PRE-BID MEETING TENDER FOR SUPPLY, INSTALLATION,COMMISSIONING AND VALIDATION OF ULTRA FILTRATION AND STERILE FILTRATION SYSTEMS AT PII, COONOOR

Document No.:	:	**NPI/110831/EQP/TD/04**
Venue:	:	**HLL Lifecare Ltd,**
Date:	:	**31st July 2014**
Project:	:	**Revival of DPT group of vaccine manufacturing Facilty PII, Coonoor**
Attendees:	:	See attached list of attendees
Issued By:	:	**CEO HBL**
Issued On:	:	**5th August 2014**

Agenda	
1.	Pre bid Meeting Tender for Supply, Installation, Commissioning and Validation of Ultra filtration and sterile filtration systems at PII, Coonoor

<table>
<tr><th>S. No.</th><th>Clarifications on queries</th></tr>
<tr><td></td><td>Tender for Supply , Installation, commissioning and Validation of Ultrafiltration and Sterile filtration systems at PII, Coonoor
Doc No: NPI-110831-EQP-TD-04</td></tr>
<tr><td>A</td><td>Discussion on Tender Enquiry Document: NPI/110831/EQP/TD/04</td></tr>
<tr><td></td><td>General Discussion Points</td></tr>
<tr><td>1.</td><td>There are no changes in terms and conditions of Tender Enquiry Document: NPI-110831-EQP-TD-04</td></tr>
<tr><td>2.</td><td>Last date for the tender submission is extended up to 19th Aug,2014@15:00hrs as per the vendor request.</td></tr>
<tr><td colspan="2">Clarifications on URSs</td></tr>
<tr><td colspan="2">Sterile Filtration Systems
NPI_110831_EQP_URS_B1(D)-SFS 01, NPI_110831_EQP_URS_B1(D)-SFS 02 and NPI_110831_EQP_URS_B2-SFS 01</td></tr>
<tr><td></td><td>URS Point number and excerpt* / description of the specification *</td><td>Point changed as / Comment</td></tr>
<tr><td>3.</td><td>6.4 Level of instrumentation<table><tr><th>Type of control/test</th><th>Purpose</th><th>Instrumentation</th></tr><tr><td>Temperature</td><td>Monitor and indicate the temperature (during SIP)</td><td>Temperature probe</td></tr></table></td><td>6.4 Level of instrumentation<table><tr><th>Type of control/test</th><th>Purpose</th><th>Instrumentation</th></tr><tr><td>Temperature</td><td colspan="2"><u>Deleted</u></td></tr></table></td></tr>
<tr><td>4.</td><td>6.7.4 Steam traps</td><td>6.7.4 Steam traps should be provided at the drain line.</td></tr>
<tr><td colspan="3">Sterile Filtration Unit
NPI_110831_EQP_URS_B1(D)_SFU 01 and NPI_110831_EQP_URS_B2_SFU 01</td></tr>
<tr><td></td><td>URS Point number and excerpt*/ description of the specification *</td><td>Point changed as / Comment</td></tr>
<tr><td>5.</td><td>4.1 Desired / Suggested Capacity</td><td>4.1 <u>Deleted</u></td></tr>
<tr><td>6.</td><td>6.2 Failure mode detection
Emergency stop activated (manual shut down)</td><td><u>Deleted</u></td></tr>
<tr><td>7.</td><td>6.4 Level of instrumentation</td><td><table><tr><th>Type of control/test</th><th>Purpose</th><th>Instrumentation</th></tr><tr><td>Temperature</td><td colspan="2"><u>Deleted</u></td></tr></table></td></tr>
</table>

