USER REQUIREMENT
FOR
STEAM STERILIZER

1 SCOPE:

This specification is intended to cover the minimum requirements to be met by the vendor in the design, manufacture and supply of one horizontal steam sterilizer.

2 EQUIPMENT AND PROCESS DESCRIPTION:

2.1 Equipment Objective

Double door steam sterilizer for pass through operations. The sterilizer should be suitable for the sterilization of glassware, garments, solutions, machine parts and other accessories to be used in the production. The system will be with Bung processing capability

3 TECHNOLOGICAL STANDARDS:

3.1 Chamber:

Size: 600 mm x 600 mm x 1200 mm (or the nearest standard size available)

S.No.	Specification	Accomplish		Remarks
		Yes	No	
3.1.1	Operating Temp: 135 degree with error +/-0.5 C with empty chamber			
3.1.2	Vacuum breaker sterilizing filter 0.22µm			
3.1.3	It should have pressurisable chamber with jacket and double door.			
3.1.4	Chamber should be made up of Stainless Steel AISI 316 L with appropriate wall thickness.			
3.1.5	Finish of inner surface Ra ≤ 1µm			

3.2 Jacket:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
3.2.1	Standard jacket should be provided.			
3.2.2	Jacket should be made up of Stainless Steel AISI 304 with appropriate wall thickness			

3.3 Doors:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
3.3.1	Doors should be Vertical at Bottom close open arrangement type.			
3.3.2	Two doors should be there made up of Stainless Steel AISI 316 L.			
3.3.3	Inner surface should have finish of Ra ≤ 1µm			
3.3.4	Gasket should be of silicon with tubular cross section			

3.4 Insulation:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
3.4.1	Insulation should be of resin bonded glass wool with an outer cover of AISI 304			

3.5 Equipment Mounting:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
3.5.1	The stand for mounting sterilizer should be of stainless steel AISI 304.			
3.5.2	The skid /framework to place sterilizer mounted on stand should also be stainless steel AISI 304.			
3.5.3	Panelling should also be of stainless steel AISI 304 with finish of Ra ≤ 1µm.			
3.5.4	The equipment should have a **Contamination seal** (stainless steel AISI304) mounting between sterilizer chamber and sterile area to avoid cross flow between sterile and non-sterile side.			

3.6 Working Conditions:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
3.6.1	To be operated in Grade D environments on the loading side while Grade C on the unloading side under laminar flow hood of Grade A.			

3.7 Accessories:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
3.7.1	All piping of stainless steel AISI 304 with full argon welding			
3.7.2	All the control valves should be of pneumatic type approved make			
3.7.3	Solenoid valves for the actuation of control valves.			
3.7.4	Steam condenser fabricated from stainless steel AISI 304 fitted in the exhaust vacuum drain line. Safety valves for jacket, chamber and steam generator.			
3.7.5	Jacket with pressure gauge.			
3.7.6	Chamber with compound gauge.			
3.7.7	Air filter for breaking vacuum (with SIP provision).			
3.7.8	Two validations port one on each side.			

3.8 Available Supplies:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
3.8.1	Pure steam			
3.8.2	Plant steam			
3.8.3	Purified water			
3.8.4	WFI water			
3.8.5	Compressed air.			
3.8.6	Power supply (400 volts, three phase, 50Hz frequency)			
3.8.7	Cooling water			

4 Complementary aspects

4.1 Training

S.No.	Specification	Accomplish		Remarks
		Yes	No	
4.1.1	Training of Customer's operators. The Vendor shall supply all available information for the adequate exploitation of equipment. For the compliance of this purpose at the job site and/or at the Vendor's shop. Vendor's technical staff shall train Customer's personnel. The scope of the training will be agreed during the contract signature.			

4.2 Pre Delivery Qualifications (PDQ)

S.No.	Specification	Accomplish		Remarks
		Yes	No	
4.2.1	Pre-Installation at the Vendor's Shop. The system or its parts as provided for in the scope of supply shall be pre-installed at the Vendor's shop prior to delivery to Customer's site. Installation will be completed and documented including mechanical parts as well as electrical connections of all parts to facilitate taking-over tests at Vendor's shop prior to delivery.			
4.2.2	After the installation of the equipment at the Vendor's shop, Factory Acceptance Tests (FAT) shall be performed and accurately documented.			
4.2.3	FAT tests shall be performed and documented according to a main protocol agreement between the Vendor and the Customer. At least two months before FAT tests are scheduled to be performed, the documents where the results of such test will be recorded should be delivered to the Customer for approval.			

