

EBOOK

How 4 Pre-Market MedTech Companies are Leveraging Greenlight Guru Quality

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Table of Contents

2 Puzzle Medical: Revolutionizing Patient Care with Innovative Medical Devices

- 3 The Challenge
- 3 The Solution
- 3 The Results

5 Delta Development: Designing Critical Devices for Military and Emergency Applications

- 5 The Challenge
- 5 The Solution
- 6 The Results

7 Avenda Health: Artificial Intelligence for Prostate Cancer Mapping and Treatment

- 7 The Challenge
- 7 The Solution
- 8 The Results

9 Photonicare: Enhancing Diagnosis and Treatment for Ear Infections

- 9 The Challenge
- 9 The Solution
- 10 The Results

11 Get your devices to market faster with Greenlight Guru Quality

Getting a medical device to market is an intricate and demanding process for even the most talented of teams. Working through design and development, navigating regulatory requirements, ensuring a smooth design transfer—these are some of the challenges that every pre-market MedTech company must face sooner or later.

That's why a best-in-class quality management system (QMS) solution, like [Greenlight Guru Quality](#), is paramount to the success of pre-market companies. With so much to accomplish in so little time, most early stage MedTech companies simply can't afford to worry about manually documenting design controls, chasing down signatures, and maintaining a fully traceable system.

Pre-market MedTech companies need a QMS solution that does all of that for them. At Greenlight Guru, we've been helping MedTech companies get their devices to market for more than a decade, and we're proud to have supported our customers in their journeys to become market leaders.

So let's take a look at how four of those companies leveraged Greenlight Guru Quality to accelerate development, simplify compliance, and deliver life-changing medical devices to patients around the world.

1 **Puzzle Medical: Revolutionizing Patient Care with Innovative Medical Devices**

[Puzzle Medical](#) is dedicated to enhancing survival rates, reducing hospital readmission rates, and improving the quality of life for patients. Their minimally invasive heart pump, the ModulHeart, is designed to avoid blood damage and stroke risk while providing stability, enabling patients to engage in proper outpatient therapy.

The Challenge

Puzzle Medical faced several challenges in developing their Class III medical device prototypes, including comprehensive regulatory and development documentation, selecting reliable manufacturers, and ensuring stringent quality control over supply chain processes.

The precision and quality of the prototypes was paramount, requiring them to meet all quality checks and testing requirements. Additionally, creating a unique device necessitated the development and documentation of new test methods to support its innovation.

The Solution

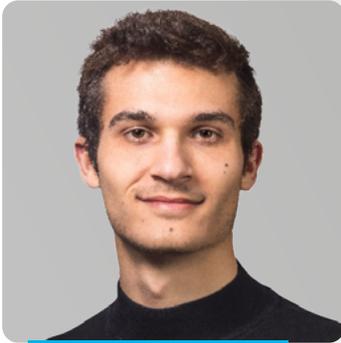
To overcome these challenges, Puzzle Medical set specific goals. They aimed to manufacture precise and high-quality prototypes in a fast-paced environment while maintaining compliance. They focused on connecting research and development, quality, manufacturing, and supply chain documentation and processes.

The team at Puzzle Medical also needed to achieve [ISO 13485 certification](#) and capture all testing data, protocols, risk assessments, and processes within their QMS. Collaborating with partner teams to develop components of their ModulHeart device was also a crucial part of their strategy.

To accomplish all of this, they turned to Greenlight Guru Quality.

The Results

Puzzle Medical achieved remarkable results through their partnership with Greenlight Guru. They accelerated their go-to-market timeline by five months year-over-year. The use of Greenlight Guru's QMS software saved an average of 5-10 hours of work per employee per week across various activities such as change orders, training, design & development, risk management, and audits. On top of all that, the Training Management workspace in Greenlight Guru Quality ensured that 100% of their employees had up-to-date training records.



Greenlight Guru was instrumental in implementing our quality system. With them, we can bring safer, high-quality medical devices to success while maintaining a quality culture throughout our entire device lifecycle.

