

### Leverage AI to Increase Productivity and Meet Growing Patient Needs

Patients and regulators have high expectations for complaint handling and effective quality event management of pharmaceuticals, medical devices, and other life science products. With ever-increasing volumes of quality records and growing product, process, and supply chain complexity, quality teams are pressed to stay on top of critical issues and consistently make the right decisions, efficiently and effectively. By leveraging innovations in digital quality, organizations can uncover new insights from today's quality data.

QualityWise.ai provides powerful, AI-assisted workflows to automatically suggest categories and correlate complaints and quality events, unlocking the value of quality data and augmenting decisions made by quality teams. With Auto-Categorization and Insights, QualityWise.ai provides robust solutions to decrease cycle-times, speed up response times, and deliver on customer expectations.

### Benefits

**Quickly prioritize high risk issues, identify adverse trends, and reduce patient impact**

**Increase efficiency, responsiveness, and customer satisfaction**

**Decrease cycle time of complaints and quality events, freeing up quality resources to focus on higher value tasks**

**Gain consistency and traceability with systematic categorization and correlation**

**Minimize errors, compliance risk, and associated regulatory actions**

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## QualityWise.ai Auto-Categorization

### **Automatic and Systematic Classifications**

With increasing volume and complexity, the ability to quickly classify and triage quality events is critical in prioritizing the focus of quality teams. Notification windows of regulatory reports, such as Field Alert Reports and Medical Device Reports, begin when the company is aware of the issue, not when the company correctly identifies an event as reportable. Mis-categorizing complaints can trigger the wrong set of actions and missed deadlines.

QualityWise.ai Auto-Categorization accurately and systematically classifies events to identify severity and risk levels early on in process to help quality teams quickly triage and initiate appropriate action.

### **Natural Language Processing (NLP)**

Leverage NLP to analyze and convert unstructured data into actionable classifications for complaints and quality events based in historical records, standardizing and removing bias at the earliest stages to improve accuracy.

### **Signal Detection**

Readily detect signals of potential high-risk patient impacts for increased prioritization and responsiveness

### **Right First Time**

Avoid unnecessary investigations by improving right first time categorization of complaint classification, reportability, and risk.

### **Confidence Levels**

View confidence levels of AI suggestions to indicate the likeliness of correct recommendations

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## QualityWise.ai Insights

### **Autocorrelation of Related Quality Events**

Investigations involve highly complex processes and expert knowledge. Disparate data and low visibility of relevant information across a typically document-based system makes investigations difficult and time consuming.

QualityWise.ai Insights rapidly searches through all available current and historical data to find related quality events instantaneously allowing quality teams to gain efficiency and a fuller picture of the overall presence of a quality event. TrackWise Digital and QualityWise.ai speeds up investigations by helping quality teams identify correlations, trends, and patterns that were previously invisible across related events to avoid duplicate investigations of complaints and quality events, including out of specifications, deviations, non-conformances, and CAPAs.

### **Avoid Duplicate Investigations**

Leverage QualityWise.ai Insights to identify related quality events and avoid repeating the same investigation multiple times, reducing Remediation Costs and the overall Total Cost of Quality.

### **Adverse Trend Identification**

Improve current adverse trend identification processes by holistically capturing all related events, ensuring all decisions by quality personnel are made with the maximum amount of relevant data.

### **Quality Correlation**

Efficiently and effectively connect disparate items of quality data, including complaints, out of specifications, deviations, non-conformances, and CAPAs, that are often integrally linked by cause and effect.

### **Shared Quality**

Ensure there is visibility of outcomes of quality events throughout the organization, regardless of the business unit or location, to improve efficiency and effectiveness of investigations and other quality activities.

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## Delivering World-Class Security and Compliance

Leveraging industry leading AI capabilities from Amazon Web Services (AWS) and AWS SageMaker, the TrackWise Digital QualityWise.ai technology stack and algorithms are purpose built for quality, and support the use of GxP compliant data. For more information, contact an account executive for Sparta System's Security and Compliance White Paper.

## TrackWise Digital Quality Suite

TrackWise Digital® quality management system automates and integrates quality and compliance management processes, complaint handling, document control, training management, supplier quality, risk management and more on an easy-to-use cloud platform. Built on over two decades of quality experience, TrackWise Digital combines industry-leading best practices with the user-friendly and trusted Salesforce platform. With reporting and analytics across all processes, quality teams can leverage quality data to strengthen their culture of quality and impact company-wide performance.

Founded in 1994, Sparta Systems is the world's premier provider of cloud and on-premise quality management software. We offer the solutions, analytics, and expertise that speed up quality and compliance. Companies in life sciences, consumer products, discrete manufacturing and more, rely on Sparta. Learn why at [www.spartasystems.com](http://www.spartasystems.com)

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