Greenlight Guru's Quality Management Solutions

Transform quality and fuel business growth with the industry's leading quality management software designed exclusively for medical devices companies.

Greenlight Guru's Quality Management solutions are designed to help you bring innovative products to market faster, more efficiently, and with less risk. By choosing to modernize your quality management system with us, you gain access to a suite of tools that unlock new efficiencies, enhance operational capabilities, and support the strategic growth of your business. We focus on delivering tangible value, working closely with you to tailor a solution that fits your specific needs and scales with your business. Start with us and see your quality management transform into a direct driver of your business success.

1200+ Customers Globally

2000+ Market Approvals

5000+ Audits Passed

100+ Years of In-house Industry Experience

Core

Establish an efficient, compliant quality system that's easy to use and ready to grow with your business.

Quality Events

Gain a clear overview of your quality activities, ensuring every detail is traceable and managed effectively.

Product Development

Bring safe and effective products to market faster and more efficiently.

Guru Services

Tap into our experts' insights and guidance to navigate challenges and achieve your goals at every stage.

**Greenlight Guru's Core package is required to purchase additional modules for Product Development, Quality Events, and Guru Professional Services.*

Core

Establish an efficient, compliant quality system that's easy to use and ready to grow with your business.

Unite and elevate your quality efforts with our Core package: a user-friendly, scalable, and comprehensive quality system. This package not only ensures compliance and operational efficiencies but also serves as a foundation for quality, connecting your team, processes, and data into a single, reliable source of truth. Experience a quality system that not only meets your current needs but also propels your business forward.

75% **Faster QMS implementation**

1/2 **The prep time for audits**

75% **Reduction in time spent on managing training activities**

"Greenlight Guru was instrumental in implementing our Quality System. With them, we can bring safer, higher-quality medical devices to success while maintaining a Quality Culture throughout our entire device lifecycle."

Maxime Rochon,
Director of Quality, Puzzle Medical

Features

Platform:

- Role-based Security
- Activity History & Audit Trails
- End-to-end traceability
- Data Exports & APIs*
- Single Sign On (SSO)*

Document Management:

- Part 11 Compliant Signatures
- Flexible Review & Approval Workflows
- Custom Attributes and Views

Change Management:

- Review & Approve Change Orders
- Generate Critical Change Documentation
- Track Change Order Status

Training Management:

- Assign & Automate Training Requirements
- Train on Document Changes
- Track Training Status

System Migration & Implementation:

- 300 Documents Included
- User Configuration (10 Users)
- Training Set-Up (10 Requirements)

Always Included:

- Dedicated Customer Success Manager
- Guru-Led Onboarding & Implementation
- In-App Support
- Validation Packages
- Project Plan & Work Instructions

*Access varies with subscription type

Product Development

Bring safe and effective products to market faster and more efficiently.

Accelerate medical device development with our purpose-built software, designed to seamlessly integrate with your QMS and eliminate data silos. Streamline every phase, from design to market, with intuitive, integrated modules for risk management and documenting design controls. Greenlight Guru simplifies complex processes, helping ensure compliance, efficiency, and quality throughout your product's lifecycle.

35% **Reduction in time to market**

144 **Hours saved with Automated DHF**

50% **Reduction in time spent on development and design documentation**

"Our matrix was built, design reviewed, and approved in record time. Things that normally take us months took weeks, things that took us weeks took days. Some things now are even taking mere hours to complete."

Nick Punsalan, PMP
Principle Mechanical Design Engineer, MicroAire Surgical Instruments

Features

Platform:

- Create, manage, and archive design and risk projects
- Interlink and connect between projects and QMS
- Compliance with 21 CFR Part 820, ISO 13485, and ISO 14971

Design Controls:

- Auto-generated Design History File
- Flexible Design Reviews
- Jira Integration

Risk Management:

- In-Line Editing of Risk Matrices
- RIsk Reviews

Product Management:

- Bill Of Materials
- Items / Product Families

Quality Events

Gain a clear overview of your quality activities, ensuring every detail is traceable and managed effectively within your QMS.

These tools enable you to uphold product safety, refine quality processes, and transform customer feedback into effective improvements, ensuring robust, efficient operations ready for any challenge. Enhance your organization's collaboration and compliance, preparing you for any complaint or audit with confidence.

30% **Less time managing quality events**

35% **Reduction in labor hours needed per recall/return/ adverse event**

25% **Reduction in time to handle audit findings & correction actions**

1/2 **Preparation time for audits cut in half**

"All of our documentation, quality events, and training materials are connected in the system, and this makes it clear who is responsible for each action. Rather than saying, 'Oh that's not my department,' people are now drawn into the process. Everything is connected in the system and tasks can be easily assigned."

Petra Elischer,
Quality Manager, Hart Biologicals

Features

- Custom workflow and automated tasks
- Auto-generated quality review records
- Creates linkages throughout the platform
- Part 11 complaint audit trails

CAPA:

- Effectively manage CAPAs with the right data, documents, and design at your fingertips.

Audit Management:

- Conduct thorough and efficient audits with ease.

