



TRACKWISE DIGITAL[®]

TrackWise Digital[®] is a cloud-based quality and compliance solution that offers fully integrated solutions for managing quality, documents, training, complaints, risk and supplier quality.

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END-TO-END DIGITAL QUALITY SOLUTION

Built on over two decades of quality experience, TrackWise Digital combines industry-leading quality and compliance best practices with the user-friendly and trusted Salesforce platform. With QualityWise.ai, TrackWise Digital is also the industry's first quality management solution with AI-augmented decision-making capabilities, enabling a shift from reactive to proactive quality management.

CREATE POWERFUL BUSINESS INSIGHTS

Improve company-wide performance by tracking and analyzing quality data across all quality processes to increase operational excellence at every stage of the product lifecycle.

INCREASE WORKFORCE EFFICIENCY

Reduce errors and accelerate productivity by enabling quality teams with smarter systems, best practice processes, automation and cross-functional collaboration.

EXTEND YOUR CULTURE OF QUALITY

Create a culture of quality across your organization, suppliers and contract services with communication and collaboration tools built into a centralized quality platform.

ENSURE REGULATORY COMPLIANCE

Proactively manage regulatory compliance with out-of-the-box best practice industry templates, automated validation and 21 CFR part 11 compliance.

ACHIEVE PROACTIVE QUALITY WITH TRACKWISE DIGITAL

TrackWise Digital is the world's first AI-enabled quality management system. The solution's integrated modules work together to support quality and compliance and enable more efficient and effective decision-making to help organizations achieve proactive quality.



Using an end-to-end, digital system for all quality processes offers closed-loop tracking and reporting in a familiar, easy-to-use platform – increases efficiency for end users and visibility for management.

QUALITY MANAGEMENT

TrackWise Digital cloud QMS allows you to create and manage core quality processes with intelligent workflows to streamline reviews and respond to issues quicker. With QualityWise.ai, leverage AI-augmented quality processes to automatically suggest categories and correlate quality events, unlocking the value of operational data to augment decisions.

- Nonconformances and deviations can be managed, along with associated trends, investigations, approvals and resulting records
- Corrective and preventive action (CAPA) is a fully integrated CAPA system with automated routing, notification, delivery, escalation and approval capabilities
- Change control manages changes from request, through pre-approvals, change execution, follow-up approvals and implementation
- Audit management is an integrated tracking system and a powerful workflow engine that automates all steps in the audit lifecycle

COMPLAINT MANAGEMENT

Manage the entire complaint lifecycle—from complaint to investigation, root cause analysis and regulatory reporting. Track, triage, escalate and share records in a centralized and validated platform.

- AI-augmented complaint management with QualityWise.ai suggests categories, risks and reportability and correlates complaints to boost productivity and reduce investigation time
- Adverse event reporting (FDA eMDR submission)
- Configurable questionnaires or decision trees can be used for complaint assessments, reportability assessments and safety assessments

DOCUMENT MANAGEMENT

Centralize content to promote knowledge sharing and collaboration in a controlled and audited environment.

- Centralize information on a single platform for regulatory and document management
- Rule-based, automated workflows with review, annotate and approval capabilities
- Maintain compliance by utilizing document quality, controls that ensure everyone is working off a single version of the truth

TRAINING MANAGEMENT

Automate company-wide training policies and regulatory requirements. Training activities are scheduled and tracked through completion, offering proof of compliance with the latest courses and standard operating procedures (SOP).

