

MCRA Assists Occlutech through Sunshine Act Compliance and Clinical Monitoring Support

Client Need

MCRA's clinical team has been in long term partnership with Occlutech supporting various monitoring activities for the Occlutech portfolio. In preparation for US commercialization, Occlutech reached out to MCRA for Sunshine Act support in advance of FDA clearance of their first US device, the Occlutech ASD Occluder. Occlutech wanted to ensure that they are compliant with their marketing practices and procedures as they start the commercialization journey.



"This is the second project I have worked on with the MCRA monitoring team. What brought me back for our 2nd project was the consistency among their individual monitors. Their ability and willingness to collaborate with our internal team has helped lead us to success.

We continue to tap into MCRA's many offerings. What began with their monitoring services has expanded to the Healthcare Compliance team as we prepare for Open Payment reporting. The team has been phenomenal to work with as we step into this 'new to our organization' reporting requirements. We are grateful for the level of experience this team brings to the area."

Paula Kamman

Senior Director, US Clinical Affairs

Occlutech

MCRA Approach

MCRA conducted a risk assessment of Occlutech's existing policies and procedures to confirm current compliance performance. From this initial assessment, MCRA was able to tailor the client's compliance offerings to fully support Occlutech's Sunshine Act strategy through completion of compliance workflows, policy development, employee training and assisting Occlutech with its required regulatory reporting cycle. For the clinical monitoring engagement, MCRA was able to leverage the client's existing clinical site relationships to understand the intricacies at each site and ensure study sites stay on track.

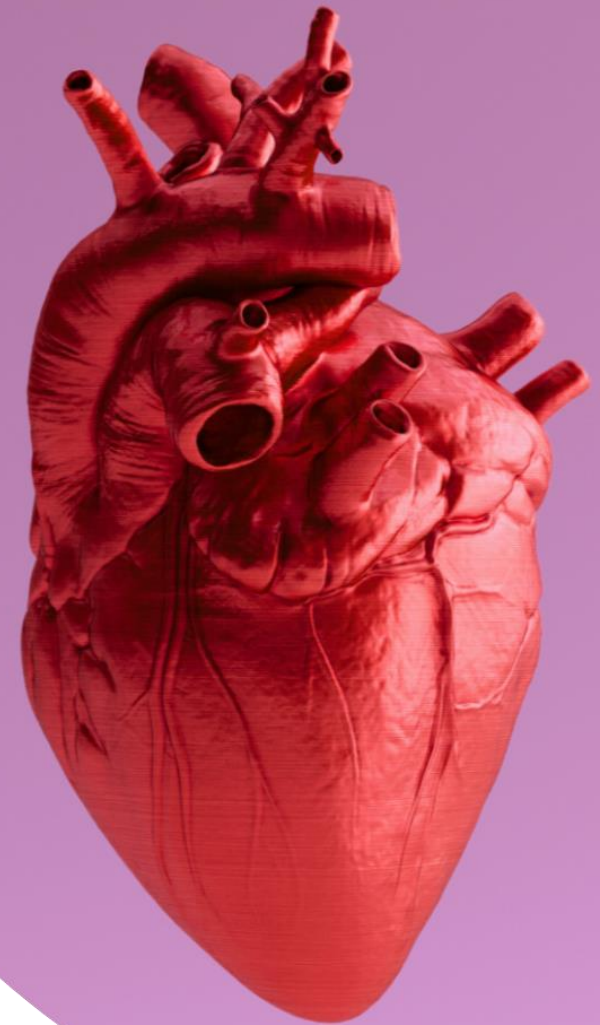
MCRA THERAPY: Cardiovascular

MCRA SERVICES: Compliance, Clinical

Outcome

Through our integrated services approach, MCRA was able to help Occlutech prepare for commercialization in the United States by building a strong foundation of procedures, policies, and employee education.

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