Get Started Quickly With the Right Documentation

Whether implementing quality documentation for the first time or refreshing yours as you move into a new system, Greenlight Guru can help you make this a streamlined, user-friendly process.

Greenlight Guru has curated audit-tested procedures, work instructions, and forms to streamline the set-up of your quality management system to save you time during implementation and put your team at ease during audits.

The QMS template packages have been proven to help companies:

- **Save time** in QMS implementation and establishing a quality manual
- **Avoid later rework** in updating core documents for the quality system
- **Reduce compliance risk** by ensuring proper documentation in the face of an audit
- **Follow medical device industry** best practices from the start

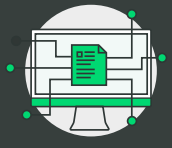
> **We passed our stage 1 notified body audit with 0 nonconformances! Very big thanks to gg for the help, including the templates provided – great help. My quality manual is a copy and paste from yours."**

> **With these templates, we were able to get our system up and running quicker than we expected. We were able to tackle the documentation in-house without wasting additional time or resources."**

Audit-tested templates for your QMS

Quality Manual

Management Review Template



Project and Risk Plans

Quality Event Procedures and Templates

Supplier Survey Forms

BOOST TEMPLATES

FRM-02-01	Management Review Minutes Form
FRM-03-01	Project Plan Form (Hardware & Software)
FRM-03-02	EU MDR Declaration of Conformity Form
FRM-03-03 (IVDR)	GSPR EU IVDR Checklist Form
FRM-03-03 (MDR)	GSPR EU MDR Checklist Form
FRM-03-04	Test Protocol Form
FRM-03-05	Test Report Form
FRM-04-01	Risk Management Plan Form (Hardware and Software)
FRM-04-02	Risk Management Report Form
FRM-05-01	Approved Supplier List Template
FRM-05-02	Supplier Survey Form
FRM-05-03	Supplier Evaluation Form
FRM-06-01	Purchase Order Form
FRM-07-01	Incoming Inspection Form
FRM-09-01	Device Master Record Index Form
FRM-13-01	Customer Feedback Form
FRM-14-01	Adverse Event Determination Form
FRM-16-01	Master Validation Plan Form
FRM-17-01	Rework Protocol Form
FRM-18-01	Production Equipment List Form
FRM-18-02	Preventive Maintenance Log Form
FRM-21-01	Job Description Template
FRM-21-02	Training Requirements Matrix Form
FRM-21-03	Training Record Form
FRM-21-04	Quiz Template
FRM-22-01	Audit Schedule Template
FRM-22-02	Audit Plan Form
FRM-22-03	Audit Checklist Form
FRM-22-04	Internal Audit Report Form
FRM-23-01	Post-Market Surveillance Plan Form
FRM-23-02	Post-Market Surveillance Report Form
FRM-23-03	Periodic Safety Update Report Form
FRM-23-04	Post-Market Clinical Performance Follow-Up Plan Form
FRM-23-05	Post-Market Clinical Performance Follow-Up Report Form
FRM-25-01	Regulatory Compliance Summary Template
FRM-26-01	Clinical Evaluation Plan Form
FRM-26-02	Clinical Evaluation Report Form
IMP-001 (Legacy QMS)	Greenlight Guru Implementation Plan (Legacy QMS)
IMP-001 (New QMS)	Greenlight Guru Implementation Plan (New QMS)
JD-XXX	Job Description-Person Responsible for Regulatory Compliance
QM-01	Quality Manual
SOP-01	Document and Change Management Procedure
SOP-02	Management Responsibility and Review Procedure
SOP-03	Design and Development Procedure (Hardware and Software)
SOP-04	Risk Management Procedure
SOP-05	Supplier Evaluation Procedure
SOP-06	Purchasing Procedure
SOP-07	Receiving and Incoming Inspection Procedure
SOP-08	Customer Orders Procedure
SOP-09	Device Master Record Procedure
SOP-10	Control of Nonconformances Procedure
SOP-11	Corrective and Preventive Action Procedure
SOP-12	Work Environment Procedure
SOP-13	Customer Feedback Procedure
SOP-14	Adverse Event Reporting Procedure
SOP-15	Reporting Corrections and Removals Procedure
SOP-16	Master Validation Procedure
SOP-17	Rework Procedure
SOP-18	Preventive Maintenance Procedure
SOP-19	Calibration Procedure
SOP-20	Analysis of Data Procedure
SOP-21	Training Management Procedure
SOP-22	Internal and Supplier Audit Procedure
SOP-23	Post-Market Surveillance Procedure
SOP-24	Identification and Traceability Procedure
SOP-25	Strategy for Regulatory Compliance
SOP-26	Clinical Evaluation Procedure
SOP-27	Installation and Servicing Procedure
WI-01	Document and Change Management Work Instruction
WI-03-01	Design and Development Work Instruction
WI-03-02	CE Mark Technical Documentation Work Instruction
WI-10	Control of Nonconformances Work Instruction
WI-11	Corrective and Preventive Action Work Instruction
WI-13	Customer Feedback Work Instruction
WI-21	Training Management Work Instruction
WI-22	Audit Work Instruction

SOFTWARE TEMPLATES

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 Meeting 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	Unresloved Software Anomalies Form
SW-FRM-02-01	Software Documentation Level Evaluation Form
SW-FRM-02-02	Software Safety Classification Matrix Form
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-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
SW-SOP-01	**Software Devolopment Procedure**
SW-SOP-04	**Software Safety Classification Procedure**
SW-SOP-03	**Software Risk Management Procedure**
SW-SOP-02	**Software Verification and Validation Procedure**
SW-SOP-05	**Software Change Management Procedure**
SW-SOP-06	**Software Security Vulnerability Management Procedure**