



HOW GREENLIGHT GURU IS LAYING THE FOUNDATION FOR SUCCESS AT AMNION LIFE

The majority of medical device companies operate on an emphasis of high quality outcomes and scalability. Early investment decisions are daunting for game-changing startups, like Amnion Life. It is important for early stage companies to lay the foundation for success that minimizes risk and unnecessary complexity that can limit their path to market – and it all starts with a strong quality management system during design and development.

When investing in an electronic quality management system (eQMS), it is essential for medical device companies to identify a solution that they are confident will improve their processes and allow them to scale effectively. A spreadsheet or paper-based system may sound like a quick or cheap solution, but sacrificing quality in your quality system will only come back to bite you down the road.

AMNION LIFE SETS OUT TO IMPROVE OUTCOMES FOR PRETERM INFANTS

Founded in 2016 by Dr. Amir Fassihi, Amnion Life has pursued designing a safe and effective medical device, the *AmionBed*. This novel Class II device recreates womb-like conditions in order to promote ongoing development and reduce complications following premature birth.

The AmnioBed is a complex device, and one that has no predicate already on the market. For this reason, Amnion Life is following the De Novo pathway, designed for novel medical device products to get their device to market. The future of success for Amnion Life and their cutting edge medical device(s) relies on being able to handle the evolving quality and regulatory requirements.

For the team at Amnion Life, the goal is to be a medical device company that will not be satisfied with being “*good enough*,” but instead to be on the leading edge – with **True Quality** acting as the foundation of everything they do.

OVERCOMING THE LACK OF IN-HOUSE EXPERTISE IN THE MEDICAL DEVICE INDUSTRY

Majority of the team at Amnion Life was new to the medical device industry and uncertain of what makes a medical device company successful. Challenges that their team faced stemmed from anxieties, such as:

- “Are we doing this right?”
- “Are our processes compliant?”
- “What else do we need to be concerned about?”
- “Is there someone else I can ask?”

These anxieties ultimately challenged the efficacy of the team and left them feeling overwhelmed with the work associated with establishing processes and managing multiple ad-hoc quality systems.

The Amnion Life team became aware that they would need guidance through implementing a QMS and understanding the quality and regulatory requirements for medical devices for maintaining compliance. Rather than looking for an eQMS that would simply check these boxes, they were in search of a provider who would also serve as a partner, supporting their efforts along the way.



Amnion Life

HQ: Orange County, CA, USA

Device Classification: Class II

Market Pathway: De Novo

Previous Solution: Various digital platforms

Greenlight Guru Champions: Amir Fassihi, M.D., CEO & Founder; Milos Radovanovic, Lead Engineer



GREENLIGHT GURU WAS ESSENTIAL FOR US TO ESTABLISH A STRONG FOUNDATION FOR SUCCESS.



Amir Fassihi, M.D.

Founder and CEO of Amnion Life



GREENLIGHT GURU

DELIVERS A SOLID FOUNDATION FOR AMNION LIFE WHERE OTHERS COULD NOT

Amnion Life had tried implementing other QMS platforms, but found that their “bulkiness and clunkiness” were not intuitive for the unique needs of a medical device company. While many of these platforms claimed “out-of-the-box” functionality, they lacked industry specific workflows; therefore, it would take their team additional time to learn, configure and validate the system. After trying a myriad of project management, product lifecycle management (PLM), and collaboration platforms, they found they were all missing one vital piece for medical device development – **Design Controls**.

When Greenlight Guru’s eQMS solution came across their radar, they immediately realized it was everything they needed to establish a solid foundation for their company. To justify the cost of Greenlight Guru as an early-stage company with limited funds, Dr. Amir Fassihi described it as a means to their company’s success. While following the content provided by Greenlight Guru’s blog and podcasts for over a year, Amnion Life received enough funding and immediately purchase Greenlight Guru’s eQMS software.

Greenlight Guru provided Amnion Life with a true “out-of-the-box” solution designed specifically for the needs of a medical device company. With little experience in using a QMS, Greenlight Guru’s software and Guru Services were able to streamline processes and remove the regulatory burden for compliance with FDA and ISO regulations and requirements.

“

IN MY OPINION, SOFTWARE PLATFORMS SHOULD RELIEVE YOU FROM HAVING TO THINK OF ALL THE TINY DETAILS.

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Milos Radovanovic,
Lead Engineer at Amnion Life

These “*tiny details*” that Greenlight Guru handles to help simplify both product development and quality management refer to industry specific needs like:

- Linkages between design inputs and outputs
- Advanced user permissions for document control
- Collaborating with external partners
- Fully integrated risk management that aligns with ISO 14971 requirements
- Multi-level design control locking when performing digital design reviews

SWITCHING TO GREENLIGHT GURU

Amnion Life was given a test account to work through and learn from during their implementation process. Since they did not have existing procedures in place, they found immense value in the established workflows of Greenlight Guru and naturally transitioned into using them. They also found the user interface and experience was very clear and easy to navigate on their own.

Their team, especially Milos, appreciates not having to manually manage design controls through their prior methods of spreadsheets and tedious paperwork. Greenlight Guru has simplified their processes leaving them feeling more confident in their performance, design, and development processes. In addition to its QMS software, Milos discovered just how valuable the Guru Services provided by Greenlight Guru were. These dedicated industry experts became an extension to the Amnion Life team, providing clarity into matters relating to their quality management system.

Leveraging this partnership has allowed Amnion Life to learn more about things such as audits or best practices in capturing/ documenting product development activities that will be used in their Design History File (DHF) – further solidifying their foundation to success.

GAINING PEACE OF MIND WHILE ACHIEVING RESULTS

After experiencing an easy implementation process, Amnion Life now has *Peace of Mind* that they have laid a strong foundation with their QMS. The team at Amnion Life now has a reliable partnership with Greenlight Guru who will support their quality and regulatory related efforts.

Dr. Amir Fassihi now can focus more on strategic activities and leave the day-to-day meetings and project development in the hands of his team and trusted industry experts at Greenlight Guru. Milos is confident and also has *Peace of Mind* in his team’s ability to avoid major setbacks in their design development while using the software.

By partnering with Greenlight Guru, Amnion Life has laid a foundation for success that will continue to meet their needs with accelerating product development and transitioning to both clinical trials and post-market surveillance stages of the device lifecycle.