Nonconformance:

- Efficiently identify, document, and resolve nonconformities in your operations.

Customer Feedback (Complaints):

- Turn customer feedback into actionable quality improvements.

Guru Services

Producing high-quality medical devices while effectively managing quality throughout the entire product life cycle is complex and challenging to execute. With our Guru Services, you can leverage our 500+ years of combined in-house experience to gain clarity around regulatory requirements and leverage industry best practices to confidently meet your objectives at each stage of your medical device journey. Our Gurus have helped companies efficiently navigate medical device regulations, reduce business risk, and prepare for successful launches and audits.

- **Achieve Your Goals Faster**
- **Gain Insights into Industry Best Practices**
- **Discover Fanatical Support**

Guru Assist

On-Demand Guru Support

Includes:

- On-demand assistance and coaching
- Easy, in-app functionality
- Expedited software support

Guru Guidance

Dedicated Industy Expert

Includes:

- Strategically scheduled calls with industry expert
- Actionable coaching and support
- Journey checklist and resources provided by state

Professional Services

Project-based & Custom Services

Leverage our in-house and extensive partner network for...

- System configuration & implementation
- Design Control and Risk Review
- Process Automation
- Audit Preparation
- and much more...

QMS Templates

Audit-tested QMS Templates

Library of 80+ QMS templates that have passed FDA, ISO, & MDSAP, including:

- Quality Manual
- Management Review Template
- Project and Risk Plans
- and many more...

Tap into our Global Partner Network

Leverage our distinguished network of over 200 partners offering the right expertise and services for every stage of your journey.

Guru Professional Services

Enhance your team with an extension of ours for custom-scoped engagements geared more toward specific objectives or initiatives.

Platform:
With over 500 years of combined industry experience, our Gurus bring deep expertise in supporting companies at every stage.

Tailored to You:
We understand that each project has its unique challenges and opportunities. Let's work together to customize a plan that fits your needs.

Our services are scoped by hours of work provided by a Guru and billed as a one-time cost. Each engagement has a recommended project length, engagement, and collaboration activities to ensure project success. These can be further customized to your specific needs.

> *"Partnering with Greenlight Guru provides you with a team that's on your side, who are all medical device industry pros and understand what companies like ours go through."*

Morris Sherwood,
Person Responsible for Regulatory Compliance, Zyris

Features

System Configuration:

- Complete setup and optimization of your QMS, including user roles and initial configurations.

Document & Training Implementation:

- End-to-end documentation setup and customized training, covering SOP templates, document management, and training assignments.

Design Control & Risk Management:

- Hands-on support in building and migrating design control and risk matrices, ensuring compliance and efficiency.

Quality Process Automation:

- Implementation of advanced automation solutions, focusing on' streamlining quality events and workflows.

Audit Preparation & Support:

- Comprehensive services for audit readiness, including follow-up preparations and direct support during audits.

Additional Expert Services:

- A spectrum of specialized services tailored to enhance your quality management and operational efficiency. Just ask us!

Need help in another key area of your business? Let us know.

Between our in-house expertise and extensive partner network we can ensure we get you set up with the right expertise to keep your team moving.

SOP Template Library

Streamline the Setup of Your Quality Management System

We've created 70+ audit-tested procedures, work instructions, and forms to save you time during implementation and put your team at ease during audits.

- **Save time** in QMS implementation and establishing a quality manual.
- **Reduce compliance risk** by ensuring proper documentation in the face of an audit.
- **Avoid later rework** in updating core documents for the quality system.

INCLUDED WITH SUBSCRIPTION:

Project implementation plans and applicable work instructions are included with your software subscription.

IMP-001	Implementation Plan (New QMS)
IMP-001-A1	Execution Spreadsheet (New QMS)
IMP-001	Implementation Plan (Legacy QMS)
IMP-001-A1	Execution Spreadsheet (Legacy QMS)
GG-IQ-001	Greenlight Guru Installation Qualification
GG-VAL-001	Greenlight Guru Validation Test Report
WI-01	Document and Change Management Work Instruction
WI-21	Training Management Work Instruction
WI-03-01	Design and Development Work Instruction
WI-04	Risk Management Work Instruction
WI-11	Corrective and Preventive Action Work Instruction
WI-22	Audit Work Instruction
WI-10	Control of Nonconformances Work Instruction
WI-13	Customer Feedback Work Instruction

AVAILABLE TEMPLATES:

