

REQUEST FOR QUOTATION FOR GOODS AND SERVICES



PM

**ONDERSTEPSPOORT BIOLOGICAL PRODUCTS LTD
PRIVATE BAG X7, ONDERSTEPSPOORT 0110**

From: Supply Chain Department
Date: Jul 06 2026
Tel: 012 522 1500
Fax: N/A
Email: purchasing@obpvaccines.co.za

To:
Supplier:
Tel:
Fax:
Email:

Kindly provide the quotation for the following: RFQ/OBP094/2026/27

Compulsory Document Requirements	Yes/No
Provide a detail proposal submission with the RFQ as per the TOR requirements	
Demonstrated experience in GMP-regulated pharmaceutical environments minimum of 2 reference letter not older than 5 years.	
At least five (5) pharmaceutical clean steam generator installations completed within the last ten years. Provide 5 reference letters, must be signed/stamped	
provide a minimum of 3 Reference sites with contactable clients,	
CIDB REQUIREMENTS - minimum grading of 02 ME (Valid CIDB registration to be submitted)	

Compulsory Sight Briefing Date: Jul 13 2026 10:00:00

Address: 100 Old Soutpan Rd Onderstepoort, Pretoria, 0110

Evaluation of Price and Preference

All Bids will be evaluated on a points system based on weighted average score for Price and Preference as per Preferential Procurement Framework Act of 2000 (Act 5 of 2000).

Preference Point allocation – 80/20

Price / Preference	Weighting percentage
Preference:	20%
Price:	80 %
Total must equal:	100%

OBP Onderstepoort Biological Products will award preference points as follows: Specific Goal	Points	Evidence required	Yes/No

Historically disadvantaged by unfair discrimination on the basis of Race	10	A valid BBBEE Certificate showing at least 51% black ownership	
Historically disadvantaged by unfair discrimination on the basis of Gender (women)	8	A valid BBBEE Certificate showing at least 30% women ownership	
Historically disadvantaged by unfair discrimination on the basis of disability	2	A doctor's note confirming disability, confirmation of disability from the Department of Labour, BEE certificate or equivalent confirmation.	
Total points	20		

NB: Please note that if any of the above requirements is not submitted with the quote it will be an immediate disqualification.

TO APPOINT A SUPPLIER TO PROVIDE THE FOLLOWING ITEM/S OR SERVICE AS PER SCOPE BELOW.

Quantity	Product/Item Code	Specification
2 EA	new pharmaceutical-grade Clean Steam Generators (CSGs)	<p>DESIGN BASIS Each Clean Steam Generator shall meet or exceed the following minimum design requirements.</p> <p>Mechanical Design Data Shell Side</p> <p>Parameter Requirement Design Pressure 750 kPa Design Vacuum -90 kPa Maximum Allowable Working Pressure 750 kPa Operating Pressure 600 kPa Initial Hydrostatic Test Pressure 995 kPa Maximum Design Temperature 175°C Minimum Design Temperature 10°C Operating Temperature 165.04°C Corrosion Allowance 0 mm Internal Volume 0.48 m³</p> <p>Tube Side Parameter Requirement Design Pressure 900 kPa Design Vacuum -90 kPa Maximum Allowable Working Pressure 900 kPa Operating Pressure 800 kPa Initial Hydrostatic Test Pressure 1195 kPa Maximum Design Temperature 180°C Minimum Design Temperature 10°C Operating Temperature 175.43°C Corrosion Allowance 0 mm Internal Volume 0.035 m³</p> <p>CLEAN STEAM PERFORMANCE REQUIREMENTS The bidder shall determine the required capacity based upon site demand. The proposal shall include:</p> <ul style="list-style-type: none"> • Steam generation rate • Peak demand • Continuous demand • Turndown ratio • Response time

		<ul style="list-style-type: none"> • Efficiency calculations • Heat balance <p>The bidder shall perform a complete process study before final design.</p> <p>STEAM QUALITY REQUIREMENTS The clean steam produced shall comply with pharmaceutical industry expectations and shall be suitable for:</p> <ul style="list-style-type: none"> • Sterile manufacturing • SIP • Sterilisation processes <p>Steam quality shall satisfy current GMP expectations including:</p> <ul style="list-style-type: none"> • Pyrogen free • Non-condensable gases within accepted limits • Dry saturated steam • Free from contaminants • Free from corrosion products • Free from process chemicals <p>The bidder shall demonstrate compliance during commissioning.</p> <p>FEED WATER REQUIREMENTS The system shall operate using existing pharmaceutical purified water/RO water. The bidder shall specify:</p> <ul style="list-style-type: none"> • Minimum feedwater quality • Conductivity • Silica limits • TOC limits • Hardness limits • Temperature requirements <p>Any required pretreatment shall be identified.</p>
--	--	--

