NOTICE TO THE PUBLIC
June 21, 2022

RFQ#1255878

The Food and Drug Administration (FDA) seeks competitive offers which will be awarded via a purchase order.

Project Title
Single Pass Tangential Flow Filtration System (SPTFF)

Period of Performance:
06/27/2022-06/28/2023

Statement of Work
Single Pass Tangential Flow Filtration System (SPTFF)

The FDA has a requirement for a Single Pass Tangential Flow Filtration System (SPTFF). This equipment will be integrated into a continuous manufacturing process being developed in FDA labs and will provide a better understanding of the technology and regulatory concerns associated with this technology.

The SPTFF systems shall be designed to allow for in-line concentration of proteinaceous solutions including monoclonal antibodies. The systems will be used in a continuous manufacturing process at two potential locations: harvest and downstream post-polishing. The system shall include all pressure gauges/sensors, flow meters/sensors, filter holders and select filters required to perform SPTFF required to achieve in line concentration targets mentioned in section 3. The SPTFF units (2 total) shall be capable of concentrating both harvested/clarified cell culture fluid as well as purified protein solutions depending on the application needed. The systems shall be capable of concentrating harvested/clarified cell culture fluid in the range of 10-60 liters per day from starting titers of <1g/L. Additionally, this SPTFF unit shall also be capable of concentrating purified protein solutions with concentrations up to 15mg/mL.

Technical Specification for the System

The system shall include the following:

- Two (2) SPTFF systems
    - Shall include all necessary items required for initial use:
        - Digital pressure gauges (0-60 PSI range) with sanitary connectors

        - In-line flow sensors
        - Tubing and clamps (3/4inch sanitary fitting and tri-clamps)
        - Filters (see below)
        - Filter holders with extended rods if required (stainless steel preferred)
            - Mini cassette holders preferred due to small filter areas
        - SPTFF kits including all divertor and retentate plates and gaskets
- Filters
    - Individual filter areas should be $0.1m^2$ to $0.3m^2$ with up to four (4) filters to be used per system at one time
    - Regenerated Cellulose or Polyether Sulfone (PES) membranes preferred
    - Molecular weight cut offs (MWCOs)
        - Four (4) 100kDa MWCO filter with a coarse screen
        - Four (4) 30kDa MWCO filter with a coarse screen
- Fluid concentration
    - Ability to concentrate harvested/clarified cell culture fluid in the range of 10-40 liters per day from starting titers of <1g/L.
    - Ability to concentrate purified protein solutions starting from 5-10 g/L with a volumetric range of 2-10 liters per day.
    - Total filter areas may range from $0.1m^2$ to $1.5m^2$ (TBD)

1. Tasks/Deliverables

- 2 SPTFF systems accessories to be delivered:
    - Digital pressure gauges with sanitary connectors (at least 2 per system)
    - In-line flow sensors (if required)
    - Tubing and clamps (3/4inch sanitary fitting and tri-clamps) (4 boxes of tubing and sanitary fittings with clamps and gaskets for connection to filter holder ports)
    - Filters (see below)
    - Filter holders with extended rods if required (stainless steel preferred) (2 total)
        - Mini cassette holders preferred due to small filter areas
    - SPTFF kits including all divertor and retentate plates and gaskets (one for each holder)
- Filters
    - Individual filter areas should be $0.1m^2$ to $0.3m^2$ with up to four (4) filters to be used per system at one time

    - Regenerated Cellulose or Polyether Sulfone (PES) membranes preferred
    - Molecular weight cut offs (MWCOs)
        - Four (4) 100kDa MWCO filter with a coarse screen
        - Four (4) 30kDa MWCO filter with a coarse screen
    - Warranty should cover all parts for at least 1 year.
- Proposal pricing should be inclusive of shipping costs.

2. Shipment/ Destination

The vendor shall provide shipping, handling and inside delivery to CDER's facilities on-site at CDER's facilities in: Silver Spring, MD (10903 New Hampshire Ave, Building 52/72 Room 2228, Silver Spring, MD 20903), unless otherwise indicated.

The FDA's Technical Point of Contact (TPOC) will approve all tasks and deliverables.

3. High-Level Timeline/Schedule

Upon award of contract, the vendor shall meet with the TPOC/COR to discuss specifics of the system:

- Within 4 weeks of award, meet with TPOC/COR to discuss specifics required to ensure proper design of system (appropriate filter modules, etc.) and installation needs.
- Within 60-120 days, deliver SPTFF system(s) and install systems in FDA labs (this may be delayed based on current COVID restrictions to shipping and product availability)

Administrative Information Regarding Invoicing

352.232-71 Electronic Submission of Payment Request (FEB 2022)

(a) Definitions. As used in this clause-

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

b. FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)

a. All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP). http://www.ipp.gov/vendors/index.htm

b. Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in in FAR 32.905(b), Content of Invoices and the applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions - Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov.

c. (1) The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 - 5 business days of the contract award for new contracts or date of modification for existing contracts.

(2) Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

(3) The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

(4) If your company is already registered to use IPP, you will not be required to re-register.

(5) If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

d. Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

e. Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.

At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;

Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirect)- show rate, base and total amount;

Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;

Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;

Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;

Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and

Fee - amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

f. Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

(a) list of all invoices submitted to date under the subject award, including the following:

(1) invoice number, amount, & date submitted

(2) corresponding payment amount & date received

(b) total amount of all payments received to date under the subject contract or order

(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.

g. Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.

h. If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.

i. Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

j. The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

k. Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

All quotes must be received by 10:00 a.m., Eastern Standard Time on June 26, 2022, via email to Linda Troutman at Linda.Troutman@fda.hhs.gov. The FDA intends to make an award immediately after the response date of this notice. The award will be made in accordance with FAR Part 13, Simplified Acquisition Procedures. Please enter in the subject line of the email the RFQ#1255878