MCRA Supports CamDiab with FDA Approval for Artificial Pancreas Software

Client Need

CamDiab Ltd is a digital health and personalized medicine company focused on the design, development, and commercialization of its world leading, interoperable CamAPS FX closed loop app. CamDiab retained MCRA's team of Digital Health and Quality Assurance experts to assist with the FDA submission process for the CamAPS FX app.

"CamDiab is grateful for the invaluable support provided by MCRA's team in achieving FDA clearance for our innovative diabetes treatment app, CamAPS FX. The dedication and expertise of MCRA's Digital Health and Quality Assurance teams were instrumental in our success, and we appreciate their tireless efforts in paving the way for this milestone."

Dr. Roman Hovorka, Founder, CamDiab

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MCRA Approach

Due to the nature of the software used, the MCRA team assembled a pre-determined change control plan (PCCP) to ensure the software could be updated easily, without the need for additional FDA submissions.

MCRA THERAPY: Digital Health

MCRA SERVICES: US Regulatory, Quality Assurance

Outcome

The pre-determined change control plan is an impressive achievement for MCRA and CamDiab, as it is a relatively new concept from the FDA with a high-level of expertise needed. In the end, CamDiab successfully obtained FDA clearance for the CamAPS FX app with the support of MCRA.

Alex Cadotte, VP of Digital Health, AI & Imaging at MCRA states, "We helped CamDiab navigate FDA policy and feedback on a really short timeline to turn this PCCP into a win for both FDA and CamDiab. We're really excited about the clearance and how it expands options for patients."

Nima Akhlaghi, Director, Digital Health & Imaging Center Lead at MCRA states, "MCRA's team is thrilled to have helped support CamDiab's new app for diabetes treatment, CamAPS FX. Our Digital Health and Quality Assurance teams worked diligently to provide an avenue to success for this innovative diabetes app and are proud to have assisted in obtaining FDA clearance."