



POWERFUL, AI-ASSISTED RECOMMENDATIONS

Managing quality events and effective complaint handling is a regulatory expectation for both pharmaceuticals and medical device companies.

The path to properly classify, evaluate and identify root cause and determine the necessary actions to prevent further occurrences involves sifting through tremendous amounts of data and is often not straightforward. With ever-increasing volumes of records and growing product and process complexity, quality teams are pressed to stay on top of critical quality issues and prioritize those most urgent.

QualityWise.ai provides powerful, Al-assisted recommendations to automatically classify, categorize and streamline complaints triage, quality event handling and complaint intake. The ability to accurately and systematically classify events early on in process helps quality teams to quickly triage and ensure timely, and appropriate action is taken to minimize recurring product issues and negative customer impact. With Auto-Categorization, TrackWise Digital provides next generation Al capabilities that are purpose-built for quality management to deliver maximum value and better outcomes.

PRIORITIZE HIGH-RISK **ISSUES, FASTER**

Instantly comb through large volumes of data to prioritize high risk issues and identify adverse trends.

INCREASE RESPONSIVENESS AND CUSTOMER SATISFACTION

Quickly triage complaints and quality events, reducing cycle time and negative impact and risks to patients.

BOOST OPERATIONAL EFFICIENCY AND EFFECTIVENESS

Easily manage growing volumes and complexity with AI-augmented decisions.

ENSURE REGULATORY COMPLIANCE

Minimize human bias and errors, reduce compliance risk and associated regulatory actions.

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.

Autocategorization accurately and systematically classifies events to identify severity and risk levels early in the process to help quality teams quickly triage and initiate appropriate action.



ACHIEVE PROACTIVE QUALITY WITH QUALITYWISE.AI

QualityWise.ai is the premier Al-enabled platform designed to augment quality management decision making. The TrackWise Digital QualityWise.ai solutions are purpose built for quality management and support the use of GxP compliant data for regulated industries.



FEATURES



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 Al suggestions to indicate the likeliness of correct recommendations.

For more information

To learn more, visit www.spartasystems.com

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