

## Quality Management Platform enabling Medical Device Companies To get Products to Market Safer and Faster with Less Risk



**David DeRam**  
CEO & co-founder

**CEOCFO:** *Mr. DeRam, what is the concept behind greenlight.guru?*

**Mr. DeRam:** We are in the golden age of medical devices. People are doing sci-fi things with medical devices, there are robotic arms and drilling into kids' heads to cut out specific amounts of tumors, and putting flexible circuits on people's hearts. This is one of the most enjoyable parts of this journey, which is being able to work with these companies that are improving the quality of life, and that is our mission. Our mission is to help these companies get their products to market faster, safer and with less risk. They are the same business that we are in, and we help them improve the quality of life.

**CEOCFO:** *What do you understand about taking a medical device from concept to market, that others do not?*

**Mr. DeRam:** It is a complicated and expensive process. It is not the kind of thing that you can do on a limited budget. We are not talking about paperclips. We are talking about brain surgery, which is in a regulated industry. Therefore, taking a product to market in a regulated industry requires that you operate with a set of controls. Those controls are very specific and it is a complex process.

**CEOCFO:** *Would you tell us about the software that you provide to enable companies to navigate the process?*

**Mr. DeRam:** The software is one of the pieces of our company. We exist to help them get their product to market in a variety of ways. We happen to have a cloud based, secure, integrated, cohesive, easy to use platform that integrates many of the concepts that we have been working on over the last 17 years. Our founders are very experienced, our management team is very experienced, and they have instilled those learning experiences from bringing 40 plus products to market. They have built that into a platform that has workflows that are specific to med devices, so you see a number of other systems that are great for building rocket ships, airplanes and cars, but do not fit well inside the workflows for med device. Med device is all that we do.

**CEOCFO:** *What is a typical engagement?*

**Mr. DeRam:** We can go all the way from a medium sized company down to a startup, and our engagements run everything from helping with regulatory strategy, helping to get the wheels on the car moving to an experienced team that has brought products to market several times, and is looking for a superior way to do that.

**CEOCFO:** *How would someone find greenlight.guru? How do you reach out? If they were doing an internet search, what terms or phrases would they use that would bring them to you?*

**Mr. DeRam:** One of the easiest ways that people run into us is that we contribute heavily to the Thought Space in the industry. We have several eBooks, several webinars, and when we run a webinar there are 1,100 people on the webinar. We are really advanced in Thought Space around risk management, which is a changing piece of the industry, and it is changing fast. We have been helping companies to get their hands around that and get out in front of the regulatory changes. People will also find us in web searches, but primarily through the content that we share.

**CEOCFO:** *Are many companies coming to you to walk them through the whole process, soup to nuts, or more typically specific pieces?*

**Mr. DeRam:** It is the whole gamut. We can help soup to nuts and we can help in specific areas, but because our platform is so integrated, we will for example, allow you to take risk management and put it into the entire product lifecycle. There may be a team that is very experienced that does not need a great deal of help with regulatory strategy, and already have the rock moving down the hill, so we would just help them pace on that rock.

**CEOCFO: Do you vet the device and look at what they are doing before getting involved?**

**Mr. DeRam:** Right from the beginning, if they are not a good fit for us, we will let them know.

**CEOCFO: Does personality play a role as well? An inventor may be close to their product, but may not have the business sense?**

**Mr. DeRam:** Personality is definitely a factor, as you will get engineers that are brilliant. However, that is where our management team and our customer success team can step in and provide a great deal of value. We have done things with our startups that we work with, and helped them get their desired outcomes. We have made introductions to key investors, help with pitch strategy to win pitch contests, and key introductions to sterilization vendors that do a very specific type of sterilization. By doing that we can change the trajectory of the company that we are working with. That is one of the most exciting and enjoyable parts of this journey, which is contributing beyond the software platform to the growth of these startups.

**CEOCFO: Are startups today realizing earlier on that they need help and are seeking outside assistance, or still trying to navigate the process themselves?**

**Mr. DeRam:** You see both. In this area, if you have not been through the regulatory process, you are going to seek out help. In the past there has been a great deal of reliance on bringing in outside expertise, and even when we work with the top consultants, they do not want to spend their time doing low value add activities. Therefore, what we have done is automated all of those low value add activities and brought hundreds of hours back into the projects that our customers are working on. The consultants love it, the companies love it, and we provide a great deal of efficiency.

**“What surprised me is how well our solution has been received. I can be on the phone with a prospect for 8 minutes before they decide to become part of our family.”- David DeRam**

**CEOCFO: Are you licensing out your technology? Do you work with partners?**

**Mr. DeRam:** We have a network of partners, and they are critical for us because there is so much knowledge imbedded that piece of the industry, so they are able to leverage our platform to help their clients achieve success.

