



August 31st, 2021

Micron Provided Support for the Development Software as Medical Device (SaMD:) and has Already Received 20 Contracts.

Micron Inc. (Head Office: Minato-ku, Tokyo; President & CEO: Michita Sato; Micron Inc.), a subsidiary of CE Holdings Co., Ltd. and provider of support services for imaging technology and clinical trials, announced today that since it began providing support for the development of Software as Medical Device (SaMD:) since August 2018, Micron has already received 20 contracts.



The Pharmaceutical and Medical Devices Law has been revised and the development of SaMD has been actively conducted both in Japan and overseas. By 2020, the U.S. Food and Drug Administration (FDA) has approved approximately 50 Software as Medical Device programs, but only a few of them have been approved in Japan. Micron has received more than 20 contracts for SaMD certification and approval consulting, PMDA consultations, trial planning, monitoring and STED preparation, and 8 contracts for certification and approval.

The development of SaMD is unique in the design of clinical trials, unlike conventional pharmaceuticals and medical devices. In order to meet the reliability criteria, it is often necessary for medical specialists to make a central decision on the images, and it is important to have the know-how that can only be obtained from handling medical images as an imaging CRO. Unlike consumable medical devices, medical device sales also require in-house systems and dedicated technical staff.

Micron, which holds certification in medical device manufacturing and marketing business as well, is "a company that comprehensively studies imaging trials and evolves" and is capable of providing integrated support from development to sales.

There are many cases where clients who get to know each other through INDICATE* activities are confused because they don't understand the difference between Japanese certification and approval. As this confusion may cause a lag, we provide smooth development support after consulting with clients.

The Ministry of Health, Labour and Welfare has published a report titled "Compilation of the Social Security and Work Style Reform Headquarters with a Perspective of 2040". In the face of increasing manpower constraints, the need to secure medical and nursing care services is a challenge, and the clinical positioning of SaMD is expected to change. We also offer observational and intervention studies for insurance coverage, including regulatory coordination. For SaMD development consultation, please contact a specialized CRO.

* INDICATE (**I**nnovative **D**iagnostic **I**maging **C**apabilities **A**doption **T**o **E**nd-users delivers innovative imaging technology to your doorstep) is the project launched with the theme of “Bridging the gap between SaMD and diagnostic technologies”. In this project, we are introducing and proposing image analysis technologies that incorporate AI and other advanced technologies.

Micron, Inc. Company Information

President	Michita Sato
Head Office	3-13-16 Mita, Minato-ku, Tokyo, Japan
Established	October 3, 2005
Business Contents	<ul style="list-style-type: none"> - Supports the development of pharmaceuticals, diagnostics, medical devices, and biomarkers by utilizing imaging technologies - Clinical development support (monitoring, quality control, imaging core lab, image analysis, central imaging review, etc.) - PET tracer manufacturing support - Consulting for clinical development
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Contact

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