



Customer Success Story: **RefleXion Medical**

Establishing Design Control Processes for Today and the Future

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.



At a Glance

Mission:

Revolutionizing cancer care

Growth Environment:

3x the team in 18 months

Best Thing about Arena:

Confidence in design control

Process Gain:

Cycle-time reductions

Success Factor:

Every single person uses Arena

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 BOMs and standard operating procedure documentation rollout and then continued to utilize Arena for product revision control. The company uses Arena's document, quality, training, and project management functionalities for product processes, including NCRs and DHF organization. Arena is integrated with the company's downstream QAD ERP system for purchasing processes.

Dipali shares about RefleXion's choice, "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."



Dipali Pattanayak

Senior Quality Systems Specialist

“ Arena is the solution we can grow with. ”