Requirements from the supplier (To be used to select the contractor)

- SCM Administration requirements:
- SBD4 Bidders Disclosure - All suppliers MUST Complete, sign & submit the SBD4 declaration with their bid application
 - Bidder must submit CSD report and must be register on CSD

Government Procurement: all quotations of goods and services are subject to the General conditions of Contract July 2010

Requirements from SCM department:

- All bidders MUST register their company (in advance) on the NEW OBP's E-Procurement portal, the link can be found on the official OBP website under supply chain.
- Once bidders account registration is approved by the OBP Supply Chain, login credentials will be supplied, whereby bidders will be able to login and apply for opportunities.

- All open opportunities will reflect on the portal for bidders to part take in.
- All required company documents, proposed submissions or additional requirements MUST be uploaded with your bid application.
- Any additional questions or Queries can be directed via email (purchasing@obpvaccines.co.za) or telephone (012 522 1500), note NO SUBMISSIONS WILL BE ACCEPTED via EMAIL.
- OBP reserves the right to cancel or re-advertise RFQ's (Request for quotes).

SBD 4

BIDDER'S DISCLOSURE

1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

2. Bidder's declaration

2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest¹ in the enterprise, employed by the state? **YES/NO**

2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

Full Name	Identity Number	Name of State institution

2.2 Do you, or any person connected with the bidder, have a relationship with any person who is employed by the procuring institution? **YES/NO**

2.2.1 If so, furnish particulars:

.....

¹ the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.

2.3 Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract?

YES/NO

2.3.1 If so, furnish particulars:

.....
.....

3. DECLARATION

I, the undersigned, (name)..... in submitting the accompanying bid, do hereby make the following statements that I certify to be true and complete in every respect:

- 3.1 I have read, and I understand the contents of this disclosure.
- 3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect.
- 3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement, or arrangement with any competitor. However, communication between partners in a joint venture or consortium² will not be construed as collusive bidding.
- 3.4 In addition, there have been no consultations, communications, agreements, or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.
- 3.5 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.
- 3.6 There have been no consultations, communications, agreements, or arrangements made by the bidder with any official of the procuring institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.
- 3.7 I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.

2 Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

.....
Signature	Date
.....
Position	Name of bidder

Terms and Conditions:

- Submission should be no later than **(Jul 20 2026 15:00:00)**
- Please indicate your offer validity and lead time: _____
- All prices must be VAT exclusive, (Vat vendor please indicate as such) if no indication, prices will be evaluated as exclusive.
- Quotation must be on a company letter head and **strictly** on a PDF format (**Quotations sent on Word or Excel format will not be accepted.**)
- Supplier must register on or before any submission can be done , supplier number will be allocated to supplier.
- Submission and Quotations must be done online with all attachments required to be uploaded : any queries can be send to purchasing@obpvaccines.co.za
- **If no reply after 14 days of closing date your RFQ was unsuccessfully.**
- Please indicate if you are unable to quote and state the reason why
- Please note that fluctuations in the exchange rate (where applicable) will not be for the account of OBP.
- *Payment terms: 30 days after statement*
- *Bidders must be registered on CSD (Central Supplier Data Base National Treasury) and be tax compliant*
- **Government Procurement: all quotations of goods and services are subject to the General conditions of Contract July 2010**

I agree that the offer herein shall remain binding upon me and open for acceptance by OBP during the validity period indicated.

Signature

Date

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2022

This preference form must form part of all tenders invited. It contains general information and serves as a claim form for preference points for specific goals.

NB: BEFORE COMPLETING THIS FORM, TENDERERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF THE TENDER AND PREFERENTIAL PROCUREMENT REGULATIONS, 2022

1. GENERAL CONDITIONS

1.1 The following preference point systems are applicable to invitations to tender:

- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included); and
- the 90/10 system for requirements with a Rand value above R50 000 000 (all applicable taxes included).

1.2 To be completed by the organ of state

(delete whichever is not applicable for this tender).

