, including maintenance or service that may be required in the first year of installation.	
2.2.8	Bidders are to provide after sales and technical support for a period of 12 months after official handover. This includes a 48 hour turnaround time once a case has been logged.	
2.2.9	The bidder must supply an illustrated operations manual, service plan, and product catalogue with part numbers and a list of spares when handing over upon project completion.	
2.2.10	Bidders are required to include technical drawings, process flow diagrams, and data of equipment offered as per bid specification.	
2.2.11	Bidders are not allowed to remove any page from the original tender document as issued. Bidders are required to ensure that the completed document with all	

NO	SPECIAL CONDITIONS & ADMINISTRATIVE REQUIREMENTS	COMPLY (YES / NO)
	attachments are submitted on or before the closing date of the tender.	
2.2.12	Submission of mandatory administrative documents. Bidders must fully complete and submit the following documents, certified copies must not be more than six (6) months: i. SARS Tax pin. ii. Certified copies of the bidders CIPC documents listing the type of organisation and director information. The company must not be on deregistration status or on awaiting deregistration status. iii. Certified ID Copies of all directors iv. A certified copy of the B-BBEE certificate (or an original affidavit signed by a Commissioner of Oaths regarding the B-BBEE status).	
2.2.13	The bidder must submit three (3) bid proposals as follows: i. Two (2) hard copies (one original and one copy) ii. One (1) electronic copy in PDF format saved on a memory stick, clearly marked, and indexed. iii. Bid proposals must be *properly bonded (not stapled), **clearly numbered and ***divided indexed	

2.4. EVALUATION CRITEARIA

The bid evaluation process consists of several stages that are applicable according to the nature of the bid as defined below:

Stage 1: Compulsory Requirements of the Tender

Stage 2: Compulsory Technical Requirements of the Tender

Stage 3: Technical Functionality Requirement of the Tender

Stage 4: Price and B-BBEE evaluation

NOTE: The bidder must qualify at each stage to be eligible to proceed to the next stage of the evaluation.

2.5 COMPULSORY REQUIREMENTS FOR THE TENDER

The bidders shall provide the ARC (accompanying the bid document on the closing date/time) with the following information:

Criteria	Description of the criteria
2.5.1	Attendance of the compulsory briefing session. It is important for all bidders to attend briefing session as essential information relevant to the bid will be shared with all prospective bidders.
2.5.2	Submission of mandatory administrative documents. Bidders must fully complete and submit the following documents, certified copies must not be more than six (6) months: i. SARS Tax Pin. ii. Certified copies of the bidders CIPC documents listing the type of organisation and director information. The company must not be on deregistration status or on awaiting deregistration status. iii. Submission of proof of the bidder's registration on the CSD (Full report) iv. Standard bidding documents completed in full and signed off by a duly authorised person. (SBD 3, SBD 4, SBD 6, SBD 8, SBD 9)

2.6 COMPULSORY TECHNICAL REQUIREMENTS FOR THE TENDER

2.6.1 **ISO 9001 Accreditation**	Comply	Do Not Comply
2.6.2 **Factory Qualification Protocol**	Comply	Do Not Comply
2.6..3 **Operation Qualification Protocol**	Comply	Do Not Comply
2.6.4 **Installation Qualification Protocol**	Comply	Do Not Comply
2.6.5 **Design Acceptance Protocol**	Comply	Do Not Comply
2.6.6 **Opera Rotation Acceptance Protocol**	Comply	Do Not Comply

N.B Failure to submit all the above documents will lead to disqualification

2.7. EVALUATION OF BIDS: TECHNICAL FUNCTIONALITY REQUIRMENT

Criteria	Description	Point Allocation	Weighting Allocation
1. Company experience	1.1 Proof (services agreement of similar, previous installations) of installation. • Five (5) years relevant experience in provision and installation of bio-pharmaceutical infrastructure to the combined value of at least R 20 million. • Four (4) years relevant experience in provision and installation of bio-pharmaceutical infrastructure to the combined value of R 15 million. • Three (3) years relevant experience in provision and installation of bio-pharmaceutical infrastructure to the combined value of R 10 million. • Two (2) years relevant experience in provision, installation of bio-pharmaceutical infrastructure to the combined value of R 5 million • One (1) years relevant experience in provision, installation of bio-pharmaceutical infrastructure to the combined value of less than R 5 million.	5 4 3 2 1	20