<table>
<tr><th>S. No.</th><th>Clarifications on queries</th></tr>
<tr><td colspan="3">Filter Integrity Testing Machine - NPI_110831_EQP_URS_FIM_01</td></tr>
<tr><td>8.</td><td>4.0 SPECIFIC REQUIREMENT
a) The system should include following:
e) Pneumatic connections:
f) Communication ports:
g)Internal printer:
h) External printer with:
k) Self-test:
The system has to be automatically run an internal self-test once per day when it is switched on or when it is initiated by a user at any time. The test shall be saved and can be printed at any time The following conditions shall be checked out during the self-test:
o) Preffered makes:</td><td>a) v, vi, vii. <u>Deleted</u>
e) Pneumatic connections:
i. Compressed air inlet: Integrity connector nipple
ii. Compressed air outlet: Integrity connector coupling
iii. <u>Deleted</u>
f) Communication ports:
USB / RS 232 C / Ethernet
g) Internal printer:
Thermal printer / Dot Matrix Printer to be provided and specifications of printer to be provided by vendor.
h) <u>Deleted</u>
k) Checks <u>(Deleted- Introduction Paragraph)</u>
o) <u>Deleted</u></td></tr>
<tr><td>9.</td><td>5.0 OPERATING PARAMETERS</td><td>All operating parameters shall be in the range specified or vendor to specify range.</td></tr>
<tr><td colspan="3">Ultrafiltration System -NPI_110831_EQP_URS_B1(D)-UFS 01 and NPI_110831_EQP_URS_B2-UFS 01</td></tr>
<tr><td>10.</td><td>2.1Operating Conditions:
• Surface area of the membrane: 5 m2 with a provision to increase the filter area to 10m2 (size of modules)
• Minimum working Volume: 0.01% of Total Volume</td><td>2.1Operating Conditions:
• Surface area of the membrane: 0.5 / 0.7m2 with a provision to increase the filter area to 7 m^2/14m^2 (size of modules)
• Minimum working Volume: 0.5 % of Total Volume</td></tr>
<tr><td>11.</td><td>2.2 System Specifications
<table>
<tr><th>S. No.</th><th>Description</th><th>Purpose</th><th>MOC</th><th>Capacity /Size</th></tr>
<tr><td>2.</td><td>Cassette holder</td><td>To hold filter cassettes</td><td>SS316 L</td><td>5 m2 with a provision to increase the filter area to 10m2</td></tr>
</table></td><td>2.2 System Specifications
<table>
<tr><th>S. No.</th><th>Description</th><th>Purpose</th><th>MOC</th><th>Capacity /Size</th></tr>
<tr><td>2.</td><td>Cassette holder</td><td>To hold filter cassettes</td><td>SS316 L</td><td>0.5 m^2/0.7m^2 with a provision to increase the filter area to 7m2/14m2</td></tr>
</table></td></tr>
<tr><td>12.</td><td>2.3 Vessel Specifications
TABLE 2
<table>
<tr><th>S. No.</th><th>Description</th><th>Purpose</th><th>MOC</th></tr>
<tr><td>2.</td><td>Top closure</td><td>Flat Lid</td><td>SS316L</td></tr>
</table></td><td>2.3 Vessel Specifications
TABLE 2
<table>
<tr><th>S. No.</th><th>Description</th><th>Purpose</th><th>MOC</th></tr>
<tr><td>2.</td><td>Top closure</td><td>Torospherical</td><td>SS316L</td></tr>
</table></td></tr>
<tr><td>13.</td><td>2.5 D. Flush bottom valve</td><td>D. Vessel Bottom port</td></tr>
</table>

S. No.	Clarifications on queries	
14.	**I. General characteristics of the Ultrafiltration membrane:** • Filter area of 5 m2 with a provision to increase the filter area to 10m2 • Void free composite PES membrane with 0.5M caustic compatibility. Membrane made up of equivalent polymer with above characteristics is optimal for use	**I. General characteristics of the Ultrafiltration membrane:** • Filter area of 0.5 /0.7 m2 with a provision to increase the filter area to 7 /14 m2 • PES membrane with 0.5M caustic compatibility. Membrane made up of equivalent polymer with above characteristics is optimal for use-***Point deleted***
15.	**M. Nozzles Schedule :** **Top Head Plate** • Port for level sensor with accuracy of ± approx. 0.1% of the total range **Lower wall/Bottom connections:** • Port for temperature transmitter	**M. Nozzles Schedule :** **Top Head Plate** • Port for level sensor **Lower wall/Bottom connections:** • ***Deleted***
16.	**N. All points of the IRS except the below mentioned would be applicable for the equipment**	**N. All points of the IRS except the below mentioned would be applicable for the equipment.** • 5.6 –***[Point included]***
17.	**3.2.1 The equipment will be used for concentration of toxoid** f) A separate provision to be made for product recovery to flush the module.	**3.2.1 The equipment will be used for concentration of toxoid** f) A separate provision to be made for product recovery
18.	**4.1 Desired/ suggested capacity** b) Feed Vessel: 5L (Minimum) and 150L (Maximum working Volume)	**4.1 Desired/ suggested capacity** b) Feed Vessel: 7.5 L (Minimum) and 150L (Maximum working Volume)
19.	6.1.2 Following parameters shall be controlled by the equipment h) Conductivity	h) ***Deleted***
20.	**6.2.1** c) Alarm is activated in case Temperature is out of range	**6.2.1** c) ***Deleted***
21.	6.3.3 Flow measurement on the feed inlet line	***6.3.3- Deleted***

