



HOW SOLIUS REPLACED PAPER WITH EQMS TO GAIN ISO 13485:2016 CERTIFICATION IN WEEKS

It can be challenging for small companies to navigate the medical device regulatory pathways, especially when the team lacks the industry experience. This was the case for SOLIUS.

After realizing the limitations this posed on their companies goals, they were able to achieve great results from quickly implementing Greenlight Guru, like receiving their ISO 13485:2016 certification.

SOLIUS FOCUSES ON WELLNESS BY STIMULATING VITAMIN D PRODUCTION

SOLIUS was founded by a duo seven years ago, but their product development efforts have ramped up in the past several years. Their device is a Class II phototherapy device that bridges a medical device and a wellness device that stimulates the body to produce Vitamin D—something the body is already meant to do. SOLIUS' device is the first of its kind in terms of its labelling and conditions for use. This makes their pathway to market a bit more unique and may present some challenges. Their goal is to successfully bring their device to market with its current labelling with Health Canada, then meet with the FDA to assess how the device will be received.

CHALLENGES

The vision at SOLIUS was to bring the product to market as a medical device, meaning that their team was aware of the quality management regulations they would have to comply with. With four team members at the time, managing compliance and a QMS was an immediate hurdle they needed to overcome.

They began to vet solutions that would help them manage the regulatory and quality requirements of their target markets, without them becoming overwhelmed with compliance efforts. They began searching for a solution that was:

- Cloud-based
- Scalable
- Secure
- And came with advice from industry experts that could guide them along the way
- Affordable

SOLUTION

No one on the SOLIUS team had any expertise in medical device quality management at the time, leaving them thoroughly impressed by the talent and experience onboard at Greenlight Guru. These industry experts gave team at SOLIUS the confidence in what they were doing with the software and industry knowledge.



HQ: Bainbridge Island, WA, USA

Device Classification: Class II

End Market: Canada & U.S.

Previous Solution: Greenlight Guru
Champions: Linda Cox, Senior Vice President, QA/RA/Clinical Initiatives;
James Wu, Quality Engineer at SOLIUS



I'VE WORKED IN QA AT A FORTUNE 500 COMPANY WITH A CUSTOM SOLUTION. YOUR FLOW IS BETTER. IT SAVES TIME AND IT DOESNT BREAK UP MY THOUGHT PROCESS. WITH GREENLIGHT GURU I'M ABLE TO FOCUS ON QUALITY.



Linda Cox,
Senior VP, QA/RA/Clinical Initiatives at SOLIUS



When it came down to making a decision, SOLIUS went with Greenlight Guru

- The stability of Greenlight Guru as a company
- Impressive talent industry gurus onboard
- The stability of Greenlight Guru as a company

Linda Cox, Senior VP, QA/RA/Clinical Initiative at SOLIUS, assessed the cost of Greenlight Guru and decided that it was well worth it. Along with the software, they found immense value in the on-boarding process, knowledge base, and QMS templates. It was Greenlight Guru's Customer Success Team that played a paramount role, providing guidance and mentorship during their earlier days.

IMPLEMENTING GG

SOLIUS' CTO worked with Greenlight Guru to get the software up and running, and found that the team was excellent in helping them get the system in place. It took them a few months to transfer all of their data into the system, due to initial hesitancy that they would make mistakes. Once they transfer over their data, they realized that there was really no way for them to mess it up. The team at SOLIUS worked with Greenlight Guru's Customer Success Team on adopting the product and ensuring that their processes were sound. The guidance provided by Greenlight Guru was reassured SOLIUS that they had made the right decision.

Having a software platform like Greenlight Guru made a remarkable difference when it came to their audit-readiness, as well as the confidence their auditor showed in their QMS practices. They were able to walk the auditor through all parts of their processes on their screen, basically giving them a demo of the software itself. The auditor was able to clearly see they had everything he asked them for and that everything was clearly linked and showed full traceability.