	1.2 Experience in post installation support (services agreement of similar, previous installations) • 4 years' experience of post-installation support services • At least 3 years' experience of post installation support services • At least 2 years' experience of post installation support services • At least 2 post installation support services • One year and less experience of post installation support services	5 4 3 2 1	10
	1.3 Signed letters of Contactable references/clients/customers in relation to the experience mentioned above on the company's letterhead, where similar services have been delivered. NOTE: The ARC reserves the right to contact the listed references for verification of claims made. Re • Five (5) contactable Client/developers reference on work conducted to with the entire project value of more than R5 million • Four (4) contactable Client/developers reference with the entire project value of R4 million • Three (3) contactable Client/developers	5 4 3	10

	reference with the entire project value of R3 million • Two (2) contactable Client/developers reference with the entire project value of R2 million • One (1) contactable Client/developers reference with the entire project value of R1million or less = 1 point	2 1	
2 Technical capacity of key personnel/project leaders (Sales/engineers/maintenance etc.)	2.1 CVs, certified copies of certificates and on the job experience in the relevant field of expertise. (i.e, marketing for sales teams / engineers or Artisans for the technical teams who will form part of project leaders in their respective disciplines) **Note! Failure to submit proof of qualifications will result in no score allocation.** • Qualified professional in life sciences/ engineering/ sales and marketing/ trade technicians with 10 or more years' experience in the field of expertise • Qualified professional in life sciences/ engineering/ sales and marketing/ Artisans with 9 to 7 years' experience in the field of expertise • Qualified professional in life sciences/ engineering/ sales and marketing/ Artisans with 3 to 6 years' experience in the field of expertise • Qualified professional in life sciences/ engineering/ sales and	5 4 3 2	15

	marketing/ Artisans with over 1 to 2years' experience in the field of expertise • Qualified professional in life sciences/ engineering/ sales and marketing/ trade technicians with a year(1) or less experience in the field of expertise	1	
	2.2 The organogram of the proposed project team, which will lead the project. • Key personnel mentioned in 2.1, with post graduate qualification in the field of expertise and 10 or more years on the job experience • Key personnel with undergraduate qualification in the field of expertise and 15 or more years on the job experience • Key personnel with Matric (Grade 12 or equivalent) and over 20 years on job experience • Key personnel with Matric (Grade 12 or equivalent) and less than 20 years on the job experience • Key personnel without matric but with more than 20 years on the job experience	5 4 3 2 1	5
Method of approach for:	Conceptualisation project, design, procurement and installation of the production systems, as well as validation and training. The bidder has displayed extensive logical and in-depth understanding of the scope of works (SoW). • The bidder has addressed the	5	

	methodology steps accordingly with the drawings, Gantt charts, rollout plans and timelines. • The bidder has displayed extensive logical according to his or her own interpretation with a clear timelines and a roll out plan. • The bidder has displayed a fair understanding according to his or her own interpretation. Timelines and a roll out plans are evident. • The bidder has displayed some understanding of but has not provided any meaningful no clear basis of approach • The bidder has displayed no understanding and logical understanding of the approach proposed	4 3 2 1	30
Handover	Company capacity for after sales support. Provide proof of validation certificates (Installation, operation qualification reports/records) for similar systems previously installed, as proof of technical capacity and maintenance support post installation. • Provide said reports/certificates of at least 4 installations of similar systems (locally or internationally) with at least 1 of the 4 being proof of local technical support post installation • Provide said reports/ certificates of 3 installations of similar systems, 1 locally as proof of local technical support post installation	5 4	10

	• Provide said reports/ certificates of at least 2 installations of similar systems as proof of technical support post installation • Provide said reports/ certificates of at least 1 installations of similar systems as proof of technical support post installation • Installation of similar systems without said reports/certificates.	3 2 1	
TOTAL			100
Minimum required to qualify for Price and BBBEE evaluation			65

2.5 EVALUATION ON PRICE AND THE BBBEE LEVEL OF CONTRIBUTION

The 80/20 principle will apply in terms of the Preferential Procurement Policy Framework Act 5 of 2000.

