HOW PRIORITY DESIGNS USED GREENLIGHT GURU TO GAIN ISO 13485:2016 CERTIFICATION

We have many different types of companies using Greenlight Guru to help them create a compliant quality management systems that allow them to focus squarely on quality–sometimes even companies who don't specialize entirely in medical devices.

Priority Designs, an industrial design consulting firm, specializes particularly in product design and cover a range of industries, including medical devices. Although they are not a medical device manufacturer, they're using Greenlight Guru as a real **competitive advantage** for their business.

PRIORITY DESIGNS: A WELL-ESTABLISHED CONSULTING FIRM SPECIALIZING IN PRODUCT DEVELOPMENT DESIGN

Priority Designs has been in business for over 30 years, specializing in research, human factors, strategy, prototyping and brand development. They've designed truly innovative products for some of the most well known brands in the world like Nike, GE and TaylorMade, as well as medical devices including surgical instruments and dental products. They also took part in the early prototyping, conceptualization and development work on the Q Collar, a medical device worn by NFL All-Pro Luke Kuechly to protect against mild traumatic brain injury caused by concussive events.

With a team of about 65 employees, they have the ability to prototype rapidly and a design team who can iterate quickly within a workshop space that is designed for rapid development of new products.

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HQ: Columbus, Ohio, USA

Year Founded: 1990

Company Type: Design/Consulting Firm

Greenlight Guru Champion: Donna Philput, Senior Quality/Regulatory Specialist at Priority Designs

> ***AS A DESIGN FIRM, OUR ISO 13485 CERTIFICATION IS A COMPETITIVE ADVANTAGE. GREENLIGHT GURU MADE GETTING IT EASY.***
>
> **Donna Philput,**
> Senior Quality/Regulatory Specialist at Priority Designs

TAKING THEIR BUSINESS TO THE NEXT LEVEL

While Priority Designs has done a number of projects in the medical device field, they felt that they weren't getting the work further up the design phases as they didn't have the knowledge or ability to take a product through the full process and turn it over to manufacturing. Potential customers would often ask them whether they had any ISO certifications and a quality system in place, but they would ultimately say no.

Their team finally realized that they needed to get these things in order to bring those extra projects onboard. This initiated their search to find a solution that would help them win more design work with medical devices, eventually leading them to Greenlight Guru.

THE QUEST FOR A QUALITY MANAGEMENT SYSTEM

The whole idea for the team at Priority Designs was to find structure in a quality system that would store their records and create a design history file (DHF). The team was doing all the right things; however, they weren't recording what they did and weren't aware of the regulations around record-keeping for the design of medical devices.

It was when Senior Medical Design Device Specialist, Reade Harpham, came across Greenlight Guru online that he saw the potential of an eQMS system purpose built for medical device companies. He was searching for a software platform that:

- Was intuitive
- Included good customer service
- Would meet their requirements for a medical device quality management system

He discovered that several companies similar to Priority Designs were using Greenlight Guru, which prompted him to look further into it.

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> ***OUR DESIGNERS AREN'T ACCUSTOMED TO BEING UNDER A QUALITY SYSTEM. BUT YOUR SIMPLE INTERFACE MADE IT POSSIBLE TO ADOPT.***
>
> ***Donna Philput,*** *Senior Quality/Regulatory Specialist at Priority Designs*

The decision to go with Greenlight Guru's software came down to the simplicity of the system. Although managing a QMS was a new concept for their team and they lacked anyone with QMS-specific experience, they new that paper-based solution would be too difficult. When Reade looked at Greenlight Guru, he felt that the simple interface would make it easy to bring new team members up-to-speed with requirements for medical devices.

IMPLEMENTING GREENLIGHT GURU

Donna Philput, Priority Designs' Senior Quality/Regulatory Specialist, had come from a consulting background and started at Priority Designs just in time for the implementation of Greenlight Guru. Not all of their projects at the time involved a quality system, and it was important that the system they put in place be lean and avoid placing any large burdens on their additional, fast-paced projects.

Donna shared that implementation went very smoothly as she met with the Greenlight Guru Customer Success Team once per week to get training on all the medical device regulations and their new quality system. They also purchased Greenlight Guru's audit-tested templates as they knew they wanted to obtain their ISO 13485:2016 certification as quickly as possible. Together, they devised a plan of attack to implement Greenlight Guru and had all of their QMS documentation customized, uploaded and ready within a few months.

In the past, Donna had been part of implementing a different electronic system at another company. She found that it was very difficult to use and challenging to implement throughout the company. As a result, people didn't understand it and really didn't use it. She describes Greenlight Guru as **"so much better"** and a well-rounded system overall.

> ***WHERE NEEDED, APPROVAL IS EASY WHEN EVERYTHING IS ELECTRONIC. IN A BUSY ENVIRONMENT, IT'S NICE TO KNOW EXACTLY WHERE THE DOCUMENTS ARE AND THAT YOU CAN PUSH A BUTTON TO GET SOMETHING DONE. THE USER INTERFACE WITH NOTIFICATIONS AND REMINDERS IS VERY HELPFUL. IT IS WELL SET UP TO BE ADOPTED BY NEW PEOPLE ON THE QUALITY TEAM IN THE FUTURE.***
>
> **Donna Philput,**
> Senior Quality/Regulatory Specialist at Priority Designs

GETTING TO ISO 13485:2016 CERTIFICATION

Priority Designs conducted internal audits and ran a couple of projects through the Greenlight Guru to fully understand the platforms functionality and double check their processes. Two members of the Greenlight Guru Customer Success Team came out on site at Priority Designs to help Donna go through audit requirements and major talking points to better understand the priorities of auditors. This helped prepare their team for their first audit in October 2017, around a year after having turned on Greenlight Guru.

During their first, virtual audit, all Donna had to do was go into the Greenlight Guru software and download the documents to send. She knew exactly where everything was and could easily find and send required documents. It was also helpful for their December audit, which was conducted on-site, as they could show the auditor exactly where everything was and provide a clear document trail. The validation protocols provided by Greenlight Guru showed how everything was validated and working properly as per the regulations, and saved their team a lot of work. Using Greenlight Guru left their auditor impressed by the clarity of the design controls and validation process.

Priority is using the Greenlight Guru software to manage its QMS as a whole and deal with any adjustments of documents. Donna is the quality manager for any project that goes through. She controls deliverables, training and project plan through the software and uses it to regularly upload and keep things current.

Greenlight Guru is helping to give a competitive advantage, by facilitating a compliant quality system that allowed them to easily gain ISO 13485:2016 certification. A medical device specific quality system may seem unusual in a traditional product design firm as it's often out of the realm of creatives. Having the ISO 13485 certification gives them an edge over competing design firms for those medical device projects.