FACT SHEET

QMS by Octalsoft

Quality Management System

Automate Everything
End-to-end workflow automation

Future-Ready Architecture
Cloud-ready, Scalable, and Compliant

Fit Your Way
Precision customization for ultimate Efficiency

Connect Seamlessly
Instant integration with your Ecosystem

To know more, email us at
info@octalsoft.com
inquiry@octalsoft.com
+1 (240) 547 4400
+91 (972) 336 1568

Schedule a **Demo** with our Product Specialist today!

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KEY FEATURES OF OCTALSOFT QMS

Document Control

Manage and maintain protocol-related documents, SOPs, forms, work instructions, and templates with version control, secure access, e-signatures, and role-based permissions.

Deviations and CAPAs

Capture, track, and manage process deviations, audit findings, and quality issues with structured root-cause analysis, preventive and corrective actions, and escalation mechanisms to prevent recurrence.

Training Management

Maintain end-to-end training compliance for GCP, protocol-specific training, system training, and SOP curricula with centralized records, assessments, and auto-scheduling to ensure workforce compliance and readiness.

Inventory

Track, manage, and monitor stock levels with real-time visibility, automated alerts, and complete traceability for materials and consumables. Include calibration tracking, AMC management, service scheduling with auto-alerts.

Audit Management

Plan, schedule, and execute internal audits, vendor audits, investigator site audits, and sponsor audits with automated notifications, audit trails, and integrated CAPA tracking.

Supplier Evaluations

Assess and monitor qualifications of central labs, technology vendors, imaging vendors, and other suppliers to ensure ongoing compliance with quality and regulatory expectations.

> Octalsoft QMS is a smart, end-to-end platform that elevates quality, ensures regulatory compliance, and drives operational efficiency. Built for pharma, healthcare, manufacturing, and life sciences, it digitizes document control, automates audits, tracks supplier performance, and delivers actionable insights—empowering continuous improvement with transparency and traceability.

Pankti Verma
Senior Technical Manager

Risk Management

Proactively manage risks across your QMS ensuring critical processes stay compliant and quality-driven. Prioritize actions, implement mitigation, and maintain excellence with real-time risk oversight.

Reporting & Analytics

Generate dashboards and study quality insights to monitor training status, audit outcomes, CAPA effectiveness, supplier performance, and operational KPIs for data-driven decision-making.

OUR UNIQUE CUSTOMER SUPPORT STRUCTURE

Detailed User Manuals/Guides

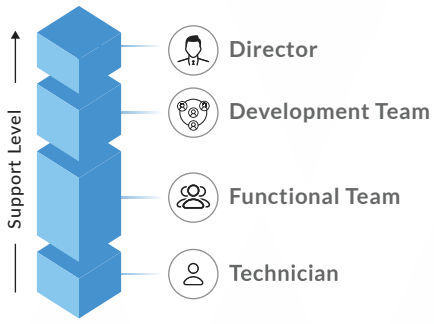
One Stop-Hassle Free Support

- Detailed user guides & training sheets for every product module
- Guided video tutorial sessions to address user queries
- Exhaustive FAQ sheets per product module

24 X 7 Help Desk Support

Our Specialists are Always Available to Resolve Your Queries

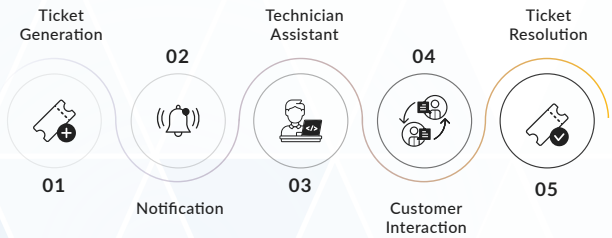
1. Customized screen for every user
2. Integrated online & offline support
3. Comprehensive repository of common queries
4. Module embedded chatbot



Embedded Agile Ticketing Feedback System

Your Query is Our Priority

Issue based (bug, enhancement, data rectification & others) ticket resolution system to address urgent queries on priority



AI Powered Module Specific Chatbot

Personalized Just for You!

1. Specific key phone number allocation to every client
2. Local & international support
3. Integrated online & offline support

Meet Quinn

(Quality Manager)

Quinn, working at a Medical Device company needed a solution to ensure regulatory compliance, elevate product quality, and streamline operations. Octalsoft's QMS delivers just that and more!

With automated compliance alerts, secure version-controlled documents with e-signatures, and supplier performance tracking, it simplifies quality management. Its CAPA and root-cause analysis tools drive continuous improvement, while advanced analytics uncover trends and opportunities for quality enhancement.

By tackling compliance, operational efficiency, and quality challenges in one platform, Octalsoft's QMS empowers Quinn to transform his company's quality management into a strategic advantage.

WHY CONSIDER OUR eCLINICAL SOLUTION?

Single Unified Mobile-Enabled Platform

End-to-end physically & logically secured cloud solution that effortlessly manages data collection, IP supplies, randomization, study compliance, and documents

Regulatory Compliant

Compliant with all current & highest regulatory guidelines:

GDPR | FDA 21 CFR Part 11 | EU COMPLIANT Annex 11 | GAMP 5 | cdisc | HIPAA COMPLIANT | GxP | ICH GCP

Patient Centric

Integrated ePRO & eConsent enables you to conduct patient-centric virtual trials to access diverse population all over the world for smarter and faster trials

Audit Ready Database

End-to-end physically & logically secured cloud solution that effortlessly manages data collection, IP supplies, randomization, study compliance, and documents

Global Mega Trials in Multiple Languages

Experience conducting global trials for all types of studies and trial phases with US FDA Submission | EMA Submission | DCGI Submission

Fast Study Startup

Shortest build times with over 90% of studies deployed within 2-4 weeks. Easy-to-use trial builder allows quicker configuration of eCRFs

Configurable, Customizable, Cost Effective & Easy to Use

The platform can easily integrate with your existing system and can also get designed as per your requirements for increased flexibility, mobility and scalability

Unparalleled Global Customer Support

End-to-end physically & logically secured cloud solution that effortlessly manages data collection, IP supplies, randomization, study compliance, and documents

Our Values

For 15+ years, we've mastered the art of Simplifying Technology so that greater discoveries can happen sooner. As a leading eClinical Solution provider, we've always invested in the right expertise, experts, and technology that keeps us, and you at the forefront of science and medicine. As a trusted tech partner for some of the world's leading clinical trial initiatives, our values of innovation, reliability, and client satisfaction guide everything we do.

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