- Create and manage training plans for users and groups of users
- Measure knowledge and understanding using tests and examples
- Track compliance against due dates to ensure that your workforce is properly trained and that you're ready for your next audit

INTEGRATED RISK MANAGEMENT

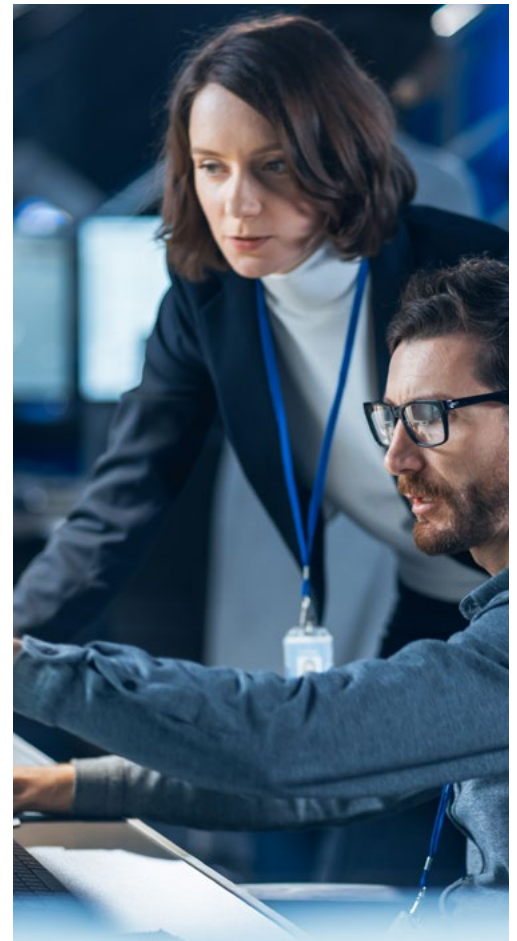
TrackWise Digital Risk Management provides a complete solution to proactively manage risks of pharmaceutical products, combination products, medical devices and more.

- Maintain ISO 14971:2019 and ICH Q9 compliance
- Configure templates for FMEA and Hazard Analysis
- Manage risks for the entirety of a product lifecycle directly within TrackWise Digital using data from other quality processes, such as TrackWise Digital complaint management

SUPPLIER QUALITY MANAGEMENT

Effectively manage and collaborate with suppliers and contract manufacturers across your supply chain directly within TrackWise Digital. The supplier quality management application allows quality teams to manage supplier relationships from onboarding to auditing and scorecard analytics.

- Manage supplier data, onboarding, audits, incidents, correct action, analytics and more
- Collaborate with suppliers on audits, corrective actions, changes and more through the TrackWise Digital supplier portal



FEATURES



Quality Process Accelerators (QPAs)

Built on over two decades of quality experience, TrackWise Digital's fully validated quality process accelerators enable quick implementation and support automated validation through software updates—minimizing the burden on IT departments, lowering total cost of ownership and accelerating time to value.

QualityWise.ai - AI-Augmented Decision-Making Capabilities

With QualityWise.ai, TrackWise Digital applies machine learning and natural language processing to auto-categorize and autocorrelated complaints and quality events. This supports improved productivity and intelligent decision making across the organization.



Compliance

TrackWise Digital is built from the ground up around compliance with control over processes and information, enforced compliance with internal and external requirements and 21 CFR Part 11 compliance including electronic signature and audit trail.

Centralized System of Record

Managing all quality processes on a single, centralized system streamlines cross-functional quality processes and enables robust reporting and analytics capabilities. The easy-to-use platform includes automated configurable workflows, productivity tools like tasks and alerts and reports and dashboards.



Salesforce Platform

Built on the Salesforce platform, TrackWise Digital leverages Salesforce's security, stability and native features such as global compliance standards, integration with many third-party solutions, form builder, reporting, process builder, configurability and access control to name a few.

Usability

TrackWise Digital leverages the Salesforce Lightning interface, which improves ease-of-use and searchability, promotes rapid user adoption and nurtures productivity.

Mobility

A mobile-enabled and modern user interface provides a familiar look and feel. Access TrackWise Digital from desktop and mobile, enabling remote working and remote audits.

For more information

To learn more, visit
www.spartasystems.com

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**THE
FUTURE
IS
WHAT
WE
MAKE IT**

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