- a) The applicable preference point system for this tender is the **90/10** preference point system.
- b) The applicable preference point system for this tender is the **80/20** preference point system.
- c) Either the **90/10 or 80/20 preference point system** will be applicable in this tender. The lowest/ highest acceptable tender will be used to determine the accurate system once tenders are received.

1.3 Points for this tender (even in the case of a tender for income-generating contracts) shall be awarded for:

- (a) Price; and
- (b) Specific Goals.

1.4 To be completed by the organ of state:

The maximum points for this tender are allocated as follows:

	POINTS
PRICE	80
SPECIFIC GOALS	20
Total points for Price and SPECIFIC GOALS	100

- 1.5 Failure on the part of a tenderer to submit proof or documentation required in terms of this tender to claim points for specific goals with the tender, will be interpreted to mean that preference points for specific goals are not claimed.
- 1.6 The organ of state reserves the right to require of a tenderer, either before a tender is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the organ of state.

2. DEFINITIONS

- (a) “**tender**” means a written offer in the form determined by an organ of state in response to an invitation to provide goods or services through price quotations, competitive tendering process or any other method envisaged in legislation;
- (b) “**price**” means an amount of money tendered for goods or services, and includes all applicable taxes less all unconditional discounts;
- (c) “**rand value**” means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;
- (d) “**tender for income-generating contracts**” means a written offer in the form determined by an organ of state in response to an invitation for the origination of income-generating contracts through any method envisaged in legislation that will result in a legal agreement between the organ of state and a third party that produces revenue for the organ of state, and includes, but is not limited to, leasing and disposal of assets and concession contracts, excluding direct sales and disposal of assets through public auctions; and
- (e) “**the Act**” means the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000).

3. FORMULAE FOR PROCUREMENT OF GOODS AND SERVICES

3.1. POINTS AWARDED FOR PRICE

3.1.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

$$Ps = 80 \left(1 - \frac{Pt - Pmin}{Pmin} \right) \text{ or } Ps = 90 \left(1 - \frac{Pt - Pmin}{Pmin} \right)$$

Where

Ps = Points scored for price of tender under consideration

Pt = Price of tender under consideration

Pmin = Price of lowest acceptable tender

3.2. FORMULAE FOR DISPOSAL OR LEASING OF STATE ASSETS AND INCOME GENERATING PROCUREMENT

3.2.1. POINTS AWARDED FOR PRICE

A maximum of 80 or 90 points is allocated for price on the following basis:

$$P_s = 80 \left(1 + \frac{P_t - P_{max}}{P_{max}} \right) \text{ or } P_s = 90 \left(1 + \frac{P_t - P_{max}}{P_{max}} \right)$$

Where

P_s = Points scored for price of tender under consideration

P_t = Price of tender under consideration

P_{max} = Price of highest acceptable tender

4. POINTS AWARDED FOR SPECIFIC GOALS

- 4.1. In terms of Regulation 4(2); 5(2); 6(2) and 7(2) of the Preferential Procurement Regulations, preference points must be awarded for specific goals stated in the tender. For the purposes of this tender the tenderer will be allocated points based on the goals stated in table 1 below as may be supported by proof/ documentation stated in the conditions of this tender:
- 4.2. In cases where organs of state intend to use Regulation 3(2) of the Regulations, which states that, if it is unclear whether the 80/20 or 90/10 preference point system applies, an organ of state must, in the tender documents, stipulate in the case of—
- (a) an invitation for tender for income-generating contracts, that either the 80/20 or 90/10 preference point system will apply and that the highest acceptable tender will be used to determine the applicable preference point system; or
 - (b) any other invitation for tender, that either the 80/20 or 90/10 preference point system will apply and that the lowest acceptable tender will be used to determine the applicable preference point system,
- then the organ of state must indicate the points allocated for specific goals for both the 90/10 and 80/20 preference point system.

Table 1: Specific goals for the tender and points claimed are indicated per the table below.

(Note to organs of state: Where either the 90/10 or 80/20 preference point system is applicable, corresponding points must also be indicated as such.)

Note to tenderers: The tenderer must indicate how they claim points for each preference point system.)