80 Points will be allocated to price, and 20 points will be allocated to the BBBEE as per level of contribution. The ARC shall evaluate bids that comply with the specifications as stipulated in this bid and reserves the right to exclude any proposal that does not meet the requirements BBBEE points in terms of the Preferential Procurement Policy Framework Act Regulations 2017 will be allocated as follows:

B-BBEE Status Level of Contribution	Number of points (80 / 20 system)
1	20
2	18
3	14
4	12
5	8
6	6
7	4
8	2
Non-compliant contributor	0

2.6 PRICE BREAKDOWN

See Annexure B

Annexure A: Reference Letter: "Letter of recommendation"

REFERENCE LETTER FORMAT			
Bidder's Letterhead We are submitting a bid for the contract described below. We appreciate your assistance and effort in completing, on your letterhead, the reference as set out below on your experience with us.			
Reference Letterhead	Reference Legal Name		
The name of the company you are giving a reference for			
Describe the Contract / Project work and/or Service the above bidder provided to your organisation:			
Project/Contract period (start date)			
Project/Contract period (end date)			
Project/Contract cost that the bidder was responsible for (Vat Incl)			
Please rate the above bidder according to the following criteria by ticking the relevant column and providing comments / details in the space provided below if relevant:			
Criteria	Doesn't meet requirements	Meets requirements	Exceeds requirements
Project was completed within **budget and within the required time frame**			
Queries resolved timeously.			
The bidder understood and delivered successfully on the **scope of work**			

Professionalism			
Quality of workmanship			
Quality of materials used / adherence to given specifications (Did all equipment, material and liquid nitrogen used comply with the requirement of the Occupational Health and Safety Act, National building regulation, South African National Standard and any other relevant legislation?)			
Availability of company resources, sales, service and technical backing. Was the equipment serviced as prescribed?			
Overall satisfaction with the firm's resource availability			
Overall Impression / Satisfaction with bidder			
Further details on any of the points above, or any other comments			
Number of times used in the past 48 months			
Would you use the provider again	Yes / No		
Completed by:			
Designation:			
Signature:			
Company Name:			
Contact Telephone Number:			
Date:			

ANNEXURE B PRICE BREAKDOWN

1. BUFFERS/REAGENTS PREPARATION SUITE.

ITEM	SPECIFICATIONS	QUANTITY	PRICE (RANDS)		
			COST/UNIT	TOTAL excl VAT	TOTAL incl VAT
250 LITRES STAINLESS STEEL (WORKING VOLUME) STORAGE TANK WITH A LID	• Steam in place • 316L steel (inner wall in contact with product) • Surface finish with 0.6 micron internal RA electro polish and 1.2 micron external RA • Applicable for sterile applications and capacity for sterile liquid transfer • Sampling port • Glass window • Capacity for sterile harvesting (complete emptying) • Leak proofed	1			
200 LITRES (WORKING VOLUME) SINGLE-USE BIOPHARMACEUTICAL STORAGE BAGS (MEDIUM STORAGE BAGS)	• Sterile • Non leachable and extractable material • Integrity tested • 0.2µm venting filter • Sampling port made of C-flex pharmaceutical grade tubbing • Transferring tubbing (preferable bio-weldable C-flex pharmaceutical grade tubbing, suitable for use with peristaltic pumps)	90			

BAGS STORAGE AND TRANSPORTATION CARTS FOR STORAGE OF 200 LITRES SINGLE USE STORAGE BAGS.	• Bins, drums or carts on wheels • Wheels to withstand transfer to different production suites on smooth and rough concrete terrains • Suitable for sterile applications	4			
STERILE LIQUID TRANSFER SYSTEM	• aseptic tube connections and disconnections • Transfer of liquid aseptically to various process vessels	1			
BIOPHARMACEUTICAL TUBE CLAMPS	• Thin-walled tube clamps fit wall thicknesses 1/32″ (0.79 mm) to 3/32″ (2.38 mm) with a max OD of 1/2″ (12.7 mm). • Tube clamps fit wall thicknesses 1/8″ (3.2 mm) to 1/4″ (6.4 mm) with a max OD of 1″ (25.4 mm). • Large tube clamps fit wall thicknesses 1/8″ (3.2 mm) to 1/4″ (6.4 mm) with a max OD of 2.5″ (63.5 mm).	30 30 30			
DIRECT FILTRATION SYSTEM	• 8 - 10 µm Filter sheet pre-filtration application	10 boxes of x sheets per box			
	• 0.45 µm reusable steam in place filters cartridge with free standing stainless steel filter domes/housing	20			
	• 0.2 µm reusable steam in place filters cartridge with free	20			

	standing stainless steel filter domes/housing				
LIQUID TRANSFER TO NEXT PROCESS	• Peristaltic pump transfer media to next vessel • Pump speed 10/litre per minute	1			
LOAD CELL WEIGHING SCALE	5-500 kg for in-process addition of reagents. To form part of the process control parameters	1			