**CEOCFO: How important are trends?**

**Mr. DeRam:** Trends are really important. You do have a great many “me too” products. However, when you talk about trends, there are also the regulatory trends, where for years people have been using paper to manage the quality and design controls behind their products. The trends are pointing to the idea that with risk management becoming such a critical piece that the relationships are too complex to continue to manage them on paper. Therefore, there is a regulatory trend that is raring its head that everyone is aware of, so the tools are going to have to improve.

**CEOCFO: What were some of the challenges in putting together technology to handle so many different pieces?**

**Mr. DeRam:** It is a very complex problem to solve. What we want our software to do is to be as easy to use as something like LinkedIn. Therefore, what we did was brought in terrific designers, and user experience experts, to refine the product until it was an easy to use system that previously did not exist. That was a challenge because we are not in an industry that is simple. If it were simple there would not be so much of an industry surrounding it in consulting and advising on regulatory strategy. With our management team and their combined experience in bringing 40 plus products to market, we were able to leverage their knowledge, experience and connections. Then also work with the people who wrote the regulations, and bring them in and bring their passion. If you were involved with writing the regulations, you are going to be passionate about it. Hence, we are able to leverage much of that knowledge, and then turn that lose into our platform. I have 24 years in commercial software and 20 years in my own startups, and we have brought in some of the best talent that I have been around in those years. Therefore, we have assembled a fantastic team, and when you have a team that is clicking like this you can build very complicated products.

**CEOCFO: Are you primarily working with companies for the US market or across the globe?**

**Mr. DeRam:** We are spread out globally, which is another one of the things that I enjoy about this journey. I get to work with different customers all over the world. We just had a customer from Germany, come in and visit our facility and we had an awesome couple of days with them.

**CEOCFO: What has changed in your approach over time? What have you learned along the way?**

**Mr. DeRam:** One of the big thing that I have learned is that in assembling a team it is very similar to the hockey team from the 1980's that showed that it is not always about having the best players at every position. It is about the right players

and about a team that can work together. If you understand the DNA of your company and your core values, you will live and recruit by those core values. Then you will end up with a team that respects each other, and you do not have that one guy who is the black hole of ideas, or the black hole of negativity that makes life difficult. You have a team of people who respect each other, and you get this intimacy where you are playing for each other. That really evolves into something special.

**CEOCFO: *Your site indicates “Quality is your friend”. Why do you need to point that out?***

**Mr. DeRam:** That is a fantastic question. The regulations are not there to make your life miserable. They are there to help you build better products. Risk management is a great example of that. Our customers tell us that we they invest in risk management and they do not want it to be a binder that sits on a shelf. The reason they invest in risk management is because they want to build better products and run better companies. Therefore, by not looking at this as some documentation to check off at the end of the process, you actually become a better company and build better, safer products. In addition, you get them to market faster, and you turn what might be a competitive disadvantage into a competitive edge.

**CEOCFO: *What surprised you as greenlight.guru has grown and evolved?***

**Mr. DeRam:** What surprised me is how well our solution has been received. I can be on the phone with a prospect for 8 minutes before they decide to become part of our family. In one case it was an individual who had been in med device for 30 plus years, and he was able to leverage our technology with first time entrepreneurs that had never been through the regulatory process. That has been fantastic and just the way that our thought leadership and product has been embraced.

**CEOCFO: *Are you funded for the next steps that you would like to take?***

**Mr. DeRam:** We did a funding round and we are eyeing a Series A. With the growth that we are experiencing we are not sure whether or not we are going to pull the trigger on a Series A, but that is on our radar.

**CEOCFO: *Why pay attention to greenlight.guru today?***

**Mr. DeRam:** We are changing the industry. I heard a hedge fund manager on a podcast say that he would never get back in the industry and be an implementer or executer. I chuckled because that is exactly what this team has been assembled to do. Our mission is to disrupt the way that devices are built and to get them to market on an expedited time line, with a whole new collaborative level, and a whole new respect for the process, and that is what we have done. Our customers are tell us that they are bringing products to market faster than they ever have before. They are tell us that their culture has improved, because they are actually enjoying going through the regulatory process. We just continue to put our foot on the gas. We know that we are just getting started and we are going to change the entire industry.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

---



**greenlight.guru**

For more information visit:  
[www.greenlight.guru](http://www.greenlight.guru)

Contact:  
Nick Tippmann  
260-438-8708  
[nick.tippmann@greenlight.guru](mailto:nick.tippmann@greenlight.guru)