The specific goals allocated points in terms of this tender	Number of points allocated (90/10 system) (To be completed by the organ of state)	Number of points allocated (80/20 system) (To be completed by the organ of state)	Number of points claimed (90/10 system) (To be completed by the tenderer)	Number of points claimed (80/20 system) (To be completed by the tenderer)
A valid BBBEE Certificate showing at least 51% black ownership		10		
A valid BBBEE Certificate showing at least 30% women ownership		8		
A doctor's note confirming disability, confirmation of disability from the Department of Labour, BEE certificate or equivalent confirmation.		2		

DECLARATION WITH REGARD TO COMPANY/FIRM

4.3. Name of company/firm.....

4.4. Company registration number:

4.5. TYPE OF COMPANY/ FIRM

- Partnership/Joint Venture / Consortium
- One-person business/sole propriety
- Close corporation
- Public Company
- Personal Liability Company
- (Pty) Limited
- Non-Profit Company
- State Owned Company

[TICK APPLICABLE BOX]

- 4.6. I, the undersigned, who is duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the specific goals as advised in the tender, qualifies the company/ firm for the preference(s) shown and I acknowledge that:
- i) The information furnished is true and correct;
 - ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;
 - iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 1.4 and 4.2, the contractor may be required to furnish documentary proof to the satisfaction of the organ of state that the claims are correct;
 - iv) If the specific goals have been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the organ of state may, in addition to any other remedy it may have –
 - (a) disqualify the person from the tendering process;
 - (b) recover costs, losses or damages it has incurred or suffered as a result of that person’s conduct;
 - (c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;
 - (d) recommend that the tenderer or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and
 - (e) forward the matter for criminal prosecution, if deemed necessary.

<p>.....</p> <p>SIGNATURE(S) OF TENDERER(S)</p>
<p>SURNAME AND NAME:</p> <p>DATE:</p> <p>ADDRESS:</p> <p>.....</p> <p>.....</p> <p>.....</p>

CIDB REQUIREMENTS

Grading Required

CRS Number	Status	Grading	Expiry Date
-----	-----	-----	-----

Register with CIDB: must submit proof of CIDB account is active

- *It is estimated that tenderers must have a cidb contractor grading designation of ...ME02... or higher...*
- *It is estimated that tenderers must have a cidb contractor grading designation of ...ME02 or higher potentially emerging enterprises who satisfy criteria stated in the Tender Data may submit tender offers.*

C.2.1 Only those tenderers who are registered with the cidb or are capable of being so prior to the evaluation of submissions, in a contractor grading designation equal to or higher than a contractor grading designation determined in accordance with the sum tendered, or a value determined in accordance with Regulation 25 (1B) or 25(7A) of the Construction Industry Development Regulations, for a ...ME...* class of construction work, are eligible to have their tenders evaluated.

Every member of the joint venture is registered with the cidb;

- 2. the lead partner has a contractor grading designation in the ...ME.....* class of construction work; or not lower than one level below the required grading designation in the class of works construction works under considerations and possess the required recognition status.**
- 3. the combined contractor grading designation calculated in accordance with the Construction Industry Development Regulations is equal to or higher than a contractor grading designation determined in accordance with the sum tendered for a ...ME....* class of construction work or a value**

determined in accordance with Regulation 25 (1B) or 25(7A) of the Construction Industry Development Regulations.	
---	--

TOR - PROCUREMENT: NEW PHARMACEUTICAL-GRADE CLEAN STEAM GENERATORS (CSGS)

INTRODUCTION

OBP invites suitably qualified and experienced service providers to submit proposals for the complete turnkey design, fabrication, supply, installation, testing, commissioning, qualification support and documentation of **two (2) new pharmaceutical-grade Clean Steam Generators (CSGs)**. The equipment will be installed within OBP's pharmaceutical manufacturing facility operating under current Good Manufacturing Practice (cGMP). The clean steam generated shall be used for critical pharmaceutical applications including, but not limited to:

- Sterilisation-in-Place (SIP)
- Autoclaves
- Vessel sterilisation
- Process equipment sterilisation
- Sterile manufacturing processes
- Other GMP critical applications

The proposed solution shall represent current international best practice and shall be suitable for operation within a highly regulated pharmaceutical manufacturing environment.

The successful bidder shall provide a **complete turnkey solution**, including all engineering, design, statutory approvals, fabrication, factory testing, delivery, installation, commissioning, validation support and training.

PROJECT OBJECTIVES

The objectives are to:

- Replace ageing clean steam generation assets with modern, highly reliable systems.
- Improve clean steam quality and reliability.
- Reduce maintenance requirements.
- Improve energy efficiency.
- Improve operational redundancy.
- Ensure long-term spare parts availability.

