



Polarion Software's Powerful Application Lifecycle Management and Requirements Management Enables IEC 62304 and FDA 21 CFR Part 11 Regulatory Compliance for Medical Device Companies

Alameda, CA (March 31, 2010) – Polarion Software, a leader in application lifecycle management and requirements management and a disruptive force in the software marketplace, announced today the availability of its MedPack plug-in, providing a turn-key lifecycle management solution for compliance to critical regulations governing the medical device industry including FDA 21 CFR Part 11 and IEC 62304.

Software reliability within computer controlled medical devices, such as pacemaker presents a significant risk for medical device manufacturers, who must prove compliance to regulations established to protect against personal injury, and most critically -- loss of human life. FDA and IEC regulations demand that a company put in place and prove through an auditing process a rigorous lifecycle and requirements management process that ensures device quality and mitigates risk. Failure of an internal audit can result in steep financial penalties for a manufacturer, and potentially, a shut-down of manufacturing operations.

Today, it is virtually impossible for medical device manufacturers to verify software quality and process integrity post-development without a comprehensive application lifecycle management (ALM) and requirements management (RM) solution. Polarion's MedPack plug-in enhances an already proven turn-key ALM and RM solution for medical device manufacturers with an automated and cost-effective pathway to regulatory compliance. Polarion's MedPack plug-in includes:

- Key ALM functions necessary for regulatory compliance including requirements management, test case management, change and defect management, project control, risk management and risk analysis, traceability analysis, document management
- Medical device project templates for fast implementation
- Configurable user roles for managers, developers, auditors
- Centralized standards library
- Pre-configured workflows and processes providing immutable audit trails and enabling adherence to FDA 21 CFR Part 11

"The Polarion MedPack plug-in marries Polarion's combined years of consulting experience with dozens of medical device customers, to bring to market a turn-key solution developed specifically to address regulatory compliance in this demanding and quality-obsessed industry," Sven Wittorf, MedPack Project Manager.

Polarion ALM with MedPack has gained broad adoption across the medical device industry, including such companies as Frensius, GE Healthcare and Phonak AG, making it a 'must-have' for companies manufacturing or managing life-critical medical products, devices and processes. Further information on the MedPack plug-in is available from Polarion Software's web site at http://www.polarion.com/products/medical/index_de.php.

"Polarion provides a complete infrastructure to support embedded software development for medical devices and for related regulatory compliance. Polarion's solution includes all the critical components including configuration management,



traceability, process support, documentation and checklists and provides these elements pre-configured and fully integrated,” said Professor Dr. Christian Johner, Institute for Information Technologies in Healthcare.

About Polarion Software

Polarion Software is a global leader in the field of Requirements Management and comprehensive ALM software solutions and services. With over 750,000 users globally and hundreds of Fortune 1000 organizations; Polarion provides companies with fully integrated, web-based solutions to lower costs and increase efficiencies while replacing legacy client server dinosaurs with disruptive low prices sourced via multiple channels for ease of purchase, installation, and customer support. For more information, visit www.polarion.com.

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