MINUTES OF THE MEETING

PRE BID MEETING OF TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF MICROFILTRATION SYSTEM AT PASTEUR INSTITUTE OF INDIA, COONOOR

Document No.	:	**NPI/110831/EQP/TD/03**
Venue	:	**HLL Lifecare Limited, Chennai**
Date	:	**31.07.2014**
Project	:	**Revival Of DPT group of Vaccine Manufacturing Facility-PII,Coonoor**
Attendees	:	**See attached list of attendees**
Issued by	:	**CEO HBL**
Issued on	:	**4th Aug 2014**
Issued from	:	**NNE Pharmaplan India Limited, Bangalore**

Agenda	
1.	Pre-bid Meeting for supply, installation, commissioning and validation of Microfiltration system at PII,Coonoor

<table>
<tr><td>S. No.</td><td colspan="2">Clarifications on queries</td></tr>
<tr><td></td><td colspan="2">Tender for supply, installation, commissioning and validation of Microfiltration system at PII,Coonoor - TE Doc No: NPI-110831-EQP-TD-03</td></tr>
<tr><td>A</td><td colspan="2">Discussion Tender Enquiry Document: NPI-120310-EQP-TD-03</td></tr>
<tr><td></td><td colspan="2">General Discussion Points</td></tr>
<tr><td>1.</td><td colspan="2">There is no changes in terms & conditions of this Tender Enquiry Document: NPI-110831-EQP-TD-03</td></tr>
<tr><td>S. No.</td><td colspan="2">Clarifications on URSs</td></tr>
<tr><td>B</td><td colspan="2">URS: – D-MFS 01, T-MFS 01</td></tr>
<tr><td></td><td>URS Point number and excerpt* / description of the specification *</td><td>Point modified as/Comment/Inclusion</td></tr>
<tr><td>1.</td><td>2.1 Operating Conditions:
Temperature range: 0-40°C during process and 134 °C during SIP</td><td>2.1 Operating Conditions:
Temperature range: 0-40°C during process and 121°C during SIP..</td></tr>
<tr><td>2.</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>1</td><td>Top Closure</td><td>Flat Lid</td><td>SS316L</td></tr><tr><td>5</td><td>Jacket</td><td>Hollow type; For temperature control</td><td>SS304</td></tr></table></td><td>2.3 Vessel Specifications TABLE 2
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<tr><td>3.</td><td>2.4 Vessel design Specifications TABLE 3
<table><tr><th>S.No.</th><th>Description</th><th>Purpose</th></tr><tr><td>1</td><td>Geometric volume</td><td>500L</td></tr></table></td><td>2.4 Vessel design Specifications TABLE 3
<table><tr><th>S.No.</th><th>Description</th><th>Purpose</th></tr><tr><td>1</td><td>Geometric volume</td><td>Vendor to specify</td></tr></table></td></tr>
<tr><td>4.</td><td>A. Dosing unit for feed/buffer/saline: Fermentor broth shall be transfer to feed tank of the system with the fixed piping with the help of sterile nitrogen/ sterile air through a sterile valve assembly.</td><td>A.Dosing unit:-
i.For Buffer:- Reusable sterilizable SS housing with 0.22µm liquid filter (Code 7 type) with sterile valve assembly, which is to be sterilized along with vessel.
ii.For Feed: Fermentor broth shall be transfer to feed tank of the system with the fixed piping with the help of sterile air through a sterile valve assembly.</td></tr>
<tr><td>5.</td><td>D. Air Filters:
Inlet Air filters:
• Reusable and sterilizable SS housing with 0.2/0.22µm sterile filter (Code 7) with manual diaphragm valve, which is to be sterilized along with vessel.
• Exhaust Air filters: Exhaust filter with manual diaphragm valve</td><td>D. Vent Filters:
• Reusable sterilizable SS housing with 0.22µm sterile filter (Code 7 type) with manual diaphragm valve, which is to be sterilized along with vessel.</td></tr>
<tr><td>6.</td><td>F. Flush bottom valve:It should be zero dead leg type valve attached directly to the bottom of the vessel. The diaphragm shall be of PTFE type.</td><td>F. Vessel bottom valve: Diaphragm valve to be provided at the vessel outlet.</td></tr>
<tr><td>7.</td><td>G. Feed Line:</td><td>G. Feed Line:
• Flow switch & Temperature sensor<u>[point Included</u>]</td></tr>
<tr><td>8.</td><td>H. Permeate Line:</td><td>H. Permeate Line:
• Electromagnetic flow meter for measuring the flow of conductive fluids in process applications <u>[point Included</u>]</td></tr>
<tr><td>9.</td><td>I. Retentate Line:</td><td>I. Retentate Line:
• pH sensor <u>[point Included</u>]</td></tr>
</table>