Gabriel Georges, Co-founder and Chief Scientific Officer, Puzzle Medical

The company received the FDA's [Breakthrough Device Designation](#), affirming the novelty of their device and its potential for providing more effective treatment based on preclinical data. Additionally, Puzzle Medical was granted two patents with five more in progress, and in 2023 closed a CAN\$ 34 million Series A funding round to complete the company's Human Feasibility Study.



2 Delta Development: Designing Critical Devices for Military and Emergency Applications

[Delta Development Team](#) focuses on innovative technologies for military and emergency applications. They specialize in creating high-quality, portable refrigeration units to meet the U.S. Department of Defense's needs.

The company's mission is to provide advanced solutions for critical rescue operations, and their flagship product is the Autonomous Portable Refrigeration Unit (APRU), which ensures the constant cooling of blood products, vaccines, virus samples, and temperature-controlled medications.

The Challenge

Delta Development faced several significant challenges in their journey to market. They needed to develop a portable refrigeration unit that could withstand the extreme conditions of military applications. Additionally, the product would be regulated by the FDA as a Class II exempt medical device, requiring a thorough understanding of both military requirements and regulatory guidelines.

The team was committed to keeping all product development and manufacturing in-house to maintain control over speed-to-market. This decision meant they also needed to manage regulatory aspects internally. Robert Futch, CTO, had previous quality management experience but had struggled with disconnected systems, making it crucial to find an effective quality management solution.

The Solution

To address these challenges, Delta Development adopted a comprehensive and collaborative approach to quality management. They looked for a QMS solution that would integrate all critical components, suppliers, and processes.

After exploring various options, they chose Greenlight Guru Quality for its ability to link quality system data efficiently and provide the necessary traceability and automation. The software's intuitive design, along with the use of audit-tested QMS templates and consultative services from medical device experts on its [Customer Success](#) team ensured a smooth and effective implementation process.

The Results

Delta Development saw significant results from implementing Greenlight Guru Quality. The quick implementation and intuitive flow of the software allowed them to maintain their speed-to-market while ensuring regulatory compliance. The integrated quality management system improved traceability and efficiency, particularly during audits.

As Fuch put it, “With Greenlight Guru, we’re ready for an audit long before it ever happens.”

The team benefited from the expertise of Greenlight Guru’s Customer Success team, who provided critical regulatory guidance and support, making it easier to navigate complex compliance requirements.

This partnership enabled Delta Development to focus on developing their innovative APRU device, confident in the robustness of their quality management processes. By choosing Greenlight Guru, Delta Development has been able to achieve a high level of product quality and safety, essential for their mission in military and emergency applications.



Greenlight Guru was the only way we could get our small team to move really quickly with a QMS.

Monti Lejia, CEO, Delta Development Team

3 Avenda Health: Artificial Intelligence for Prostate Cancer Mapping and Treatment

Avenda Health's artificial intelligence software supplies physicians with a cancer map with more precision and accuracy than a traditional MRI. This provides physicians with a clearer understanding of the extent of disease to improve patient outcomes.

The company's mission is to improve the quality of life, treatment planning, and outcomes for men diagnosed with prostate cancer. To get their novel device to market, Avenda needed a powerful and intuitive QMS built specifically for MedTech companies.

The Challenge

Avenda Health's team is dispersed across the country. Collaboration across product development and quality teams was difficult without a single source of truth everyone could rely on.

Additionally, navigating the regulatory climate to bring their SaMD product to market was no easy feat. Staying up to date with requirements and documentation, all while ensuring the teams from coast to coast were aligned was a top priority for Avenda.

The Solution

Avenda Health ultimately decided to go with Greenlight Guru Quality, a decision that would dramatically improve the way their teams were collaborating on medical device development.

According to Crystal Womack, Quality Manager at Avenda, partnering with Greenlight Guru has helped their team beyond providing them with a powerful QMS solution. They've also found the industry education, SOP templates, courses, training workshops, and Greenlight Guru Academy to be incredibly useful.