QM-01	Quality Manual
SOP-01	Document and Change Management Procedure
SOP-02	Management Responsibility and Review Procedure
FRM-02-01	Management Review Minutes Form
SOP-03	Design and Development Procedure (Hardware and Software)
WI-03-02*	CE Mark Technical Documentation Work Instruction
FRM-03-01	Project Plan Form (Hardware and Software)
FRM-03-02*	EU MDR Declaration of Conformity Form
FRM-03-03*	GSPR EU IVDR Checklist Form
FRM-03-03*	GSPR EU MDR Checklist Form
FRM-03-04	Test Protocol Form
FRM-03-05	Test Report Form
SOP-04	Risk Management Procedure
FRM-04-01	Risk Management Plan Form (Hardware and Software)
FRM-04-02	Risk Management Report Form
SOP-05	Supplier Evaluation Procedure
FRM-05-01	Approved Supplier List Form
FRM-05-02	Supplier Survey Form
FRM-05-03	Supplier Assessment Form
SOP-06	Purchasing Procedure
FRM-06-01	Purchase Order Form
SOP-07	Receiving and Incoming Inspection Procedure
FRM-07-01	Incoming Inspection Form
SOP-08	Customer Orders Procedure
SOP-09	Device Master Record Procedure
FRM-09-01	Device Master Record Index Form
SOP-10	Control of Nonconformances Procedure
FRM-10-01*	Nonconformance Report Form
SOP-11	Corrective and Preventive Action Procedure
FRM-11-01*	CAPA Report Form

AVAILABLE TEMPLATES (CONTINUED):

SOP-12	Work Environment Procedure
SOP-13	Customer Feedback Procedure
FRM-13-01	Customer Feedback Form
SOP-14	Adverse Event Reporting Procedure
FRM-14-01	Adverse Event Determination Form
SOP-15	Reporting Corrections and Removals Procedure
SOP-16	Master Validation Procedure
FRM-16-01	Master Validation Plan Form
SOP-17	Rework Procedure
FRM-17-01	Rework Protocol Form
SOP-18	Preventive Maintenance Procedure
FRM-18-01	Production Equipment List Form
FRM-18-02	Preventive Maintenance Log Form
SOP-19	Calibration Procedure
SOP-20	Analysis of Data Procedure
SOP-21	Training Management Procedure
FRM-21-01	Roles and Responsibilities Form
FRM-21-02	Training Requirements Matrix Form
FRM-21-03	Training Record Form
FRM-21-04	Quiz Template Form
SOP-22	Internal and Supplier Audit Procedure
FRM-22-01	Audit Schedule Template
FRM-22-02	Audit Plan Form
FRM-22-03	Audit Checklist Form
FRM-22-04	Audit Report Form
SOP-23*	Post-Market Surveillance Procedure
FRM-23-01*	Post-Market Surveillance Plan Form
FRM-23-02*	Post-Market Surveillance Report Form
FRM-23-03*	Periodic Safety Report Form
FRM-23-04*	Post-Market Clinical/Performance Follow-Up Plan Form
FRM-23-05*	Post-Market Clinical/Performance Follow-Up Report Form
SOP-24	Labeling, Identification, and Traceability Procedure
SOP-25*	Strategy for Regulatory Compliance Procedure
FRM-25-01*	Regulatory Compliance Summary Template Form
SOP-26*	Clinical Evaluation Procedure
FRM-26-01*	Clinical Evaluation Plan Form
FRM-26-02*	Clinical Evaluation Report Form
SOP-27	Installation and Servicing Procedure
SOP-28	Handling, Storage, and Distribution Procedure
SOP-29	Regulatory Audits Procedure
JD-XXX*	Job Description - Person Responsible for Regulatory Compliance

SOFTWARE:

SW-SOP-01	Software Development Procedure
SW-FRM-01-01	Software Development Plan Form
SW-FRM-01-02	User/ Software Requirements Specification Form
SW-FRM-01-03	User Interface Wireframes Form
SW-FRM-01-04	Software Configuration Management Plan Form
SW-FRM-01-05	Software Architectural Design Form
SW-FRM-01-06	Software Design Specification Form
SW-FRM-01-07	Software Deployment Plan Form
SW-FRM-01-08	SOUP Documentation Hazard Analysis Form
SW-FRM-01-09	Maintenance Release Plan Form
SW-FRM-01-10	Deployment Plan Form
SW-FRM-01-11	Verification and Test Plan Form
SW-FRM-01-12	Software Release Test Report Form
SW-FRM-01-13	System Update Communication Form
SW-FRM-01-14	Final Design Review Minutes Form
SW-FRM-01-15	Release Approval Form
SW-FRM-01-16	Software Description Form
SW-FRM-01-17	Software Version History Form
SW-FRM-01-18	Unresolved Software Anomalies Form
SW-SOP-02	Software Safety Classification Procedure
SW-FRM-02-01	Software Documentation Level Evaluation Form
SW-FRM-02-02	Software Safety Classification Matrix Form
SW-SOP-03	Software Risk Management Procedure
SW-SOP-04	Software Verification and Validation Procedure
SW-FRM-04-01	Software Verification Plan Form
SW-FRM-04-02	Software Validation Master Plan Form
SW-FRM-04-03	Software System Test Case Form
SW-FRM-04-04	Software Validation Report Form
SW-SOP-05	Software Change Management Procedure
SW-SOP-06	Software Security Vulnerability Management Procedure
SW-FRM-06-01	Software Cybersecurity Management Plan Form
SW-FRM-06-02	Software Cybersecurity Report Form
SW-FRM-06-03	Threat Modeling and Analysis Form
SW-FRM-06-04	Cybersecurity Risk Assessment Form
SW-FRM-06-05	Software Bill of Materials Form