MCRA Assists Pangea Laboratory to Achieve Breakthrough Device Designation

Client Need

Pangea Laboratory is a CAP-accredited and CLIA-certified laboratory working to develop and offer innovative diagnostic tests and services.

Pangea Laboratory approached MCRA in search of specialist IVD regulatory knowledge and experience to obtain FDA Breakthrough Device Designation for their next-generation epigenetic-based liquid biopsy bladder cancer and upper tract urothelial carcinoma (UTUC) test, Bladder CARE™.

"James Mullally & MCRA's extensive regulatory knowledge of cancer IVDs were instrumental in the development of our breakthrough device submission for our bladder and upper tract urothelial cancer test, Bladder CARE™. With the assistance of MCRA, our team was able to respond to the FDA's request for additional information in an efficient and timely manner. We look forward to collaborating with MCRA in the future."

Yap Ching Chew, Chief Operating Officer, Pangea Laboratory

MCRA Approach

MCRA provided strategic guidance toward the structure and development of the FDA Breakthrough Device Designation submission, and led the drafting and revision of the document, ensuring that key messaging was delivered to address the breakthrough statutory criteria. MCRA also led the strategy and development of Pangea Labs' response to FDA's challenging request for additional information.

MCRA THERAPY: IVD
MCRA SERVICES: Breakthrough Device Designation

Outcome

FDA's request for additional information challenged key aspects of the data provided to support the breakthrough request, including whether the performance data demonstrated a significant improvement over an existing PMA device with the same indication. MCRA's extensive knowledge of cancer IVDs allowed MCRA to provide expert strategy and guidance for the response overall, but also to meticulously counter each FDA challenge with valid scientific and regulatory arguments. The outcome was a Breakthrough Device Decision granted to Pangea Labs' Bladder CARE™ test for the qualitative detection of bladder cancer and UTUC.

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