LUCERNO DYNAMICS HAS SIMPLIFIED THE ISO 13485:2016 CERTIFICATION PROCESS WITH GREENLIGHT GURU

In a world of rapidly changing regulatory requirements, achieving new certifications, such as ISO 13485:2016, doesn't have to be a burdensome effort. Implementing an electronic quality management system (eQMS) that will scale with your company and simplify navigating the continuously changing regulatory environment is a true advantage for companies that want to lead with quality, meet regulatory requirements, and build out a foundation for growth.

Companies such as Lucerno Dynamics have taken this progressive approach by digitizing and automating their quality processes in order to smooth their path to ISO 13485:2016 certification.

LUCERNO DYNAMICS MOVES THEIR DEVICES INTO NEW MARKETS

Lucerno Dynamics currently has a line of Class I devices that dynamically detect and record the presence of radiolabeled biomarkers that may affect PET scan results. Their system is commercially available in the US, Australia, and New Zealand. Their device bears the CE Mark and they look forward to distributing their devices in the EU and other international markets in the future.

LUCERNO FACES CHALLENGES WITH THEIR "PAPERLESS" PAPER SYSTEM

Lucerno hired an outside firm to conduct a gap analysis on their existing quality system in July of 2017. The gap analysis results revealed that there were a few improvements necessary for them to achieve ISO 13485:2016 certification. This is when Tonia joined their team to lead their quality and regulatory efforts and help the company achieve their ISO 13485:2016 certification.

When starting this role, Tonia described their current system as a "paperless paper" system, consisting of documents stored in Dropbox.

MAJOR PAIN POINTS WITH AN AD-HOC SYSTEM:

- Document control disjointed from quality and compliance activities
- Inability to validate Dropbox to comply with FDA 21 CFR Part 11 and ISO 13485:2016 requirements
- Incapable of scaling with their company as they enter new markets with changing regulatory climates

Knowing the essential and high-risk role that software validation would play in the team's ability to streamline quality and compliance activities, Lucerno began searching for a new solution that better met the regulatory requirements for medical device companies. Besides document control and validation requirements, Lucerno was looking for a system that would also scale with their company given their plans to expand internationally.

LUCERNO DYNAMICS

HQ: Cary, North Carolina, USA

Device Classification: Class I

Available Markets: USA, Australia, New Zealand

Intended Market: EU

Previous Solution: Dropbox

Greenlight Guru Champion: Tonia Bryant, Director of Quality and Regulatory Affairs at Lucerno Dynamics

> *"I HIGHLY RECOMMEND GREENLIGHT GURU. THEY HAVE TAKEN A COMPLEX INDUSTRY AND MADE IT INTO A PRODUCT THAT IS SIMPLE TO USE."*

Tonia Bryant,
Director of Quality and Regulatory Affairs at Lucerno Dynamics

MAIN GOAL: IMPLEMENT A QUALITY SYSTEM THAT WOULD PROVIDE REAL-TIME VALUE TO THEIR COMPANY WITH THE ABILITY TO SCALE AS THEY REACH THEIR MILESTONES.

TIGHT TIMELINE TO IMPLEMENT GREENLIGHT GURU

It was Greenlight Guru's Design Control and Risk Management capabilities that stood out among the four QMS software companies that Lucerno was analyzing as potential solutions. General purpose eQMS software tools do not provide medical device companies with a closed-loop system that ties product development activities with post-market surveillance and quality processes. Lucerno also had a tight schedule to prepare and meet an internal audit date. With just over a week and a half to migrate their documents and validate the software, was under and the Greenlight Guru Customer Success team were able. to collectively finish the job and meet the deadline. The end result was a very successful internal audit. The auditors that were hired to perform the internal audit complimented their quality management system, as they were thoroughly impressed with how easily records could be found and the demonstration of end-to-end traceability.

Lucerno was under a tight timeline to identify an eQMS software that would streamline their efforts to achieve ISO 13485:2016 certification.

It was important they find a system that was:

- easy to validate
- could support the regulatory requirements of the markets they were already in, including FDA 21 CFR Part 820 & 11
- addressed aspects of quality that went beyond just document management controls

SIMPLIFYING THE ISO 13485:2016 AUDIT PROCESS WITH GREENLIGHT GURU

Tonia had previous experience working with an entirely paper-based quality system. She could recall that audit preparation requires a lot of manual paper shifting, taking days or even weeks to feel prepared. Compared to the audit preparation necessary when using Greenlight Guru, her experiences are **night and day.** For their most recent audit, all Tonia needed was her laptop and a notepad as the requested documentation was easily automated and provided to the auditors.

Greenlight Guru has allowed Tonia to spend only a few hours preparing for their upcoming ISO Stage II audit and more time on strategic efforts. The days of manually managing, sifting through file cabinets, and printing out reams of documents for auditors is now a thing of the past.

PARTNERING WITH A SCALABLE MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM

Greenlight Guru has provided Lucerno a "right-sized QMS" – one that can scale with their company as they grow. They are set up to manage their current devices and plans for future device development and market expansion.

Tonia also noted that implementing Greenlight Guru has had a positive influence on their quality culture at Lucerno. Rather than causing a disruption in their existing routines, they found integrating the software actually made things easier and more efficient compared to their previous Dropbox system.

> *"IT'S A GREAT BUSINESS RELATIONSHIP. I WISH ALL BUSINESS RELATIONSHIPS WERE LIKE OURS WITH GREENLIGHT. IT WOULD MAKE LIFE SO MUCH EASIER."*
>
> ***Tonia Bryant,*** *Director of Quality and Regulatory Affairs at Lucerno Dynamics*

Since Greenlight Guru listens to the voice of their customers and incorporates their feedback into the software, it is not just about the software and efficiencies gained for Lucerno. It is equally as much about having a partner that is easy to do business with and shares in the successes of their customers.