2. CELLS AND VIRUS PRODUCTION SUITE

ITEM	SPECIFICATIONS	QUANTITY	PRICE (RANDS)		
			COST/UNIT	TOTAL COST excl VAT	TOTAL COST incl VAT

SINGLE-USE CELLS AND VIRUS CULTIVATION BAGS	• Sterile
	• Non leachable and extractable material, compatible for use with low concentrations of chloroform (0.3 % final concentration)
	• Integrity tested and testable by end-user.
	• Bag assembly with:
	  • 0.2µm venting filter and a condenser.
	  • Sampling port made of C-flex pharmaceutical grade tubbing and capacity for 10 sampling times during cultivation
	  • Transferring tubbing (preferable bio-weldable C-flex pharmaceutical grade tubbing, suitable for use with peristaltic pumps)
	  • Pt 100, pH and dissolved oxygen (DO) ports and probes
	  • Pressure sensor
	  • Agitation by pitched 3-blades marine impeller for culture agitation at various agitation speeds.
	  • Temperature control system inputs, capability for cooling and heating (0 – 40 °C).
	  • Capacity for partial harvesting. Cells will be sedimented by gravitational forces for medium exchange before virus seeding
		45			

	• Inlets for in-process inoculations/additions • NB! pH will be controlled by gases and not chemically. • Gas supply (compressed air and carbon dioxide) tubing (head space and a ring sparger) and sparger as follows: • L shaped, under the lower impeller. • Micro pores of 5mm • Pores to provide enough gas flow to minimize levels of overlay air required and avoid formation of high levels of foam during sparging. • Biomass sensors (ideal not necessary) • Gas supply tubing for both head space and sparger to be fitted with sterile 0.2 µm air filters •				
CULTIVATION PROCESS CONTROL UNIT	The control unit must be easy-to-use touch screen for monitoring with actuators for the control of: • Temperature (Working temperatures of 0 – 40°C by the fermenter's Pt100 probe). • pH control by gases sparging: • Four gas rotameters with solenoid valves and mass flow controllers for gas flow control (carbon dioxide, compressed air and dissolved oxygen at 2 bar feed sources). • Gases mix option and capacity to select gas feed (by sparger or head space air inlet) • Dissolved Oxygen (DO) controllable between 45 - 100 % at 1 bar feed source, by sparging.	1			

	• • Motor controlled and magnetically coupled agitator. • Agitation according to pre-determined tip-speeds (20-200 rpms) by marine impellers. • Sensors: pH, DO, foam level and Pt100 with cables connecting to the respective probes on the fermentation bag. • Biomass (cell density) monitoring will be ideal. • Overlay line for air over layer • pH & DO calibration through the process control unit. • Overpressure safety shutdown • Data logging: • Fermenter must be operated from controller at fermenter and (free-standing computer (PC) desirable) • Free-standing PC which is compatible with the specialized software used to control and monitor fermenter from PC • Specialized software package to data logging, control and monitor fermenter from PC Software must be compatible with Microsoft windows 10 and upgradable if new software become available				
LIQUID TRANSFER TO NEXT PROCESS	• Peristaltic pump transfer media to next vessel Pump speed 10/litre per minute	1			
LOAD CELL WEIGHING SCALE	5-500 kg for in-process addition of reagents. To form part of the process control parameters	1			

3. INACTIVATION, CONCENTRATION AND PURIFICATION SUITE

ITEM	SPECIFICATIONS	QUANTITY	PRICE (RANDS)		
			COST/UNIT	TOTAL COST excl VAT	TOTAL COST incl VAT

SINGLE-USE CELLS AND VIRUS CULTIVATION BAGS	• Sterile
	• Non leachable and extractable material, compatible for use with low concentrations of chloroform (0.3 % final concentration)
	• Integrity tested and testable by end-user.
	• Bag assembly with:
	  • 0.2µm venting filter and a condenser.
	  • Sampling port made of C-flex pharmaceutical grade tubbing and capacity for 10 sampling times during cultivation
	  • Transferring tubbing (preferable bio-weldable C-flex pharmaceutical grade tubbing, suitable for use with peristaltic pumps)
	  • Pt 100 and pH ports probes
	  • Pressure sensor
	  • Motor controlled and magnetically coupled agitator.
	  • Agitation by pitched 3-blades marine impeller for culture agitation at various agitation speeds.
	  • Temperature control system inputs, capability for cooling and heating (0 – 10 °C).
	  • Capacity for complete liquid transfer
	• NB! pH will be controlled chemically.
		45			