4.2.4 General tests to be performed during FAT:

S.No.	Specification	Accomplish		Remarks
		Yes	No	

4.2.4.1	Visual inspection for compliance with the cGMP, in accordance with approved drawings.			
4.2.4.2	Sterilization temp.mapping			
4.2.4.3	Air-tightness tests (where applicable).			
4.2.4.4	Alarms checkout.			
4.2.4.5	I/O Checks			
4.2.4.6	Functional Tests for all control loops (where applicable).			
4.2.4.7	Functional tests of all moving parts			

4.3 Supplier Technical Documentation Requirements

In addition to providing the system specifications, the supplier must deliver the following documentation.

4.3.1 Drawings

Drawings should be consistent with standards and should be sufficient in detail to indicate all critical installation, operation and performance parameters.

Drawings should include:

S.No.	Specification	Accomplish			Remarks
		Prel.	Final.	As built	
4.3.1.1	Layout plans in scale 1:25				
4.3.1.2	Process Flow Diagrams (PFDs)				
4.3.1.3	Piping & Instrumentation Diagrams (P & ID's)				
4.3.1.4	Pressure vessel drawings				
4.3.1.5	Engineering drawings for mechanical equipment/systems				
4.3.1.6	Isometric piping/ducts diagrams				
4.3.1.7	Construction and installation drawings for mechanical equipment/systems				
4.3.1.8	Control and instrumentation diagrams				
4.3.1.9	Control panel (internal & external) layout, wiring and installation				
4.3.1.10	Equipment/systems electrical drawings				
4.3.1.11	Equipment/systems pneumatic circuit diagrams				

S.No.	Specification	Accomplish			Remarks
		Prel.	Final.	As built	
4.3.1.12	Point-to-point wiring diagrams				
4.3.1.13	Mechanical assembly drawings				

4.3.2 Lists

S.No.	Specification			Remarks
		Prel.	Final.	
4.3.2.1	Equipment and instrument list with component descriptions			
4.3.2.2	Electrical component parts list with descriptions			
4.3.2.3	Input /output lists for computer related systems			
4.3.2.4	Function check list			
4.3.2.5	Documentation list			
4.3.2.6	Spare parts list			
4.3.2.7	Parts list with point of origin			
4.3.2.8	List of all equipment suppliers			
4.3.2.9	List of all possible alarms and failures			
4.3.2.10	List of all safety equipment			
4.3.2.11	List of test parameters with diagram showing position of all measuring points			

4.3.3 Technical manuals

Manufacturer's operation and maintenance manuals for all equipment, sub-systems and other system components must be provided by the supplier. This includes also manuals of computer systems (PC's and PLC's). The manuals will be supplied in English language. Technical manuals should include:

S.No.	Specification			Remarks
		Prel.	Final	
4.3.3.1	Operator panel handbook			
4.3.3.2	Operating handbooks			
4.3.3.3	Trouble shooting guide			
4.3.3.4	Equipment description			

4.3.3.5	Equipment specifications			
4.3.3.6	Process description			
4.3.3.7	Process flowchart			
4.3.3.8	Calibration instructions			
4.3.3.9	Maintenance instructions			
4.3.3.10	Maintenance handbook			
4.3.3.11	Programming manual			

4.3.4 Supplier Certification and Procedures

Certification with supporting documentation is required to verify all materials of construction for product contact surfaces. This should include:

S.No.	Specification			Remarks
		Prel.	Final	
4.3.4.1	Certificate of analysis.			
4.3.4.2	Traceability of materials certificates indicating lot numbers and heat numbers.			
4.3.4.3	Verification and documentation of surface finishes.			

