Greenlight Guru's Accreditations and Certifications Summary

Greenlight Guru's adherence to **SOC 2 Type II, ISO 9001:2015**, and **ISO/IEC 27001:2022** demonstrates a robust, independently verified commitment to implementing and maintaining strong controls across key operational and security areas. These frameworks mandate documented, repeatable processes, ensuring consistency, accountability, and continuous improvement in information management and protection. We complete these three annual audits with our Certification Body.

- **SOC 2 Type II** attests, through third-party audit and continuous operational evidence, that our controls over security, availability, processing integrity, confidentiality, and privacy are not only designed effectively but also operate consistently over time.
- **ISO/IEC 27001:2022** validates that our Information Security Management System (ISMS) includes effective controls for information governance, document and version control, ISMS-required employee training, secure software development lifecycle (SDLC), backup management, and data retention—all aligned with confidentiality, integrity, and availability principles.
- **ISO 9001:2015** ensures that our Quality Management System (QMS) enforces formalized document control, change management, and process improvement mechanisms, promoting accuracy, traceability, CAPA processes, employee training, customer feedback and satisfaction, and compliance across all business operations.

It is important to note that the FDA's Computer Software Assurance (CSA) for Production and Quality System Software Guidance, finalized September 24, 2025, relieves medical device companies of the direct requirement to audit their software vendors. Acknowledging the often-limited access to vendor-specific information during assessments, the FDA suggests establishing and applying a risk-based analysis of the software vendor as a critical part of the assurance approach. Manufacturers should leverage readily available vendor documentation for this assessment, focusing on accreditations, certifications (such as Service Organization Controls (SOC 2 reports), and adherence to industry standards (e.g., ISO certifications) conducted by independent third parties.

Together, these certifications and attestations confirm that Greenlight Guru follows recognized international standards for control implementation, monitoring, and continual improvement. They provide independent assurance that processes such as document control, SDLC, backup, and retention are effectively managed and aligned with industry best practices and compliance expectations.