ASX Announcement

CLEO Successfully Completes Stage 1 MDSAP Audit

Highlights

- **Stage 1 MDSAP audit complete – a key milestone in CLEO's global regulatory strategy**
- **MDSAP enables companies to meet the regulatory requirements of multiple major jurisdictions, including the FDA, through a single harmonised audit process**
- **Positive feedback confirms the clarity and regulatory alignment of CLEO's quality management system**
- **Milestone strengthens CLEO's pathway to FDA submission and commercial launch, with Stage 2 scheduled for Q2 CY2026.**

MELBOURNE, AUSTRALIA, 30th October 2025: Ovarian Cancer diagnostics company, **Cleo Diagnostics Limited** (**ASX:COV**) (**CLEO** or **the Company**) is pleased to announce it has successfully completed Stage 1 of the Medical Device Single Audit Program (**MDSAP**), a key milestone in the Company's ISO 13485:2016 Quality Management System (**QMS**) certification pathway.

The MDSAP is a two-stage process that enables medical device companies to meet the regulatory requirements of multiple major jurisdictions, including the U.S. Food and Drug Administration (**FDA**), through a single, harmonised audit process. This significantly streamlines global market access and supports CLEO's commercial and regulatory strategy for its Pre-Surgical Ovarian Cancer Test.

CLEO received positive feedback on the clarity, completeness and regulatory alignment of its quality system documentation. Stage 2 of the MDSAP audit is scheduled for Q2 CY2026 and will assess full implementation of the QMS and ongoing compliance with international regulatory standards.

CLEO's Director of Quality & Regulatory Affairs, Emma Lester, commented:

> *"Participating in the MDSAP program reinforces CLEO's commitment to quality, safety, and regulatory readiness. Successfully completing Stage 1 represents a significant achievement for the Company and an important stepping stone toward our broader regulatory and commercial goals."*

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Commenting on the outcome, CLEO's Chief Executive Officer, Richard Allman said:

"Completion of Stage 1 of the MDSAP audit is an important reinforcement of the quality systems underpinning our technology and commercial strategy. It positions us strongly as we advance towards FDA submission and global commercialisation."

This achievement aligns with CLEO's broader regulatory roadmap and the Company's commitment to delivering solution to improve outcomes for women facing ovarian cancer."

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This ASX announcement was authorised for release on behalf of the Cleo Diagnostics Ltd Board.

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About Cleo Diagnostics Ltd ASX:COV

CLEO aims to bring to market a simple blood test for the accurate and early diagnosis of ovarian cancer based on the novel patented CXCL10 biomarker, which is produced early and at high levels by ovarian cancers but is largely absent in non-malignant disease. The test aims to distinguish benign from malignant growths in a standard format that will be readily compatible with existing equipment used by diagnostic laboratories worldwide.

The platform is backed by over 10 years of scientific Research & Development at the Hudson Institute of Medical Research, with two clinical studies conducted with over 500 patients. Pursuant to a licence agreement with the Hudson Institute of Medical Research, CLEO has a worldwide exclusive licence to commercialise the intellectual property which underpins its operations and the ovarian cancer tests.

The clinical unmet worldwide need is urgent. An accurate and early detection blood test could shift survivability for ovarian cancer significantly as seen with other cancers. CLEO is advancing the availability of its simple blood test, under a modular execution strategy which is designed to eventually address all ovarian cancer detection markets with specific tests including surgical triage, recurrence, high risk, and early-stage screening.