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<tr><th>S. No.</th><th>Clarifications on queries</th><th></th></tr>
<tr><td>10.</td><td>J. CIP(Clean in Place):
• CIP of the system to be carried out along with the tank and the associated pump</td><td>J. CIP(Clean in Place):
Manual CIP of the vessel and Auto CIP for cassettes to be carried out along with the associated pump.</td></tr>
<tr><td>11.</td><td>K. SIP (Sterilization in Place):
Inlet air filter and vent filter with associated manual diaphragm valve at the filter housing drain</td><td>K. SIP (Sterilization in Place):
• Inlet air filter and vent filter with associated manual diaphragm valve at the filter housing drain. – [Point Deleted]</td></tr>
<tr><td>12.</td><td>L. General characteristics of the microfiltration membrane:
Membrane made up of equivalent polymer with above characteristics is optimal for use.</td><td>L. General characteristics of the microfiltration membrane:
Membrane made up of equivalent polymer with above characteristics is optimal for use. [Point Deleted]</td></tr>
<tr><td>13.</td><td>N. Controller: PLC Based Controller and SCADA with a 10” industrial touch screen large HMI (Displaying data trends as Graphs, synoptic view of running parameters etc).</td><td>N. Controller: PLC Based Controller with a min. of 10” touch screen HMI (Displaying data trends as Graphs, synoptic view of running parameters ,POP-up message during sequence etc).</td></tr>
<tr><td>14.</td><td>P. Nozzles Schedule :
Top Head Plate
• GMP type Spray ball/s assembly- static type - 360°
• Sterilizing grade hydrophobic inlet filter and vent filter (0.2/0.22 µm filter) with SS housing and manual diaphragm valve
Lower side wall/ Bottom Connection:
• Port for temperatureindicator
• Port for pH transmitter
• Flush bottom valve – Flush welded to the bottom dish.</td><td>P. Nozzles Schedule :
Top Head Plate
• GMP type Spray ball/s assembly- static type - 360°- 2No.s
• Sterilizing grade vent filter (0.22 µm ,Code7 type) with SS housing and manual diaphragm valve.
Lower side wall/ Bottom Connection:
• Port for temperature indicator -Deleted
• Port for pH transmitter -Deleted
• Vessel bottom port</td></tr>
<tr><td>15.</td><td>4.1 Desired/ suggested capacity
400 L Vessel (working volume) / 500L (Gross Volume)</td><td>4.1 Desired/ suggested capacity
400 L Vessel (working volume)</td></tr>
<tr><td>16.</td><td>6.4 Level of instrumentation
<table><tr><th>Parameter</th><th>Purpose</th><th>Type of control and Instrumentation</th></tr><tr><td>Temperature</td><td>Monitor and control the temperature</td><td>RTD sensor and temperature indicator & controller on the tank and SIP drain</td></tr><tr><td>Flow rate</td><td>Monitor the rate of flow of retentate</td><td>Electromagnetic flow meter</td></tr></table></td><td>6.4 Level of instrumentation
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<tr><td>17.</td><td>6.7.15 Basic requirement shall be provided by the vendor to calculate the filter area.</td><td>6.7.15 Deleted.</td></tr>
</table>

<table>
<tr><th>S. No.</th><th colspan="2">Clarifications on queries</th></tr>
<tr><td>18.</td><td>URS Annexure 2:
List of Preferred Make of components
• 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>URS Annexure 2:
List of Preferred Make of components
• 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>
<tr><td>C</td><td colspan="2">URS:- P MFS 01</td></tr>
<tr><td>1</td><td colspan="2">All the above mentioned points will be applicable for this URS/P MFS-01 except point no. 2,8,16</td></tr>
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<tr><td></td><td>H. Permeate Line:</td><td>H. Permeate Line:
• Electromagnetic flow meter for measuring the flow of conductive fluids in process applications - <u>Deleted</u></td></tr>
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<tr><td></td><td>6.7.23
• It shall be 21CFR part 11 compliance for data acquisition</td><td>6.7.23
• It shall be 21CFR part 11 compliance for data acquisition-<u>Deleted</u></td></tr>
</table>

For HLL Lifecare Limited

Chief Executive Officer

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 Supply, Installation, Commissioning And Validation Of Microfiltration Systems

Name	Company	Signature
Renjith. M.C	HLL	
Dr. B. Sundaram	PIIC	30/7
Vinay Kumar. K.S.	PIPL	
SHREYAS. SRIDHARAN	PIPL	
Deepu Nair	Merck Millipore	
Pongraj Ponnusamy	Merck Millipore	
Dinesh krishnan	GE HC	
Shilpa Rao	NNE Pharmaplan	
K. Shivarbahw	NNE pharmaplan	
A. ANTO FELIX	HLL	