Singular Health Group Ltd: SHG

ASX Announcement

29th March 2023

Singular Attains ISO13485 Certification

- Singular Health attains ISO13485 Certification for Quality Management System for Software-as-a-Medical-Device (SaMD) manufacture and distribution.
- Successfully passes audit for the Medical Device Single Audit Program (MDSAP) which combines TGA, FDA, and Health Canada audits into a single audit.
- ISO Certification and MDSAP Audit now enables regulatory submissions for the Australian, New Zealand, Canadian and Singaporean markets for 3Dicom MD®.

29 March 2023 – Medical technology company Singular Health Group Ltd (ASX: SHG) ("Singular Health", or "the Company") is pleased to announce that it has successfully attained ISO13485:2016 certification for the International Standard for In-Vitro Diagnostics and Medical Devices.

Concurrent with the Company's ISO13485 audits, Singular also participated in Medical Device Single Audit Program (MDSAP) audits, consolidating required TGA, FDA, and Health Canada audits into a single audit to save significant time and money.

The pathway to ISO13485 and MDSAP certification was impacted heavily by the COVID-19 pandemic which prevented auditors from travelling to Western Australia and generated a very tight labour market for highly skilled regulatory consultants during 2020 and 2021 in the initial phases of implementing the complex regulatory and quality control frameworks.

Thanks in a large part to the efforts of an external European regulatory consultant in the setup, implementation, and growth of the Company's electronic Quality Management System (eQMS) and the internal team who worked across numerous time zones throughout the implementation, the eQMS was able to be established just in time for the Western Australian border to be reopened to East Coast based auditors to conduct the Stage 1 and Stage 2 Audits in mid-late 2022.

The vigorous international panel reviews involved in assessing Company's for inclusion to MDSAP and certification for ISO13485 took a further four months and demonstrates the very high barrier to entry for medical device companies, a barrier now crossed by Singular Health.

With ISO13485 Certification and the audits covered by MDSAP being prerequisites to regulatory submissions with the relevant health agencies in Canada, Australia, Singapore and many more markets, Singular Health can now make further regulatory submissions for 3Dicom MD® in addition to the existing FDA clearance in other Countries to expand the total addressable market for the diagnostic 3Dicom MD® software.

It also enables the Company to be able to provide 13485 compliant Software-as-a-Medical-Device (SaMD) development for large enterprise upon request for technical integrations and contract development.

James Hill, Singular's Group Chief Operating Officer and Regulatory Correspondent, commented on these recent quality and regulatory certifications and approvals, saying:

> "These recent quality and regulatory achievements are the result of a concerted, diligent approach by all our staff and provides external validation of the culture and skills developed at Singular Health that fosters innovation, values quality, and mitigates risk.
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> "It is a testament to our team, and the highly skilled consultants, that only three years after commencing development of the 3Dicom Software-as-a-Medical-Device, we have cleared world recognised regulatory hurdles such as ISO13485 and FDA clearance."

Ends

This announcement is authorised for release by the Board of Directors of the Company.

For further information contact

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About Singular Health:

Singular Health Group Limited (ASX: SHG) is a medical technology company utilising advanced technologies to develop patient-specific solutions.

Singular Health's 3Dicom software solutions empower patients and practitioners to better visualise, communicate, and understand medical imaging data. 3Dicom MD® is cleared for diagnostic use in the United States

Singular 3DP, a wholly owned subsidiary of Singular Health, uses advanced 3D printing and post-processing to manufacture TGA-approved patient-specific medical devices.

To learn more, please visit: www.singular.health