CENTESE TRADES IN PAPER-BASED QMS FOR MEDICAL DEVICE SUCCESS PLATFORM AND ACHIEVES FDA 510(K) CLEARANCE

CENTESE

HQ: Omaha, Nebraska, USA

Device Classification: Class II

End Market: USA,

Previous Solution: Paper

Greenlight Guru Champion: Evan Luxon, Founder & CEO of Centese

> *I HAVE A HIGH DEGREE OF CONFIDENCE THAT AS CHANGES TO THE REGULATIONS OCCUR, I WON'T HAVE TO WORRY ABOUT BEING OUT OF COMPLIANCE BECAUSE WE ARE USING GREENLIGHT GURU.*

Evan Luxon,
Founder and CEO of Centese

For many early-stage medical device companies, the default option when implementing a quality management system (QMS) is what they perceive to be the "cheapest" – paper.

Between physical paper systems, digital paper systems, or an ad-hoc combination of the two, electing to go with a disconnected, paper-based approach will:

- Lead to higher total costs associated with managing and maintaining the quality system due to the significant amount of manual oversight required
- Inhibit collaboration efforts with internal and external stakeholders
- Burden team members with inefficient processes and non-value activities necessary to demonstrate compliance
- Delay product development and device submission timelines
- Prevent the company's ability to scale up efficiently

CENTESE: IMPROVING OUTCOMES AND REDUCING COSTS IN CARDIOTHORACIC SURGERY

Centese is an early-stage medical device company working to develop the next innovative device to increase the safety, intelligence, and efficacy of post-operative surgical drainage systems. Their device, **Thoraguard,** is an intelligent surgical drainage system that automates drainage management and collects data for surgical teams to better monitor patient recovery.

CENTESE'S CHALLENGE TO FIND A QUALITY SOLUTION

When starting Centese, it was clear that the QMS being used at the previous TheraNova spinout would be too "heavy weight" and require excessive time to implement. Centese ultimately reverted back to a paper-based system in order to establish the core of their quality system with SOP's and quality manuals.

Centese knew that a paper-based approach was not the long term answer, as it would not allow the company to maximize team members' time, set the foundation for a culture of quality, or scale effectively. They immediately began searching for a digital solution that was nimble and allowed them to manage the QMS in an efficient manner that could grow with their company.

MAJOR PAINT POINTS WITH A PAPER-BASED SOLUTION:

- Use of excel to manage design controls and risk management
- Managing and updating multiple spreadsheets to maintain traceability
- Tedious and time consuming administrative work rather than value-added activities

MAIN GOAL: Find an eQMS (electronic quality management system) solution that would minimize these time-intensive manual processes and allow the team at Centese to focus on high-impact work that would positively impact their 510(k) clearance timeline.

GREENLIGHT GURU HAD EVERYTHING CENTESE NEEDED AND MORE

Centese had began researching solutions that were a good fit for medical device companies specifically. After taking a product tour and seeing firsthand how Greenlight Guru could streamline approval processes, revision control, and system wide traceability, they knew it would be a good fit. According to Founder and CEO, Evan Luxon, Greenlight Guru's tightly integrated Design Controls and Risk Management were "icing on the cake." This would allow the team to streamline product development efforts and expedite their 510(k) submission.

KEY REASONS CENTESE CHOSE GREENLIGHT GURU:

- Streamlined approval processes
- Document revision control
- System-wide traceability
- Tightly integrated Design Controls and Risk Management
- Solution that refocused their efforts on value-added activities
- Avoided creating a new position or hiring a part-time employee to provide oversight for a paper based quality management system

RESULTS AND INTERNAL SUCCESSES FOR CENTESE

The entire team at Centese is now leveraging Greenlight Guru's advanced document management capabilities in their day-to-day activities. Evan can also attest that managing all of their design control and risk management activities within Greenlight Guru streamlined their product developments efforts to help them achieve 510(k) clearance in November 2018. They are now focusing their efforts on three post-market clinical studies across the United States.

RECOMMENDING GREENLIGHT GURU AS A TRUSTED PARTNER

Compared to a paper-based or ad-hoc system, Greenlight Guru allows the team at Centese to be nimble in their development and work more efficiently as they begin to scale. Evan and the team at Centese view Greenlight Guru as a trusted partner in a medical device regulatory environment that is rapidly changing. Evan finds it extremely valuable that his team can rely on Greenlight Guru's software platform and medical device quality and regulatory experts. Their willingness to help customers navigate the regulatory environment and answer industry or software specific questions stands out above the rest.

> *"THE BIGGEST THING THAT HELPED US GET ON-BOARDED QUICKLY WAS TALKING THROUGH THE PLATFORM WITH THE CUSTOMER SUCCESS TEAM TO KNOW HOW TO TAKE ADVANTAGE OF THE SYSTEM."*
>
> EVAN LUXON, FOUNDER & CEO

With Greenlight Guru, Centese has a quality system that enables them to serve the US Market while also preparing them to scale their company while easily navigating the regulatory requirements as they expand into other international markets.

HOW CAN GREENLIGHT GURU STREAMLINE QUALITY FOR YOUR COMPANY?

Experience How Greenlight Guru Helps Medical Device Companies Lead with Quality

See the Demo