Systems which will be welded as part of the manufacturing and/or installation process require the following documentation, at minimum:

S.No.	Specification			Remarks
		Prel.	Final	
4.3.4.4	100% visual inspection of all welds fully documented			
4.3.4.5	10% boroscopy of orbital welds			
4.3.4.6	Document evidence of passivation			
4.3.4.7	Line slope verifications			
	Supplier procedures for orbital welding, passivation, material handling, etc.			

4.3.5 Computer Control System Documentation

Manufacturer’s specifications and manuals for major components of the computer control system such as:

S.No.	Specification			Remarks
		Prel.	Final.	
4.3.5.1	PLC CPU			
4.3.5.2	Power supply modules			

4.3.5.3	Digital and analog I/O Modules			
4.3.5.4	Operator interface modules			
4.3.5.5	Remote I/O modules			
4.3.5.6	Communication modules			

Specification for computer hardware components **(If applicable)** should include:

S.No.	Specification			Remarks
		Prel.	Final.	
4.3.5.7	Manufacturer			
4.3.5.8	Part numbers			
4.3.5.9	Catalog numbers			
4.3.5.10	Component type			
4.3.5.11	PLC software version number (not application software)			
4.3.5.12	Hardware configuration information (switch and jumper settings ...)			
4.3.5.13	Power requirements			

Application software

S.No.	Specification			Remarks
		Prel.	Final.	
4.3.5.14	Software Structure summary			
4.3.5.15	Detailed description of algorithms			
4.3.5.16	Fully annoted hardcopy of PLC application program			
4.3.5.17	Fully annoted program cross reference			
4.3.5.18	Backup copy of application program			
4.3.5.19	A complete listing of process variables and their memory location including:			
4.3.5.20	Process set points (ranges and limits).			
4.3.5.21	Timers.			
4.3.5.22	Counters.			
4.3.5.23	Complete listing of Input points.			
4.3.5.24	Calculations performed by the Computer Control System.			
4.3.5.25	Information flow for operator interface, PLC interface, control function and report generation.			

S.No.	Specification			Remarks
		Prel.	Final.	
4.3.5.26	Loss of power response.			

Configuration of all input/output modules including:

S.No.	Specification			Remarks
		Prel.	Final.	
4.3.5.27	Scaling values			
4.3.5.28	Switch settings.			
4.3.5.29	Input/output types.			
4.3.5.30	Input ranges.			
4.3.5.31	Operator response to alarm conditions.			
4.3.5.32	Alarm conditions and set points.			

Description of alarm conditions, including:

S.No.	Specification			Remarks
		Prel.	Final.	
4.3.5.33	Alarm Inputs and Outputs.			
4.3.5.34	Alarm messages.			
4.3.5.35	Alarm set points.			
4.3.5.36	Machine responses to alarm inputs.			
4.3.5.37	Machine reset conditions.			

Critical instruments (sensors) must be supplied with the following documentation, at minimum:

S.No.	Specification			Remarks
		Prel.	Final.	
4.3.5.38	Calibration certificates for each instrument with the certificate of the instrument used as reference for calibration			
4.3.5.39	Instrument manufacturer's specifications (range, increments, accuracy, hysteresis, etc.)			
4.3.5.40	Instrument model number			
4.3.5.41	Instrument service/usage			
4.3.5.42	Instrument materials of construction including installation connection to the system			

