

## Cost Containment and Flexible Medical Device Manufacturing Case Study

### *RenalGuard®*

RenalGuard Solutions, Inc. is a privately held medical device OEM focused on innovative technologies for the cardiac and vascular markets. Their lead product, [RenalGuard®](#), is a medical device designed to protect patients from contrast dyes used in medical imaging procedures that can be toxic to kidneys. [Clinical investigations](#) have demonstrated that RenalGuard® is effective for the prevention of contrast-induced acute kidney injury (CI-AKI) in at-risk patients.

RenalGuard® is CE-marked and sold in Europe, as well as other countries around the world. Currently, the product is limited in the US for investigational use only while they seek FDA approval for US distribution.



*"RenalGuard Solutions, Inc., is a medical device company focused on innovative technologies for the cardiac and vascular markets.*

*RenalGuard®, is designed to rapidly remove contrast dyes that are known to be toxic to the kidneys."*

*For more information, visit the RenalGuard Solutions, Inc. website.*

## **Challenge:** Cost Containment and Flexibility

RenalGuard Solutions needed a [medical device manufacturer](#) that could manage their export-only production and then scale with ease following FDA approval. As clinical studies are extremely expensive, it was crucial that Cogmedix could provide cost-effective manufacturing services that supported market penetration outside the US while RenalGuard Solutions simultaneously performed domestic clinical trials.

Prior to outsourcing medical device manufacturing to Cogmedix, RenalGuard Solutions divested a number of other technologies to focus solely on RenalGuard<sup>®</sup>. As a result of shifting focus solely to this product, reducing overhead and physical footprint was a top priority.

## **Solution:** FDA-Compliant Manufacturing and A Plan for the Future

Combined with the unpredictable order volume of the device and the expenses of exporting, RenalGuard Solutions was motivated to minimize costs and maximize efficiency. Cogmedix was willing to work with them prior to and during the FDA clinical trial period with the expectation that, once approval came, production volumes would grow significantly. Additional cost reductions were achieved by leveraging a unique relationship with [Columbia Tech](#), a fellow subsidiary of Coghlin Companies, to source PCBAs for device production.

These savings could all be reinvested into the product, including its promotion outside the US and the pursuit of FDA clearance to allow penetration of the US market. With help from Cogmedix, RenalGuard Solutions has established an avenue to manufacturing their product in compliance with FDA regulations. When their volumes increase, Cogmedix will be ready to support that growth.

## Implementation: A Relationship with Room to Grow

Turnkey medical device manufacturing services provided for the RenalGuard<sup>®</sup> console include: supply chain management, change management, quality assurance, manufacturing, and packaging. Unlike other manufacturing companies, which typically have a minimum threshold for production, Cogmedix is open to small or variable volume operations with innovative companies of all sizes. Cogmedix values not only the production quantity, but also the positive impact a medical device can potentially have for patients and the medical community as a whole.

The Caring Associates at Cogmedix set themselves apart by truly understanding what a long-term relationship means. Short-term challenges are not daunting when a team maintains focus on developing a lasting relationship with OEM clients. A strong system of competency-based cross-training ensures that the Caring Associates at Cogmedix provide excellent coverage to customers both large and small. It also gives them the flexibility of a well-trained staff that can move from one program to another with ease.

### **About Cogmedix**

*Cogmedix is a team of talented and caring associates bringing OEM medical technology to life. Providing turnkey manufacturing services to a broad range of medical and dental OEM's, Cogmedix delivers high quality products to market with compliance, competence, and commitment. Cogmedix provides a high level of flexibility in product launch and demand management and aligns itself with innovative companies that maintain similar high standards in honesty and integrity. Cogmedix is a subsidiary of Coghlin Companies, Inc., a privately held concept to commercialization firm spanning four generations. Visit Cogmedix and sign up for the e-Newsletter at <http://www.Cogmedix.com>.*



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