New Cardiology Steering Committee to Expand Awareness of Cardiology EFS

As a founder, director, and CEO of multiple companies in the cardiovascular device space who has personally experienced the benefits of the FDA’s EFS program, Rick Geoffrion wants every early-stage cardiovascular company to know about the EFS program and MDIC’s work within the program, including the creation of the MDIC EFS Tool Kit. That’s why he is co-chairing MDIC’s new EFS Cardiology Steering Committee, along with Jaime Walkowiak, General Counsel at InstilBio.

“The EFS program has been one of the most important regulatory policy initiatives in the last 20 years,” says Geoffrion. “Without an opportunity to access the EFS program, many early-stage companies, particularly Class III device companies, would find it challenging to exist.” Geoffrion is now President and CEO of Cyrano Therapeutics, Inc., which developed a treatment to restore the sense of smell and flavor in those who have lost it. He is also Vice Chair of The Mullings Group and a member of MDIC’s Board of Directors and Executive Committee.

Walkowiak also has personal experience with EFS as the former COO of the Baylor Scott & White Research Institute. The research institute conducted 13 EFS studies between 2014 and 2020, mostly involving Class III mitral valve and tricuspid valve devices. Using tools developed by the MDIC EFS Initiative, now a part of the MDIC EFS Tool Kit, helped the research institute grow its EFS Initiative.

Working with Entrepreneurs to Increase Awareness of the EFS Cardiology Program

Geoffrion and Walkowiak are recruiting members for the MDIC EFS Cardiology Steering Committee, which will include industry, clinicians, FDA, and CMS. One early priority is to increase awareness of the MDIC EFS Initiative among entrepreneurs in new device companies, who may not know about MDIC.

“Early-stage entrepreneurs will eventually show up on the doorstep of venture capital groups, CROs and selected law firms who specialize in medtech,” says Geoffrion. “It is our intent to target the VCs, CROs and law firms with an attention and awareness campaign so that emerging companies both in cardiovascular and the other medtech sectors can learn about the benefits of the EFS program and the tools MDIC has made available at the earliest stage.”

Highlighting the Benefits of the EFS Program in Videos

A series of videos on the EFS program, Emerging HealthTech: The MDIC Series, are part of the awareness campaign, along with promotion on LinkedIn. Developed by The Mullings Group, the videos provide an overview of the EFS program and include Geoffrion’s personal experience with an EFS for a class III PMA device in structural heart.

“If a company like mine did not have the opportunity to take advantage of the EFS program, we may have ceased to exist,” he says. “And I think there are many companies that would have been in the same situation.”