<table>
<tr><th>S. No.</th><th colspan="2">Clarifications on queries</th></tr>
<tr><td>22.</td><td>6.4 Level of instrumentation
<table><tr><th>Parameters</th><th>Purpose</th><th>Type of control and Instrumentation</th></tr><tr><td>Conductivity</td><td>To measure the conductivity during CIP</td><td>Conductivity meter</td></tr><tr><td>Level of the volume</td><td>To maintain the correct volume of the product</td><td>With the accuracy of 0.1% of the completed range.</td></tr></table></td><td>6.4 Level of instrumentation

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Conductivity- <u>Deleted</u>
Level Sensor with the accuracy of 1 % of the completed range</td></tr>
<tr><td>23.</td><td><u>6.7.6 Pump specification: Sterile Sanitary design</u></td><td><u>6.7.6 Pump specification: Sterile Sanitary design</u>
SIP: Yes <u>[Point Included]</u></td></tr>
<tr><td>24.</td><td>6.7.13 Performance Requirements: Vendor to demonstrate the following during FAT/SAT
• Temperature Control along with the level accuracy to be demonstrated.</td><td>6.7.13 Performance Requirements: Vendor to demonstrate the following during FAT/SAT
<u>Deleted</u></td></tr>
<tr><td>25.</td><td>6.7.14 Design Considerations:</td><td>6.7.14 Design Considerations:
• Vessel design Pressure: vendor to specify
• Vessel design Temperature: vendor to specify
• Design pressure for safety release valve: vendor to specify</td></tr>
<tr><td>26.</td><td>List of Preferred Make of components
• Pressure Gauge- WIKA/Denver/Negele
• Temperature Transmitter – Radix/Yokogawa/ Emerson
• Steam trap – Spirax Marshall
• Printer - Canon/Epsilon/HP
• Vent filter cartridge – Sartorius/PALL/Millipore
• Filter Housing – Sartorius/PALL/Millipore
• Flush Bottom valve – Novaseptic/GEMU</td><td>List of Preferred Make of components
• Pressure Gauge- WIKA/Denver/Negele/Anderson
• Temperature Transmitter – Radix/Yokogawa/ Emerson/Negele
• Steam trap – Spirax Marshall/Sterilflow
• Printer - Canon/Epson/HP
• Vent filter cartridge – Sartorius/PALL/Millipore/GE
• Filter Housing – Sartorius/PALL/Millipore/GE
• Flush Bottom valve – deleted</td></tr>
</table>

For HLL Lifecare Limited

P. Anjan

CEO

nne pharmaplan

NNE Pharmaplan India Limited, #12, Achiah Shetty Layout, RMV extn, Bangalore – 80, INDIA

List of Attendees

Date: 31 July 2014

Client: M/s. HLL Lifecare Limited, Chennai

Venue: M/s. HLL Lifecare Limited, Chennai

Project: Revival of DPT Vaccine Manufacturing Facility

Subject: Pre Bid Meeting For Supply, Installation, Commissioning And Validation Of Ultra Filtration Systeme And Sterile Filtration Syeteme

Name	Company	Signature
A. ANTO FELIX	HLL	
Shilpa Rao	NNE Pharmaplan	
K. Shekharbabu	NNE Pharmaplan	
VIGNESHKARAN.T	HLL	
D. PONRAJ	MERCK MILLIPORE	
Deepu Vasi	MERCK MILLIPORE	
Vinay Kumar. K. S.	Pall	
Dr. B. SUNDARAN	Pasteur Institute, Coonoor	31/7
Dinesh Krishnan	GE Healthcare	