Our partnership with Greenlight Guru gives us great QMS software made for us and access to so much support that helps us as a medical device company.

Crystal Womack, Quality Manager, Avenda Health

The Results

Greenlight Guru's eQMS and audit-ready SOP templates have helped Avenda Health implement their quality system, streamline compliance and get to market faster and more efficiently.

“Greenlight Guru is very user-friendly and easy to learn across all skill levels. Being able to create links to anything in the software has been a game-changer,”—Crystal Womack, Quality Manager

Their new QMS has also accelerated remote collaboration. Because Greenlight Guru Quality is so easy to use, Womack noted, even team members with no experience in the system can quickly get started.

Together with their powerful QMS and the training and support that the Customer Success team at Greenlight Guru provided, Avenda Health was able to obtain their second 510(k) clearance and bring their Unfold AI device to market. And in a [recent study](#) published in the *Journal of Urology*, researchers found that using Unfold AI significantly improved urologist's and radiologist's ability to identify prostate cancer extent in patients.

4 Photonicare: Enhancing Diagnosis and Treatment for Ear Infections

Photonicare aims to provide physicians with advanced tools to improve treatment decisions and care for children with ear infections. Their innovative device, the OtoSight, uses ultrasound-related technology that allows for more accurate diagnoses compared to the traditional otoscope. This advancement addresses the nearly 50% misdiagnosis rate associated with conventional methods, reducing unnecessary surgeries and antibiotic use.

The Challenge

As an early-stage company, Photonicare needed a more efficient way to manage documentation. Their initial paper-based QMS was disorganized and relied on employees juggling priorities. The system was time-consuming and cumbersome, and the team knew they needed a more efficient, purpose-built solution.

The Solution

Photonicare turned to Greenlight Guru Quality to solve their organizational issues and improve their efficiency. The cloud-based solution allowed for electronic routing and approval of documents, providing a clear view of all design controls in one place. And with Greenlight Guru, Photonicare could see existing gaps in their design controls and focus on higher-value activities. Additionally, the intuitive software and in-app controls guided the team in producing high-quality FDA submissions.



Greenlight Guru has been instrumental in helping us efficiently navigate the quality management system process and develop our FDA submission.

Ryan Nolan, Co-founder & VP of Clinical Operations, Photonicare

The Results

The implementation of Greenlight Guru's QMS software resulted in numerous benefits for Photonicare. They achieved 510(k) clearance for their OtoSight device, thanks to efficient processes and expert guidance from Greenlight Guru's Customer Success team. The auto-generated [Design History File \(DHF\)](#) in Greenlight Guru saved countless hours of manual preparation, allowing the team to focus on the quality of their submission.

On top of that, their fully traceable QMS software gave them confidence as they prepared for FDA and ISO audits, ensuring that relevant information was easily accessible and clearly presented. With the help of Greenlight Guru's QMS software, Photonicare was able to successfully complete their ISO 13485:2016 certification, demonstrating their ability to consistently meet strict regulatory and customer requirements.

Looking ahead, Photonicare anticipates continued support from Greenlight Guru as they leverage their intuitive software and industry expertise to stay ahead of regulatory changes



Get your devices to market faster with Greenlight Guru Quality

Though all of these companies are building very different devices, there are plenty of common themes to their stories. For one thing, paper-based systems and disconnected processes lead to slow and painful paths to market. For pre-market medical device companies that need to move quickly while maintaining compliance, paper is simply not an option.

Another theme: with the right [QMS solution](#), quality becomes a competitive edge. Automatic traceability, simplified compliance, and integrated design controls and risk management add up to a winning trifecta of speed, quality, and compliance. All of these companies increased their velocity while creating innovative, high-quality devices that are improving the quality of patients' lives around the world.

Ready to see for yourself how Greenlight Guru can help you get your device to market? [Book Your Free Demo of Our Software Now →](#)

Get to market faster
with MedTech-specific
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