EFFECTIVELY MANAGE MEDICAL DEVICE RISKS

Medical Device Risk Management

TrackWise Digital®

Honeywell

RISK MANAGEMENT IN ACCORDANCE WITH ISO 14971

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

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

RISK MANAGEMENT EMBEDDED INTO TRACKWISE DIGITAL

TrackWise Digital Risk Management allows for the storage of qualitative and quantitative information that facilitates production and post-production decision making within other TrackWise Digital quality processes. Out-of-the-box integration with TrackWise Digital Complaints allows for direct links from complaint records to individual residual risks.

A COMPLETE RISK ANALYSIS PROCESS

Bring focus to patient safety with the built in hazard analysis that links hazards and hazardous situations to harms.

AT-A-GLANCE RISK REVIEW

TrackWise Digital Risk Management features built-in dashboards that provide information on progress or completion of risk management workflows, and notification of risk control activities that are required.

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

Risk Management File
Create a risk registry that provides traceability of each hazard through risk analysis, evaluation and control for specific products, product families or a product platform. Electronic signatures and audit trail functionality, in accordance with 21 CFR Part 11, allow for efficient and compliant crosscollaboration. Authors and approvers can be configured for each element of the risk management file to allow for targeted involvement of subject matter experts.

Risk Analysis
TrackWise Digital Risk Management offers tools such as hazards analysis and failure mode and effects analyses (for use, design and process) for a complete risk analysis. Project teams can save time and resources when building a risk analysis for similar new products, or product line extensions, with the ability to leverage portions of an existing risk analysis into a new risk analysis.

Risk Evaluation and Control
TrackWise Digital Risk Management allows for consistent risk evaluations to determine risk control. Risk control activities can be tracked for completion via personnel assignments and due dates. Residual risks can be evaluated for risk reduction after risk control measures have been implemented.

Evaluation of Overall Residual Risk
A visual representation of the individual residual risks on a risk matrix shows a graphical distribution of the risks and facilitates evaluation of the overall residual risk and benefit.

Production and Post-Production Activities
As information during the production and post-production phase of a product's lifecycle is collected, existing TrackWise Digital processes, such as nonconformances, CAPAs and complaints, can be linked to specific residual risks and can be used to improve the accuracy of the risk evaluations and benefit-risk analyses. Thresholds can be configured directly within the risk management file to aid in production and post-production signal detection and quality decision making.

For more information
To learn more, visit
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