RISK MANAGEMENT CONNECTED TO THE QUALITY SYSTEM

Risk Management

TrackWise Digital®

Honeywell

PROACTIVELY MANAGE RISKS

A systematic approach for risk analysis, evaluation, control, review and post-market decision making is fundamental in managing the risks of pharmaceutical products, combination products and medical devices.

TrackWise Digital® Risk Management facilitates the development, implementation and maintenance of a risk management program in accordance with ICH Q9 and ISO 14971.

RISK INTEGRATED WITH OTHER QUALITY PROCESSES

TrackWise Digital with risk management enables companies to seamlessly link risk management processes to other quality management processes.

MAKE BETTER RISK-BASED DECISIONS

Utilizing Risk Management directly within TrackWise Digital ensures that all risk-based decisions within the Quality Management System (QMS) are handled using consistent criteria for risk analysis, evaluation, control and acceptability of residual risks.

PROACTIVE RISK MANAGEMENT

Manage risks throughout the entire product lifecycle directly within TrackWise Digital, resulting in patient safety and product quality being at the forefront of all quality decision making.

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 decisionmaking to help organizations achieve proactive quality.

FEATURES

TrackWise Digital's Risk Management connects critical quality processes to provide a truly iterative closed-loop system for risk-based decision making and the continuous improvement of product safety and customer satisfaction.

Complaints
Out-of-the-box integration with TrackWise Digital Complaints allows for direct links from complaint records to individual residual risks.

Qualitative and quantitative information within the risk management file regarding failure modes, hazardous situations, patient harm and frequencies of occurrence allow for data driven and risk-based decision making. A strong, documented link between complaint data and the risk management file enables companies to ensure the existing risk analysis, control measures and benefit-risk determinations are up to date.

Nonconformances (NC)
Nonconformance records within TrackWise Digital can be directly linked to individual residual risks within the risk management file. With this direct linkage, risk analysis and evaluations for potential or observed nonconformances are streamlined and consistent throughout the organization.

Corrective and Preventive Action (CAPA)
Leverage the relevant risk management files to aid in the determination of root causes with a direct link between CAPA records within TrackWise Digital and individual residual risks within the risk management file. With one source of truth, actions that are taken can be traced and assigned to personnel to progress the CAPA process, as well as document risk reduction within the risk management file.

For more information
To learn more, visit
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