ABOUT THE COMPANY

Imagine a cancer treatment scenario where a medical device detects, analyzes, and treats multiple tumors in a single treatment. RefleXion is pursuing a valiant mission to impact the lives of millions of cancer patients around the world with the first biology-guided radiotherapy (BgRT) system. In support of the mission, RefleXion has chosen Arena as the system of record for design and quality controls.

ADDRESSING QUALITY AND COMPLIANCE

RefleXion Medical is on a fast-paced, high-growth path with its mission to provide better options for cancer patients worldwide. Innovation drives the team’s product development. At the same time, RefleXion adheres to the highest quality and
compliance standards for life sciences companies. Almost from the beginning of product design, RefleXion knew they needed the support of a product realization platform that would grow with the team, the product, and their path through medical device compliance. “We didn’t have many processes or even paper in place before Arena. We believed Arena was the solution we needed and could grow with us,” explains Dipali Pattanayak, Senior Quality Systems Specialist at RefleXion.

The company’s growth has been aggressive, even by startup standards, tripling the team in 18 months. With fast team growth and continued product design progress, RefleXion needs everyone in sync. “Every single person at RefleXion uses Arena. Of course, people have different roles and access levels, but for product and quality, everyone goes to Arena,” says Dipali.

RefleXion began with Arena to manage parts and bills of materials (BOMs) and standard operating procedure (SOP) documentation rollout and then continued to utilize Arena for product revision control. The company uses Arena’s document, quality, training, and project management capabilities for product processes, including nonconformance reports (NCRs) and device history files (DHFs) organization. Arena is also integrated with the company’s QAD enterprise resource planning (ERP) system for purchasing processes.

Summing up RefleXion’s choice, Dipali says: “Arena is a powerful tool, optimized to control parts and BOMs, and additionally allows review and approval of design and quality system documents with integrated training. While other systems offer similar functionality, the ease of configuration and the validation quick start package made Arena the right choice for RefleXion.”