- Ensure compliance with pharmaceutical GMP requirements.
- Ensure full compliance with applicable pressure equipment legislation.
- Facilitate future digital monitoring and predictive maintenance.

GENERAL SCOPE OF WORK

The bidder shall provide a complete turnkey package including:

- Process design
- Mechanical design
- Thermal calculations
- Pressure vessel design
- Fabrication
- Factory Acceptance Testing (FAT)
- Transportation
- Installation
- Piping modifications
- Structural supports
- Electrical installation
- Instrumentation
- Automation integration
- Commissioning
- Performance testing
- Validation documentation
- Operator training
- Maintenance training
- Final documentation

Nothing necessary for a fully operational installation shall be excluded because it was omitted from this specification.

DESIGN BASIS

Each Clean Steam Generator shall meet or exceed the following minimum design requirements.

Mechanical Design Data

Shell Side

<u>Parameter</u>	<u>Requirement</u>
Design Pressure	750 kPa
Design Vacuum	-90 kPa
Maximum Allowable Working Pressure	750 kPa
Operating Pressure	600 kPa
Initial Hydrostatic Test Pressure	995 kPa
Maximum Design Temperature	175°C
Minimum Design Temperature	10°C
Operating Temperature	165.04°C
Corrosion Allowance	0 mm
Internal Volume	0.48 m ³

Tube Side

<u>Parameter</u>	<u>Requirement</u>
Design Pressure	900 kPa
Design Vacuum	-90 kPa
Maximum Allowable Working Pressure	900 kPa
Operating Pressure	800 kPa
Initial Hydrostatic Test Pressure	1195 kPa

Maximum Design Temperature	180°C
Minimum Design Temperature	10°C
Operating Temperature	175.43°C
Corrosion Allowance	0 mm
Internal Volume	0.035 m ³

CLEAN STEAM PERFORMANCE REQUIREMENTS

The bidder shall determine the required capacity based upon site demand. The proposal shall include:

- Steam generation rate
- Peak demand
- Continuous demand
- Turndown ratio
- Response time
- Efficiency calculations
- Heat balance

The bidder shall perform a complete process study before final design.

STEAM QUALITY REQUIREMENTS

The clean steam produced shall comply with pharmaceutical industry expectations and shall be suitable for:

- Sterile manufacturing
- SIP
- Sterilisation processes

Steam quality shall satisfy current GMP expectations including:

- Pyrogen free
- Non-condensable gases within accepted limits
- Dry saturated steam

- Free from contaminants
- Free from corrosion products
- Free from process chemicals

The bidder shall demonstrate compliance during commissioning.

FEED WATER REQUIREMENTS

The system shall operate using existing pharmaceutical purified water/RO water.

The bidder shall specify:

- Minimum feedwater quality
- Conductivity
- Silica limits
- TOC limits
- Hardness limits
- Temperature requirements

Any required pretreatment shall be identified.

HEATING MEDIUM

Industrial steam shall be used as the heating medium. The bidder shall specify:

- Steam pressure
- Steam consumption
- Condensate generation
- Condensate return requirements

DESIGN REQUIREMENTS

Preference shall be given to:

- Vertical construction
- Natural circulation design
- Low maintenance

- High efficiency
- Rapid start-up
- Compact footprint
- Low water hold-up volume
- High quality separation system
- Hygienic internal geometry

MATERIALS OF CONSTRUCTION

Minimum requirements:

Pressure parts:

- Stainless Steel 316L

Product contact surfaces:

- Stainless Steel 316L

Surface finish:

Internal surfaces:

Ra \leq 0.5 μ m electropolished

External surfaces:

Brushed pharmaceutical finish.

WELDING REQUIREMENTS

All welding shall comply with recognised pressure vessel codes. Requirements include:

- Orbital welding where applicable
- Full penetration welds
- Weld traceability
- Weld maps
- Qualified welders
- Qualified welding procedures

PRESSURE VESSEL REQUIREMENTS

The bidder shall provide:

- Design calculations
- Stress analysis
- Pressure vessel certification
- Hydrostatic testing
- Material traceability
- Nameplates
- Data books

INSULATION

The entire unit shall be fully insulated.