5 SAFETY AND ENVIRONMENTAL PROTECTION

Your attention is specially asked for following points:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
5.1	Safety switches according to the positive acting and forced disconnection type (see EN 1088 or B.S. 5304 section 9 or DIN 31001 sections 5).			
5.2	The only way to exclude these safeties is the use of the inching button. Key locks are not allowed. Plugging-in of the inching button makes the start button inoperative			
5.3	Hand -and adjustable wheels may not turn constantly. If these wheels are activated, the machine may not be able to start			
5.4	Emergency stop buttons have to be of the mushroom type, red with yellow background, and of the locking type.			
5.5	If the emergency stop is reset, the machine may not restart automatically but has to be restarted manually by pushing the start button.			
5.6	The emergency stop has to interrupt directly the feeding lines of the output elements (motors, valves, pushers, etc.) and not only an input on the PLC.			
5.7	The emergency stop button has to be within reach of the operator.			
5.8	After a current interruption, the machine may not start automatically but has to be restarted by the start button.			
5.9	The start and stop buttons have to be push buttons of the sunk type			
5.10	All motors have to be thermally protected (no fuses)			
5.11	Control circuit has to be 24 V			
5.12	Grounding of the entire framework is required.			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
5.13	Automatic fuses are required (circuit breakers).			
5.14	Electrical wires in the machine have to be numbered and indicated on electrical drawings.			
5.15	Noise level has to be lower than 85 dBa (complete installation in normal working conditions measured at 1 meter distance) and as low as possible.			
5.16	The machine may not damage the floor. Floor protectors are required (anti-vibration type).			
5.17	All nameplates and instruction plates have to be in English language. If necessary, translation can be provided.			
5.18	Operation and safety instructions have to be in English language.			
5.19	The manufacturer, or his authorized representative established in the community, will declare that the machinery being placed on the market complies with all the essential heath and safety requirements applying to it (Council Directive 89/392 EEC).			
5.20	The Supplier is responsible for obtaining relevant information concerning local and international regulations and statutory requirements.			
5.21	The Supplier has to fulfil the latest requirements valid at the moment the contract is placed.			
5.22	The supplier is responsible for ensuring that any new regulations, which are promulgated during the course of the project, are complied with.			
5.23	Materials, which may be carcinogenic, must be listed separately for approval.			
5.24	In general max. Surface temp. 45°C			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
	in production area.			
5.25	In general max. Surface temp. in technical areas: 45°C.			
5.26	All the installation must be in accordance with the International accepted regulations.			
5.27	All the machinery has to be in compliance in safety and design with the prescriptions and rules of the European Community and consequently EC certified from suppliers.			
5.28	The Indian/International regulations concerning safety must be applied.			
5.29	If any difference with European regulations is evidenced, the Indian norms must be followed.			

6 CLEANING MAINTENANCE AND SERVICE

S.No.	Specification	Accomplish		Remarks
		Yes	No	
6.1	In accordance with cGMP guidelines the unit(s) must be easy to clean, to disinfect, and where necessary, to sterilize.			
6.2	The Supplier should guarantee that, if required, a service team can be on site within one working day.			
6.3	The design should be such as to allow mechanical cleaning of the surfaces and that the cleanliness of the surfaces can be checked easily.			
6.4	All machine parts, in particular instrumentation, should be constructed so that they can be			

	easily removed and calibrated.			
6.5	All special tools required for running and maintenance must be included in the offer.			
6.6	A spare parts delivery guarantee of at least …… (Vendor to specify) years is required.			

7 RULES AND REGULATIONS:

7.1 General

S.No.	Specification	Accomplish		Remarks
		Yes	No	
7.1.1	The supplied equipment must conform to all the relevant current GMP, EU, and FDA requirements.			
7.1.2	In the event of conflict between standards and specifications, the governing order of priority shall be: • This specification • Referenced standards and codes.			
7.1.3	All lines should correspond to ISO-standard.			
7.1.4	Contract is based upon codes, standards and regulations, which are valid at the time the contract is signed.			
7.1.5	All relevant changes in standards or regulations must be complied with even if they are changed after the placement of the order. The Supplier must inform the Customer immediately should this occur. Temporary regulations do not have to be complied with.			
7.1.6	Anything, which meets not the codes, standards and regulations above, has to be listed and has to be added to the offer.			
7.1.7	During work on site the safety regulations must be followed strictly.			
7.1.8	The unit will be inspected at the site of the manufacture. The function,			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
	performance and conformity with all relevant safety regulations will be inspected and assessed.			
7.1.9	On installation, before any formal acceptance the supplied equipment will be tested according to the function and performance.			

7.2 International Regulations to be followed

These standards, recommendations and requirements are considered the minimum. Specifications that are more stringent or expansive take the precedence. In case of conflict between published requirements, final determination is the responsibility of the Owner's Representative.

