

QPACK FOR MEDICAL DEVICES

One Solution, All your Medical Application Management Needs

QPACK™ ALM 2.0 solution

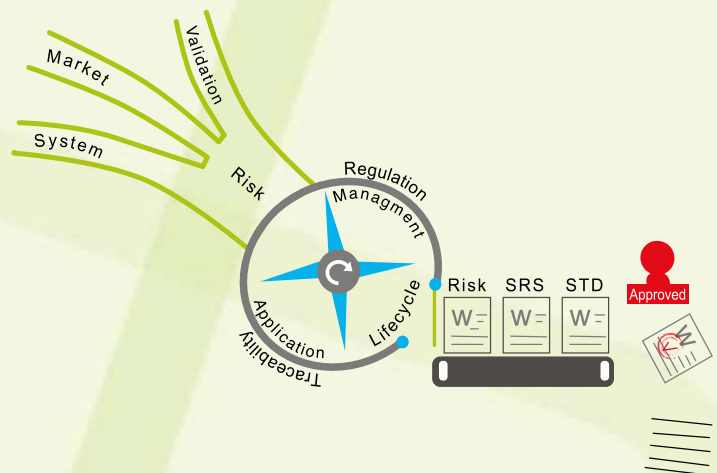
The Challenge: Today, due to ever-more stringent industry regulation compliancy requirements, medical device manufacturers are faced with increasingly painstaking administrative challenges in their everyday work processes including; Strict regulatory compliancy, requirements management, solid validation processes and increasingly faster time-to-market demands.

The Solution: QPACK MD for Medical Device Application Lifecycle Management.

QPACK MD provides one single repository for all your medical device development data. From project initiation, through to product delivery, QPACK MD provides easy-to-use data management tools for each and every phase of the medical device development process, including:

Marketing Requirements – Product Management Module integrates customer needs into the development process, resulting in products designed to precisely meet customer needs.

Product Requirements – Definition Tool & Release Manager enables users to determine the



precise feasibility of new functionality and view the impact of changes in tandem with product delivery timelines.

Development – Research and Development (R&D) Module includes all developer working items such as; detail design tasks, unit tests and defect corrections - all integrated into its natural working environment IDE.

Test Planning – Test Planning Module enables QA departments to easily plan specific requirement tests for product releases, while at the same time supporting complex products in multiple version environments.

Test Execution & Validation – QA Managers can plan testing activities for each release, create test execution sets and assign them to different testers, in addition to running both manual and automatic tests, reporting defects and tracking test results.

Defect Tracking – Users can easily submit, update, query and report product defects while maintaining correct version and increment. Managers also receive systematic updates on project quality.

Document Generation – QPACK MD produces all the necessary documents for audit submission,

together with an up-to-date traceability matrix, at the click of a button

Risk & Hazard Analysis – Meeting FMEA standards, QPACK enables easy product risk management, making external excel forms obsolete, while providing full mitigation traceability.

Product Delivery – Release Management Module encapsulates all the above activities and enables a complete 'top-down view' on delivery progress

Orcanos Company Profile

Orcanos provides advanced integrated software solutions for Application Lifecycle Management (ALM).

Founded in 2004, Orcanos has already successfully implemented QPACK in several industries including; software companies, telecommunications providers, medical organizations, embedded technology providers and finance companies.

Orcanos headquarters in Tel Aviv, Israel.

QPACK MD™ Key Features

RISK Assessment: Based on regulatory standards, QPACK MD offers a sophisticated, yet easy to use risk management module, seamlessly integrated into the flow of your medical development processes.

Traceability of Multiple Processes: Both graphical and physical traceability features complement the process of document generation.

Document Management System (DMS): QPACK MD supports the entire life-cycle for both generation and storing of product documents.

CFR 21 Part 11 Compliance: QPACK MD enables organizations to comply with FDA and CE regulatory requirements.

Document Security: QPACK MD provides a secure, strict and customizable 'Permission & Governance' tool for securing your finished documents from access and changes. The system also integrates a digital signature system that provides evidence of the signer's authenticity, thereby guaranteeing data integrity.

Support of all Development Stages: QPACK MD supports the entire organization's product life cycle management, from company marketing requirements, all the way to the system validation



Orcanos
Application Lifecycle Management

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