Preparing for this audit was effortless for the team at SOLIUS. All of their documents were easy to find by search and Greenlight Guru helped show full traceability of revision history, approvals and changes. When James was asked about change history, he easily pulled up a document that the system created automatically for that purpose. They could show how the design matrix related directly to design outputs and other documents, such as controls, rationale and risk.

RESULTS

SOLIUS achieved their ISO 13485:2016 certification with just two dedicated employees—James and Linda (as a half-time employee as her other focus is on clinical efforts). Having previously worked with a paper-based system and other ad-hoc systems before, Linda says that gaining certification with any other approach would be next to impossible with the only two resources. They usually require a number of people to get everything together, with a process already in place.

Their other achievements leading to their ISO 13485:2016 certification include:

- Making it through their audit in 3 days rather than 3.5
- Cutting down the time required to prepare for an audit by at least a week
- Taking only a matter of days to review their design matrix and check for supporting documents

In James' previous experience, there have been paper-based design history files and risk management files, along with matrices in Excel which quickly become a nightmare to manage. Greenlight Guru made it very simple to easily find and link these complex matrices. If something was referenced, then it could be found.

Linda states that if they didn't have Greenlight Guru, they would need a much larger team to help with quality and compliance. It takes more people to manage paper-based processes, especially when preparing for an audit.

USING GREENLIGHT GURU, THEIR MAIN GOALS WERE TO:



- Go through an audit comfortably and confidently (with no prior experience of an audit)
- Gain ISO 13485:2016 certification as it is crucial to get their device on the market with Health Canada



“ I WAS ACTUALLY A LITTLE NERVOUS GOING INTO
THE AUDIT, BECAUSE IT SEEMED TOO EFFORTLESS. ”

Linda Cox, Senior VP, QA/RA/Clinical
Initiatives at SOLIUS

ACHIEVING THE IMPOSSIBLE

Linda and James felt like they **achieved the impossible** in a **short amount of time**. The ISO audit was James' one year anniversary of joining the company. When he started, all they had was a set of SOPs, so he had to modify them to make applicable to their processes and the size of the company. He met with the Greenlight Guru Customer Success Team regularly to help understand more how to design their quality system for their company needs. Within a year, they had complete design and risk matrices and a complete QMS that allows them to focus on quality.

They also feel that the knowledge base of educational and prescriptive articles cannot be underestimated. The software is a great platform, but that doesn't help if you don't understand the regulations or how those fit within the software. The team at SOLIUS took advantage of Greenlight Guru's knowledge base to help put everything into context.

Linda feels that the Greenlight Guru team is **invested in their success**. She had never been in charge of quality and regulatory before, as she came from marketing, usability and clinical trials. It was helpful to have a medical device expert from the Greenlight Guru team assigned to them as a mentor, as they didn't have people with a lot of medical device experience to draw on.

KEY REASONS FOR CHOOSING GREENLIGHT GURU



- Impressive platform that helps companies meet their milestones
- Customer support and continuous software advancement
- Ongoing industry and software education including articles, webinars, and support links



FAVORITE GREENLIGHT GURU SOFTWARE FEATURES

James' favorite feature is the traceability through documents, design matrix and risk matrix. In his previous experience, those are three different systems and they had to painstakingly move between each separately, whereas with Greenlight Guru they are seamlessly linked. This flow saves a lot of time and doesn't break up his thought process.

Linda also thinks of it in terms of budget constraints for hiring. She could only have 1 Full-Time Employee (James), and couldn't comprehend how she'd manage that without Greenlight Guru. James does everything related to Greenlight Guru, largely on his own, which wouldn't be possible with a paper-based system.

Getting signatures is easy, which has made a great change for Linda. In other places, she might have had to physically walk around trying to get people to sign, whereas with Greenlight Guru, stakeholders don't even have to be onsite and they can sign quickly and easily.