The supply shall be in compliance with regulations and standards listed below and a relevant Declaration of Conformity has to be attached, if applicable:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
7.2.1	US GMP Regulations, 21 CFR, Part 2101211 and part 11.			
7.2.2	USP 29.			
7.2.3	Federal Standard 209.			
7.2.4	Commission Directive 91/356/EEC of June 13th, 1991 and as embodied in "The Rules Governing Medicinal Products in the European Union", vol. IV,			
7.2.5	"Pharmaceutical Legislation, Medicinal Products for Human and Veterinary Use, Good Manufacturing Practices".			
7.2.6	ISPE Baseline Pharmaceutical Engineering Guide, "Pharmaceutical Engineering Guides for New and Renovated Facilities", vol. III: "Sterile Manufacturing Facilities".			
7.2.7	GAMP, "Supplier Guide for Validation of Automated Systems in Pharmaceutical Manufacture".			
7.2.8	VDE regulations in general.			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
7.2.9	IEC (International Electro technical Commission).			
7.2.10	DIN 19227 (P&IDs' Symbols).			
7.2.11	European directives in general. In particular: -98/37/EC (Machinery Directive).			
7.2.12	EN ISO 11202 "Acoustics. Noise emitted by machinery and equipment. Measurement of emission sound pressure levels at a workstation and at other specified positions. Survey method in situ".			
7.2.13	EN ISO 3746 “Acoustics. Determination of sound power levels of noise sources using sound pressure".			
7.2.14	UNI EN 12096 "Mechanical vibration. Declaration and verification of vibration emission values".			

8. SCOPE OF DELIVERY:

The scope of the delivery includes:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
8.1	Units described in the specific system requirements including all necessary controls and instrumentation.			
8.2	The complete mechanical and electrical installation.			
8.3	The connections to all the necessary utilities, exhaust, and waste lines necessary for its operation…… (Vendor to specify)			
8.4	All piping and cabling of the unit(s) itself.			
8.5	Wiring and cable run: all wiring and cable run is part of the supply will supply the main power switches to			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
	be located in correspondence to the electrical and control cabinets delivered by the equipment supplier…….. (Vendor to specify)			
8.6	Pneumatic system: the supplier is to foresee the pneumatic system from the take off point placed in the proximity of the machine. The supplier is asked to indicate the number and location of the machines to be connected to the main pneumatic system and the foreseen consumption.			
8.7	All internal contacts of the supplied equipment for the required utilities.			
8.8	Unload on site of the equipment: the supplier is required to define all the necessary handling devices required to the unloading operation. The supplier will inform at least 4 weeks in advance the day of delivery and the list of required handling devices.			
8.9	Assembling operation: the required consumable, the internal transportation, the assembling tools and the required personnel are part of the supply.			
8.10	A complete set of commissioning spare parts.			
8.11	All special tools necessary for use and maintenance of the supplied equipment.			
8.12	A complete set of two years spare parts should be listed quoted and offered as option.			
8.13	All test activities as specified in this document.			
8.14	Training in the use and maintenance of the equipment.			
8.15	A complete set of documentation as specified in this document.			

9 INSTALLATION, COMMISSIONING AND TESTS:

9.1 General

S.No.	Specification	Accomplish		Remarks
		Yes	No	
9.1.1	The contractor must specify for each piece of equipment the guaranteed performance and the guaranteed system performance. These values will be tested during the acceptance tests.			
9.1.2	In addition the functionality described in the user requirements and detailed in the system specifications will be tested.			

9.2 Factory Acceptance Test (FAT)

S.No.	Specification	Accomplish		Remarks
		Yes	No	
9.2.1	The contractor will perform a Factory Acceptance Test (FAT), which will be fully documented and witnessed by representatives. The contractor will inform, according to the project timetable, 4 weeks in advance the foreseen test date.			
9.2.2	The FAT includes a full check up of the complete system (control system, change of parts, instruments, etc.).			
9.2.3	The Supplier must submit a detailed description and time schedule for the FAT to the Customer for approval.			
9.2.4	The FAT can only start once all the foreseen documents have been delivered by the supplier.			
9.2.5	If additional test should be necessary because of major function failures, the Customer expenses (travel and lodging) must be carried out by the Supplier.			
9.2.6	Shipment will only be accepted after successful test approval.			

