June 06, 2022
Notice to the Public
Request for Quotation (RFQ) #1254511

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

Project Title

Refractive Index Detector for the current Akta Avant-25 FPLC System

Period of Performance

One (1) Year Manufacture Warranty from award of the Purchase Order

Statement of Work
Refractive Index Detector for the current Akta Avant-25 FPLC System

Background

Polysaccharide molecules are commonly used as drug substance or excipients in complex drug products. Polysaccharide can have structural heterogeneities in monosaccharide type, length, branch, and modifications. To perform a comprehensive analysis of polysaccharide mixtures, prior separation is required. However, the lack of a chromophore on the molecule limited the application of liquid chromatography (LC) on polysaccharides. Instead, polysaccharides can be detected using a refractive index (RI) detector. The addition of a new RI detector onto an existing fast protein LC (FPLC) will prepare the Agency for studying many polysaccharidebased molecules in drug products. The research and regulatory application of this system will help CDER establish a scientific basis for regulatory decisions in approving biosimilar/generic or manufacture changes in addition to enhancing the level of understanding of how polysaccharide structures are distributed in complex drug mixtures.

To fill the need for the RI detection that is currently not available in the FDA/CDER/OPQ/OTR laboratory in White Oak, an addition of an IR detector to the existing Akta Avant-25 FPLC is required.

Objective

The RI detector will be used to extend the capability of OTR to perform FPLC fractionation on fractioned polysaccharide studies, not currently available.

Scope

This statement of work covers the purchase, installation and qualification of a RI detector for the current Akta FPLC system in OTR lab in White Oak, in addition to any applicable warranty period.

Deliverable Table

Deliverable	Description	Quantity/Media
1	Refractive Index Detector	1
1	Delivery, installation, installation qualification, operational qualification and onsite training	1

- Delivery shall be no later than 90 days after contract award.
- Vendor shall perform installation and operational qualification services (IQ/OQ) on delivered equipment within 30 days of delivery and provide a certificate (electronic or paper) showing IQ/OQ qualification.
- Familiarization (either onsite during installation or virtually) of instrumentation shall be provided for at least 2 users following IQ/OQ within 30 days of delivery.
- Warranty should cover all parts and installation for at least 1 year from the date of IQ/OQ.

Government-Furnished Property, Material, Equipment, or Information (GFP, GFM, GFE, or GFI)

Government furnished property includes the Cytiva Akta Avant-25 FPLC system with I/O module. The new RI detector will be attached to the existing FPLC through the Cytiva I/O E9 module. There will be no additional software required.

Requirements

Upon contract approval, the contracted company shall deliver within 90 days and install the product. Vendor shall perform installation and operational qualification services (IQ/OQ) on delivered equipment within 30 days of delivery.

- The Refractive Index (RI) detector shall be compatible with the currently available Cytiva I/O E9 module

(https://www.cytivalifesciences.com/en/us/shop/chromatography/tools-andaccessories/other-accessories/i-o-box-e9-p-04946).

- Detector range shall cover 1.0-1.7 RIU.
- Compatible flow rate shall cover 0.1-10 mL/min.

Period of Performance

The period of performance begins the date that equipment is installed and operational and continues for one year (warranty period) from the date of formal government acceptance. Instrument shall be delivered no later than 90 days after contract award. Installation and training shall take place no later than 30 days after delivery.

Delivery will be accepted during regular business hours (Monday-Friday) during the times of 8:00 AM – 4:00 PM Pacific Time.

Acceptance Criteria

Partial acceptance is made upon delivery of all the parts. Full acceptance is made after completion of Installation and Operational Qualification (IQ/OQ) by the contractor that the system meets all the specifications and requirements.

Place of Performance

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Testing and Research 10903
New Hampshire Ave.
WO52-72, G434
Silver Spring, MD 20993

******All quotes must be received by 10:00 a.m., Eastern Standard Time on June 09, 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.**