# Quality Management System (QMS) Software Vendor Checklist

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Use this helpful checklist to get started on your QMS software vendor search. Evaluate up to 3 vendors based on the listed set of common system requirements to consider when purchasing QMS software.

***TIP: Hover your mouse over each form field for more information about what text to insert, click on highlighted field to insert text.***

| | **Greenlight Guru** | | | **[Insert Vendor 2]** | | | **[Insert Vendor 3]** | | |
|---|---|---|---|---|---|---|---|---|---|
| **Vendor Details** | | | | | | | | | |
| About | Greenlight Guru provides modern purpose-built, cloud-based solutions for medical device companies to bring products to market faster, more efficiently, and with less risk. | | | [Insert Text] | | | [Insert Text] | | |
| Solution Architecture | Cloud | | | [Insert Text] | | | [Insert Text] | | |
| Built specifically for MedTech? | ✓ | | | X | | | X | | |
| **Requirements** | **Yes** | **No** | **Notes** | **Yes** | **No** | **Notes** | **Yes** | **No** | **Notes** |
| **Compliance** | | | | | | | | | |
| 21 CFR Part 820 | ✓ | | [Insert Text] | ☐ | ☐ | | ☐ | ☐ | |
| 21 CFR Part 11 | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| ISO 13485:2016 | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| ISO 14971:2019 | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Validation package provided by the vendor | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| **Platform** | | | | | | | | | |
| ISO 27001 and ISO 9001 Compliant | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Access with Single Sign-On | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Capable of interfacing with other tools/databases (APIs) | ✓ | | Export API | ☐ | ☐ | | ☐ | ☐ | |
| Analytics | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Periodic backup of the critical systems data and operational code | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Restoration and/or recovery of all system data | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ability to increase data storage | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| In-App privileges, roles, and security | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| **Services & Support** | | | | | | | | | |
| Implementation training - User and Administrative training | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Offers SOP Templates | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ongoing training - Ongoing training opportunities for QMS best practices | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Provides training about industry regulations and best practices | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 24 Hour Support | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| international support | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Help Desk Support - Available when needed for usage assistance. | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Vendor Technical Support - Available when needed for application support. | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| In-house industry advisory services | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Extensive partner network | ✓ | | 250+ medical device industry partners | ☐ | ☐ | | ☐ | ☐ | |
| Document migration services offered | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Partner program for expanded medical device requirements | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| **Collaboration** | | | | | | | | | |
| Usable across multiple locations and devices | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Dashboard for users' task summaries | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Task-based collaboration across QMS | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Manage users, accessibility, and roles | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ability to give access to supplier, consultant, partner users | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ability to organize and bookmark documents | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Streamlined review and approval processes | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |

| Workflows | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Link anything across the QMS | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| In-app workspace-specific CSV exports | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ability to obsolete items | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Document Management integrated throughout the QMS | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Supports document change order system for editing, reviewing, approving, and releasing | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Change history and activity history present throughout the QMS | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Clear Change evaluation documentation options | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Supports integrated training management | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ability to link anything to Design Control projects | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Trace matrix for Design Controls | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ability to generate living DHF | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ability to build, edit, and generate Bill of Materials (BOM) | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Supports BOM structure and file linkage for items like Design History Files | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Supports Risk Management | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Risk that clearly allows management | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| of Hazards, Hazardous situations, Harms, and severities | | | | ☐ | ☐ | | ☐ | ☐ | |
| Supports ongoing monitoring activities for Risk management post design transfer | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Provides Risk traceability into Design Control, Supplier Controls, Customer Feedback, CAPA, and Nonconformance handling | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ability to manage Suppliers | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Ability to manage Supplier Corrective Action Requests (SCAR) | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Supports Audit Management (internal/external), schedule, and results | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Supporta CAPA management | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Document export provides both PDF and original, editable document | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Support Nonconformance Management | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Supports complaint handling and customer feedback | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Provides for CAPA investigation and clear decision for path forward | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| Provides the ability to manage defects and Nonconformances from multiple sources | ✓ | | | ☐ | ☐ | | ☐ | ☐ | |
| **Additional Requirements** | | | | | | | | | |
| [Other capabilities critical for your business needs] | ☐ | ☐ | | ☐ | ☐ | | ☐ | ☐ | |

| | Greenlight Guru | [Insert Vendor 2] | [Insert Vendor 3] |
|---|---|---|---|
| **Process for Purchase** | Align with internal stakeholders to document your purchasing process and | [Insert Text] | [Insert Text] |
| **System Demonstration** | Schedule a demo here | [Insert Text] | [Insert Text] |
| **Proposal** | Talk to Sales | [Insert Text] | [Insert Text] |
| **Contact Information** | [Insert Text]<br><br>Tel: 317-960-4220 Greenlight Guru<br>601 S Meridian St Suite 500,<br>Indianapolis, IN 46225 | [Insert Text] | [Insert Text] |

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|---|---|
| **Final Recommendation** | [Insert Text] |
| **Reason for Recommendation** | [Insert Text] |