9.3 Installation and Commissioning

S.No.	Specification	Accomplish		Remarks
		Yes	No	
9.3.1	The commissioning tests will be carried out in accordance with a written test plan developed by the supplier with clearly stated test procedures and acceptance criteria.			
9.3.2	The contractor will approve successfully completed tests and will specify items requiring additional work. Representatives will attend and participate in the commissioning tests as required.			
9.3.3	The installation and commissioning of the system will be performed facility by the contractor.			
9.3.4	The commissioning can only start once all the foreseen documents have been delivered by the supplier.			
9.3.5	The installation of the computer related systems should be performed according to the suppliers standard installation procedures. The installation parameters and all the installation deviations should be thoroughly documented and provided upon successful completion of the installation and commissioning.			
9.3.6	All equipment should be properly installed, adjusted, leveled, tagged, and connected with utilities.			
9.3.7	Point to point checks on wiring and pneumatic should be performed.			
9.3.8	All instruments should be properly calibrated.			
9.3.9	All equipment (instruments) used for qualification must be listed and approved.			
9.3.10	The calibration equipment must have all the necessary documents to			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
	demonstrate their maintenance and use.			
9.3.11	The last recalibration of all this equipment must be less then 6 months old, and evidenced by certificates.			
9.3.12	Verification that the interior surfaces of equipment are free of particles and dirt and all points of product contact meet the specified material requirements.			
9.3.13	All the clearances and tolerances specified in the drawings or recommended by component manufacturers are correct.			
9.3.14	On site verification that valves and other equipment with moving parts are in their normal position if in a power down condition and move in the correct direction with the correct speed and precision.			
9.3.15	Verification that all the Input and Output points are connected and labelled according to the documentation and that all along the input values have been scaled in accordance with the system specifications and process requirements. That all equipment components requiring configuration (software, hardware, DIP Switches, Jumpers...) are configured properly.			
9.3.16	Control loop tuning should be performed. The tuning parameters must be documented. The loops should be tested and results of tests should be documented and submitted.			
9.3.17	The commissioning should demonstrate that the system supplied by the contractor has been properly installed and that the functions are in accordance. User Requirements Specifications,			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
	Vendors System Specifications, Manuals and other documentation.			
9.3.18	Tests will be carried out for: ▪ Machines / equipment ▪ System / Sub-system (group of machines: System test) ▪ Overall system (integration test). They will be performed to test equipment performances and functions.			

9.4 Site Acceptance Test (SAT):

S.No.	Specification	Accomplish		Remarks
		Yes	No	
9.4.1	This test will be carried out once the commissioning will be completed. The scope will be to verify the performance and the functionality of the system integrated with the other factory systems.			
9.4.2	The test will be carried out to verify the system response with the expected productivity of the system.			
9.4.3	Details on the test realization will be defined during the project phase. The supplier is asked to specify the proposed duration for SAT and the standard procedure proposed.			

9.5 System Acceptance criteria

The system acceptance will be reached if:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
9.5.1	During SAT and FAT the required functionality, performances and system reliability are met.			
9.5.2	The functionality described in the User Requirement Specifications and in the System Specifications are verified and met.			

9.5.3	All the documentation agreed has been delivered			

10 QUALIFICATIONS / VALIDATION:

The system installation must be accepted by the Indian, European and American authorities.

The supplier should demonstrate:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
10.1	To be ISO-9001 certified or its equivalent			
10.2	To have experience in FDA qualified projects.			
10.3	A strong Quality Assurance capability in software development, according to GAMP.			
10.4	Capability and organization to follow the project according to a quality plan			

Major attention must be given to the documentation to be developed in the different project phases (design, realization, installation, commissioning, testing).

