

## OneSource receives EIR with 'Voluntary Action Indicated' classification from USFDA for its BLD Facility

**Bangalore, India, January 28, 2025** - OneSource Specialty Pharma Limited today announced that it has received an Establishment Information Report (EIR) with a 'Voluntary Action Indicated' (VAI) status from the U.S. Food and Drug Administration (USFDA) for its BLD facility in Bangalore. The report follows an inspection of the facility, conducted from November 14 - 22, 2024.

**Commenting on the development Neeraj Sharma CEO OneSource said** “We are pleased to receive the EIR with VAI classification from the USFDA for our BLD facility. This inspection outcome reflects our commitment to maintaining high-quality standards and regulatory compliance across all aspects of our operations. Our facility stands as one of the few FDA-approved penicillin sites globally, with a long-standing legacy of supplying to the US market. As a specialty pharma CDMO, we are dedicated to continually advancing quality standards, and solidifying our position as a trusted partner in the CDMO sector globally.”

OneSource operates five state-of-the-art cGMP facilities and has a strong track record, with 138 successful regulatory and customer audits to date by all major regulatory bodies.

### About OneSource Specialty Pharma Limited

OneSource Specialty Pharma Limited formerly known as Stelis Biopharma Limited, is India’s first specialty pharma pure-play CDMO business. OneSource Specialty Pharma operates five state-of-the-art facilities in Bengaluru, India, all approved by major regulatory bodies, including the USFDA and EU authorities. Along with a team of over 1,200 professionals, including 200+ techno-commercial experts, we specialize in diverse dosage formats and advanced biologics platforms.

Our comprehensive solutions span across platforms and therapeutic modalities, including Biologics, Drug-device Combinations, Sterile Injectables, and Oral Technologies. Committed to innovation and excellence, we support global partners in delivering life-saving products efficiently.

### For further information, please contact:

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