



NOTICE OF INTENT TO SOLE SOURCE

Date Posted: December 12, 2022
Response Date: December 27, 2022
Subject: Lorenz eCTD Software
FDA ID: NOI_FDA-SS-114902

This is a notice that the U.S. Food & Drug Administration (FDA) intends to award a sole source, firm fixed-price contract to Lorenz International LLC., located at 1515 Market Street, Suite 1200, Philadelphia, PA 19102. The Government intends to issue a sole source award in accordance with FAR 6.302-1, only one responsible source and no other supplies or services will satisfy agency requirements.

Classification Code: DA10 – IT and Telecom -Business Application Development Software

NAICS Code: 513210- Software Publishers; Small Business Size standards – \$41.5 million.

The FDA requires enterprise-wide license along with support and maintenance of the Lorenz eCTD validation and review software that has been integrated into the electronic submission and review process at the FDA.

Technical Requirement - Salient physical, functional, or performance characteristics that “equal” products must meet are specified in the solicitation: The potential Contractor shall be capable of the following:

- 1) The Contractor shall have the capability to obtain an enterprise-wide license of the Lorenz eCTD software.
- 2) The Contractor shall have the experience and capability to perform maintenance of the Lorenz eCTD software.
- 3) The Contractor shall be capable to modify and upgrading the Lorenz eCTD software.
- 4) The Contractor shall be capable to deliver and install new versions of the Lorenz eCTD software after any modification/upgrades.
- 5) The Contractor shall be capable of supporting the FDA’s effort to test and implement software product releases in the FDA test and preproduction environment prior to release/implementation in the FDA production environment. This includes addressing and resolving issues identified during the release/implementation process.
- 6) The Contractor shall be capable to support CDER and CBER with their own center-specific implementations of the software.
- 7) The Contractor shall be capable of integrating eCTD COTS software interface with each center’s tracking system to display regulatory information.

This notice is not a request for competitive proposals. However, interested parties that believes it can meet this technical requirement as stated herein may submit a written capability statement that clearly supports and demonstrates their ability to perform the requirement. Capability statements shall be received by the response date and time of this notice. Submissions will be reviewed to determine if they can meet the requirement. A determination by the Government to compete this proposed contract based upon responses to this notice is solely within the discretion of the Government.

It is anticipated that an award will be issued to Lorenz International LLC., within approximately ten (10) days after the date of this notice unless the Government determines that any other organization has the capability to meet this requirement.

Response Date: December 27, 2022, by 8:00AM (EDT). Please email responses to Roosevelt Walker at roosevelt.walker@fda.hhs.gov. **No phone calls will be accepted.**