S.No.	Specification	Accomplish		Remarks
		Yes	No	
10.5	The complete list of the documentation required is to be in accordance with the FDA qualification requirements.			
10.6	The qualification plan of the system will be handed out to the supplier according to an agreed time schedule. On this time schedule, there will be indications, when IQ and OQ protocols will be ready.			
10.7	The Maintenance Qualification is responsibility of the customer. However, the supplier is responsible for delivering the basic documents for Maintenance Qualification.			
10.8	The offer has to include the costs for a qualification according to FDA-requirements.			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
10.9	This includes all side costs such as: calibration, measuring equipment and instruments; manpower (IQ and OQ will take place completely on site).			
10.10	Time schedule for IQ/OQ execution will be developed by together with the supplier.			
10.11	Suppliers personnel used for IQ/OQ must be well trained and experienced. This should be documented.			
10.12	The on site test run performed by the Supplier might become part of the Installation Qualification.			
10.13	Main IQ/OQ steps such as calibration must be performed and documented in accordance to a SOP approved.			
10.14	All equipment used for qualification must be listed and approved. The calibration equipment should be well documented.			
10.15	The last recalibration of all this equipment should be less than 6 month old. Proofed by certificates.			
10.16	OQ can only start after IQ approved.			
10.17	Installation qualification (IQ) will be carried out by during FAT and installation phase. IQ will include the tests performed by the contractor.			
10.18	Part of the operational qualification (OQ) will be carried out during commissioning, and SAT phase. OQ will include the tests performed by the contractor.			

11 TRAINING:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
11.1	The supplier is to include the			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
	personnel training activities. The contractor is to specify the foreseen time for: ▪ Operator/supervisor training ▪ Managers training ▪ Electrical maintenance training ▪ Mechanical maintenance training ▪ Electronic and software maintenance training			
11.2	The contractor is to specify the personnel background needed for each of the operators maintenance.			

12. GUARANTEE:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
12.1	The system must be guaranteed including all the sub-systems and components for a period of 12 months (or as mutually decided) from the date of the system acceptance for a 3-shift operation.			
12.2	The servicing companies involved for the sub-systems maintenance must be declared and the maintenance group organization described. Furthermore, the contractor will be directly responsible of the system assistance and the required operations will be co-ordinated by himself.			
12.3	In case of failures, the intervention will be guaranteed by the contractor within a maximum time limit. The contractor is asked to specify the maximum time limit			
12.4	The supplier is asked to propose as option maintenance and assistance contract after the guarantee expiration.			

13 Documents to be delivered by the Vendor:

13.1 Two copies, in the English language, of the following documents must be provided:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
13.1.1	P&ID diagrams.			
13.1.2	Operating Instructions Manual(s), including operating panel and safety operation warnings.			
13.1.3	Maintenance Instructions Manual(s).			
13.1.4	Assembly and installation Manual(s).			
13.1.5	Instrumentation and Calibration Manual(s).			
13.1.6	Troubleshooting list.			
13.1.7	Electrical and Wiring Manuals (including electrical drawing list, circuit diagrams, connection diagrams, cabinet layout, interconnection diagrams, etc.).			
13.1.8	Components list.			
13.1.9	Calibration certificate for each instrument installed in the equipment, including description for re-calibration.			
13.1.10	Certificate of Materials used for parts in contact with the product stream(s).			
13.1.11	Official approval document and manufacturing inspection protocol.			
13.1.12	Welding procedures and visual inspection reports.			
13.1.13	Qualification certificates of the technical personnel who has worked in welding and assembling of equipment shall be available on request.			
13.1.14	Biological compatibility certificate of all non-metallic materials in contact with process streams (like diaphragms, gaskets, O-rings, seals, couplings, etc.).			
13.1.15	TUV pressure test reports or equivalent.			
13.1.16	Software and hardware validation documentation for all automated systems (microprocessor, PLC and computer based systems).			

S.No.	Specification	Accomplish		Remarks
		Yes	No	
13.1.17	Safety. The Vendor should provide the Customer with all legal documents related with safety issues regulated by the official agencies of the country where the equipment if built. The scope of these documents will be clearly defined during the negotiation of the contract.			

13.2 Validation:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
13.2.1	All specified documents should be delivered at the Customer's site at least two months before the installation of the equipment so that they can be used in preparing the Validation Protocols.			
13.2.2	After installation of the equipment at Customer's site, complementary Installation and Operational Qualification (IQ, OQ) tests should be performed by the Customer and supervised (if required) by a member of Vendor's technical staff.			

13.3 Spare Parts:

S.No.	Specification	Accomplish		Remarks
		Yes	No	
13.3.1	The Vendors should provide as part of the quotation a list of proposed spare parts for at least two years operation.			