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# MDSAP Audit Allows Emerging Firm To Expand Internationally

by Elizabeth Orr

Blood-collection technology firm Tasso has been recommended for certification by MDSAP. The international qualification is part of a push to offer the company's technology in countries such as Australia and Canada, CEO Ben Casavant told *Medtech Insight*.

The blood-collection technology developed by emerging medtech firm *Tasso Inc.* has broad appeal.

Not only do the device's design and upper-arm placement reportedly cause far less pain than traditional blood draws, but it can be easily used in a patient's home – sparing the time and hassle of going to a lab.

So it is perhaps no surprise that the company is working on partnerships with a range of drug and health care companies. And when some of those partnership opportunities involved distributing the devices in Canada and Australia, the company opted to pursue international certification via the Medical Device Single Audit Program (MDSAP).

Certification by MDSAP, which is operated by the International Medical Device Regulators Forum (IMDRF), confirms that a device firm meets regulatory standards for Australia, Canada and the US. Additionally, the certification may streamline the process of getting regulatory authorization in countries like Japan and Brazil, which also participate in IMDRF. (Also see "*Compliance Corner: Leverage MDSAP Companion Doc To Master Your Next Audit, Train Staff, Expert Advises*" - Medtech Insight, 25 Jun, 2020.)

Tasso's blood collection technology, which includes the Tasso+ lancet and the Tasso-M20 for collection and transport of dried blood samples, amounts to "a new way for people to access health care," Tasso co-founder and CEO Ben Casavant told *Medtech Insight* during a recent interview.

“[Our technology] helps people be able to connect to diagnostic testing for a variety of needs on their own terms and on their own time,” he said. “It doesn’t have to be within the bounds and confines of a hospital.”

Tasso has partnered with medtech firms including CardioRenal, Q2 Solutions and Catapult Health, who are using the Tasso technology either for at-home screening or during clinical trials. And Casavant says other partnership announcements are coming this summer, including the use of Tasso devices in multi-country pharmaceutical clinical trials.

## ‘Very Rigorous, Very In-Depth’

The 100-employee company underwent an MDSAP audit in February and has since been recommended for certification. “MDSAP really solidifies our quality system on that end to be able to do more and help in more aspects as people look to deploy Tasso more broadly,” he said.

In addition to the strategic value, MDSAP certification also helps to “show the robustness of our quality system and how seriously we take all the regulatory standards,” Casavant said.

The MDSAP audit process is “very rigorous, very in-depth, and something that really tests the quality system,” Casavant said, adding that the process was similar in scope to other regulatory audits Tasso has experienced. Still, he would recommend obtaining certification to other smaller device companies.

“It’s something that really I think is important for companies to do to show that robustness, to be proactive with the regulatory agencies, and to show to show that compliance,” he said.

The CEO said Tasso’s technology also meshes well with a recent drive toward decentralized clinical trials, which are both less costly than the traditional model and may help increase participant diversity by making it easier to take part in a clinical trial. (Also see "*Decentralized Clinical Trial Guidance Fulfills Promise, Underlies Digitization Of Healthcare*" - Medtech Insight, 4 May, 2023.)

For example, the company is working on a trial for a drug for epilepsy. Measuring biomarkers associated with epilepsy is historically difficult, because people with epilepsy usually cannot drive to a lab directly after a seizure. Collecting blood samples at home allows for quicker collection and improves trial precision, as well as reducing participant drop-out rates.

“Painless blood collection is a really important piece, but the whole philosophy is, ‘how do we really center that whole process around the patient and around the person?’” Casavant said. “The way that we want to push healthcare forward is kind of reframing that focus.”