



Customer Success Story: **Pulse Biosciences**

Achieving Closed-Loop Design Control Across the Organization

What if treatments for some cancers could be done without the added toxicology (i.e. drug-free)? Pulse Biosciences is fulfilling this promise with a novel and proprietary platform technology called Nano-Pulse Stimulation (NPS), where nanosecond pulsed electric fields induce cancer cells in cancerous tumors to die in a natural way, by triggering the adaptive immune system response.

In this critical product mission, Pulse Biosciences is relying on Arena to manage all aspects of quality management processes—from BOM creation to design controls, device history file (DHF), records keeping, and training management—to make this dream a reality.



At a Glance

Innovative Technology:
Nano-Pulse Stimulation (NPS) for cellular and intracellular therapeutic applications

Must Have:
Good design control system

Training Compliance with Arena:
97+%

Confidence In:
Complete traceability

When evaluating solutions, Pulse Biosciences knew what they needed—one place for all product lifecycle and quality management processes. Guneet Bhogal, quality assurance specialist, shares, “We wanted to have a closed-loop system with everyone collaboratively working on the same current product definition, through the same processes, to the same goals.” For medical device companies like Pulse Biosciences, predictability and consistency are not only good, but critical.

Prior to implementing Arena, Pulse Biosciences’ product processes were paper-based, and the team expended extensive efforts to track everything manually and ensure compliance. Now, Pulse has implemented Arena’s full suite of solutions. “Arena helps us with DHF, project management, supplier management, CAPA, all our quality actions like NCMRs, change control of course, and management of training,” says Guneet.

For Pulse Biosciences, collaboration and access anytime around the world is important—whether team members are out performing clinical trials or on vacation. “It is critical that we can handle urgent changes with all the necessary security and tracking, regardless of where people physically are in the world. Arena provides all this,” says Guneet. All employees use Arena, from the CEO to engineers to the clinical team. “We do management review boards with Arena and refer to Arena Analytics dashboards to make sure everyone knows where we are now and where we can improve.”

As an apparatus-based electroceutical company, audits and compliance are ever-present requirements. With Arena in place, Pulse Biosciences has completed state-level audits, reporting that auditors appreciated the control and structure demonstrated. Arena is the company’s solution for product realization from conception to development to sustaining phase in the future. As the company grows, the team plans to expand usage of Arena even more, including secure supplier access. Guneet summarizes, “Everyone appreciates the ease, collaboration, and virtual empowerment of Arena.”



Guneet Bhogal
Quality Assurance Specialist

“Arena makes the whole product process much faster and efficient. Simply put, everyone here at Pulse loves Arena.”