CULTIVATION PROCESS CONTROL UNIT	The control unit must be easy-to-use touch screen for monitoring with actuators for the control of: • Temperature (Working temperatures of 0 – 40°C by the fermenter's Pt100 probe). • pH control by chemicals: • Minimum of two fixed speed pumps for controlled liquid additions. • • Motor controlled and magnetically coupled agitator. Agitation according to pre-determined tip-speeds (20-200 rpms) • Sensors: pH, foam level and Pt100 with cables connecting to the respective probes on the fermentation bag. • pH calibration through the process control unit. • Overpressure safety shutdown • Data logging: • Fermenter must be operated from controller at fermenter and (free-standing computer (PC) desirable) • Free-standing PC which is compatible with the specialized software used to control and monitor fermenter from PC • Specialized software package to data logging, control and monitor fermenter from PC • Software must be compatible with Microsoft windows 10 and upgradable if new software become available	1			

LIQUID TRANSFER TO NEXT PROCESS	• Peristaltic pump transfer media to next vessel Pump speed 10/litre per minute		1			
LOAD CELL WEIGHING SCALE	5-500 kg for in-process addition of reagents. To form part of the process control parameters		1			
ANTIGEN CLARIFICATION	Direct flow Filtration system	Tripod stands with inlet and outlet ports for serial connection of 0.8 and 0.45 µm filters cartridges/capsules (steam sterilisable). NB! Chloroform (CHCl3) compatible filter medium	1			
	Transfer to next process	• Peristaltic pump transfer media to next vessel • Pump speed 10 liter per minute	1			

4. FORMULATION SUITE

ITEM	SPECIFICATIONS	QUANTITY	PRICE (RANDS)		
			COST/UNIT	TOTAL COST excl VAT	TOTAL COST incl VAT
250 LITRES STAINLESS STEEL MIXING TANK WITH A LID	Steam in place Double wall (jacketed) tank • 316L steel Sterile for inner wall (in contact with product) • and 304 for outer wall (not in contact medium) • Surface finish with 0.6 micron internal RA electro polish and 1.2 micron external RA • Applicable for sterile applications and capacity for sterile liquid transfer • Sampling, pH and temperature ports • Allow for fitment of air venting filter • Supply pH and temperature (Pt100) probes with applicable cables to connect them to tanks' process control unit. • Peeping glass window • Inlet for process additions/inoculations • Leak proofed • Capacity for sterile harvesting (complete emptying) • Motor operated agitator with pitched marine impeller blades (round edges)	1			
500 LITRES STAINLESS STEEL MIXING TANK WITH A LID	Steam in place Double wall (jacketed) tank • 316L steel Sterile for inner wall (in contact with product) • and 304 for outer wall (not in contact medium) • Surface finish with 0.6 micron internal RA electro polish and 1.2 micron external RA.	1			

	• Applicable for sterile applications and capacity for sterile liquid transfer • Sampling pH and temperature ports • Allow for fitment of air venting filter • Supply pH and temperature (Pt100) probes with applicable cables to connect them to tanks' process control unit. • Peeping glass window • Inlet for process additions/inoculations • Capacity for sterile harvesting (complete emptying) • Motor operated agitator with pitched marine impeller blades (round edges)					
Formulation process control unit	The control unit must be easy-to-use and; • Have capacity to connect two mixing tanks at the same time • Have a screen that displays: • Process pH, agitation speeds and temperature		1			
Liquid transfer to next process	• Peristaltic pump transfer media to next vessel Pump speed 10/litre per minute		1			
Load cell weighing scale	5-500 kg for in-process addition of reagents. To form part of the process control parameters		1			
Filtration	Direct flow Filtration system	• Tripod stands with inlet and outlet ports for serial connection of 0.45 and 0.2 µm filters cartridges (steam sterilisable).	2			
	FILTERS	• Steam sterilisable 0.45 and 0.2 µm filters suitable for oil adjuvants	45 each			