Cladding:

- Stainless steel

Maximum external temperature:

Less than 50°C

INSTRUMENTATION

Minimum instrumentation shall include:

Pressure transmitters

Temperature transmitters

Level transmitter

Flow transmitter

Steam pressure gauges

Feedwater flow meter

Conductivity meter

Safety valves

Rupture disc (where required)

Vacuum breaker

Air vent

Steam trap

Drain valves

Sampling points

CONTROL SYSTEM

Each generator shall include a dedicated PLC.

Preferred manufacturers:

- Siemens
- Rockwell
- Schneider
- ABB

The system shall include:

- 15-inch HMI
- Alarm management
- Event logging
- Trend recording
- Batch reporting
- Historical data
- Recipe management
- Password protection
- User access levels

SCADA INTEGRATION

The system shall be fully compatible with the site's future SCADA architecture.

PHARMACEUTICAL DOCUMENTATION

The contractor shall provide complete GMP documentation including:

Design Qualification support

Functional Specification

Hardware Design Specification

Software Design Specification

Factory Acceptance Test Protocol

Site Acceptance Test Protocol

Installation Qualification support

Operational Qualification support

Performance Qualification support

Material Certificates (3.1)

Surface finish certificates

Welding records

Calibration certificates

Pressure test certificates

Passivation certificates

As-built drawings

Operation manuals

Maintenance manuals

Spare parts manuals

Instrument data sheets

Valve schedules

Loop drawings

P&IDs

Electrical drawings

PLC backups

Software source code

Password documentation

Recommended spare parts list

FACTORY ACCEPTANCE TEST (FAT)

The bidder shall perform a witnessed FAT including:

Mechanical inspection

Pressure testing

Functional testing

Instrumentation verification

Control logic testing

Alarm testing

Interlock testing

Safety testing

Steam production demonstration

Documentation review

SITE ACCEPTANCE TEST (SAT)

SAT shall include:

Mechanical completion

Electrical testing

Loop checks

Calibration

Commissioning

Steam production

Performance verification

Control testing

Alarm testing

Interlock verification

Emergency shutdown testing

INSTALLATION

The bidder shall provide:

Equipment removal (if applicable)

Rigging

Lifting plans

Foundations (where required)

Pipework

Valves

Supports

Electrical installation

Instrumentation

Cable trays

Cable management

Identification labels

Commissioning

Housekeeping

TRAINING

Provide comprehensive training covering:

Operators

Maintenance personnel

QA & Validation personnel

Training manuals shall be supplied.

WARRANTY

Minimum warranty:

- Twenty-four (24) months from commissioning

or

- Thirty-six (36) months from delivery

whichever provides the longer effective coverage.

RECOMMENDED SPARES

Provide:

Two-year operational spares

Five-year recommended spare parts list

Critical spare parts

Lead times

Pricing

AFTER SALES SUPPORT

The bidder shall demonstrate:

- Local technical support.
- Local spare parts availability.
- 24-hour technical assistance.
- Emergency call-out capability.
- Long-term product support (minimum 15 years).
- Software support and upgrade capability.
- Availability of preventive maintenance contracts.

28.

29. BIDDER EXPERIENCE

The bidder shall provide evidence of:

- At least five (5) pharmaceutical clean steam generator installations completed within the last ten years.

- Reference sites with contactable clients.
- Demonstrated experience in GMP-regulated pharmaceutical environments.
- Local engineering, commissioning, and after-sales support capability.
- Availability of certified pressure vessel designers, qualified welding personnel, automation engineers, and validation specialists.

INFORMATION TO BE SUBMITTED WITH THE RFQ

The RFQ submission/proposal shall include, at a minimum:

- Detailed technical proposal.
- Process description and design philosophy.
- General arrangement drawings.
- Preliminary Piping and Instrumentation Diagrams (P&IDs).
- Process flow diagrams.
- Equipment data sheets.
- Utility consumption schedule (industrial steam, purified water, electricity, compressed air if applicable).
- Instrument list.
- Valve list.
- Control system architecture.
- PLC and HMI descriptions.
- Preliminary software functional description.
- Project execution methodology.
- Manufacturing schedule.
- Installation methodology.
- Commissioning plan.
- Validation support methodology.
- Inspection and Test Plan (ITP).
- Quality Assurance Plan (QAP).
- Risk assessment and mitigation strategy.

- Health, Safety and Environmental (HSE) plan.
- Project programme (Gantt chart).
- Commercial proposal, clearly itemised by engineering, equipment, installation, commissioning, validation support, training, spares, and optional services.
- List of exclusions and assumptions.