

# Seamless Quality, Right on Time: How Pi-Cardia Transitioned to Dot Compliance Ahead of a Critical U.S. Launch

## The Challenge: Replacing a Legacy System at a Pivotal Moment

As a medical device company preparing to launch its product into the U.S. market, Pi-Cardia needed a fully validated, automated eQMS that could keep pace with growing regulatory demands. The company's previous quality system was a hybrid solution, partially electronic but lacking full validation, comprehensive modules, and the automation required for a scaling operation.

With revalidation of the legacy system looming, Pi-Cardia faced a decision: reinvest in an aging platform or transition to a purpose-built eQMS. There was little room for missteps. Any new system would need to ensure data integrity, minimize operational disruption, reduce the risk of lost documents, and support employees through the change, all while the company was just months away from a major U.S. product launch.

## The Solution: A Structured, Supported Transition to Dot Compliance

Pi-Cardia selected Dot Compliance to replace its legacy system and unify quality processes across the organization.

Dot Compliance assigned a dedicated project manager who worked hand-in-hand with the Pi-Cardia team throughout the rollout. Comprehensive training was delivered to the QA team and representatives from other departments, covering the full suite of modules including master documents, maintenance, complaints, change control, and deviations.

Keren Jan Wolf, Senior QA Specialist, noted the value of that partnership: "The training went really smoothly with the QA team and with other relevant representatives from the other departments. The project manager was really collaborating with us and was always available to help."

The full implementation was completed in approximately three to four months, keeping Pi-Cardia on track for its U.S. launch timeline.



**Industry** Medical Equipment Manufacturing

**Location** Israel

### About

Pi-Cardia is a medical device company and market leader in the development of a broad portfolio of leaflet modification solutions for treating heart valves. The company has years of knowledge and expertise accumulated in degenerated valves, including calcification patterns, mode of valve failure, and impact of various methods of leaflet modification. ShortCut™ is designed to provide a safe, simple, and effective way to split leaflets of a pre-existing valve to enable TAVR in patients at risk for coronary obstruction and may assist in preserving coronary access.



## The Benefits: Independence, Auditability, and Ease of Use

Since going live, Pi-Cardia has seen meaningful improvements across the organization. One of the biggest benefits has been full user independence. Departments across the company, from engineering and maintenance to QA and supply chain, now work directly within the system's modules without bottlenecks.

For Jan Wolf, the Training module has been a standout. "The training module is really intuitive. It's really easy to work with the read-and-understand assignments, the classroom training, and especially the on-the-job training with effectiveness checks. It really documents training the right way."

That quality was validated externally as well. During a recent audit, external auditors reviewed Pi-Cardia's on-the-job training records and provided positive feedback on the documentation and process.

The company has also recently implemented the medical device complaints module, which Jan Wolf noted feels more tailored to their needs as a device manufacturer. The team continues to adopt new modules and leverage system updates as they become available.

## Looking Ahead: Continued Growth on a Trusted Platform

With a validated eQMS now in place and a successful U.S. launch behind them, Pi-Cardia is positioned to scale confidently. The team continues to work closely with Dot Compliance on future enhancements and growth initiatives, supported by a responsive help desk for day-to-day questions, troubleshooting, and input on upcoming upgrades.

"Go for it, the system is great. It's easy to use, you can implement whichever modules you need, and users have full independence. You just need to train your people in advance, and that's all you need."

**Keren Jan Wolf,**  
**Senior QA Specialist**

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