

PRESS RELEASE

STUDY FINDS WIDE GAP AMONGST MED-TECH INNOVATORS AND LAGGARDS



LATEST STUDY REVEALS TWO SIDES OF THE MED-TECH INDUSTRY

September 15, 2016 – Yardley, PA. On the one side, Med-Tech organizations who have implemented closed loop change, configuration and business process management systems are able to support acceleration of high quality, complex new product introductions in a timely, cost effective and regulatory compliant manner -- these companies are Med-Tech Innovators.

On the other side are Laggards. These organizations admittedly have no closed loop processes and are most concerned with regulatory compliance over product quality. Laggards tend to operate in a reactive mode by fixing problems after they occur. They also rely heavily on documentation-driven processes, rendering them unable to evaluate financial impact changes effectively.

These are terms Innovators and Laggards are based on the results from Axendia's latest research study based on a survey of 85 world-wide Med-Tech industry practitioners as well as in depth discussions with executive thought leaders from Axendia's Industry Advisory Council.

The study identifies and analyzes leading trends, challenges, barriers and initiatives that Med-Tech companies are undertaking to effectively manage change and configuration management (C&CM) activities in an increasingly global and outsourced ecosystem. It also identifies opportunities to improve C&CM processes across the product lifecycle.

The white papers provide specific recommendations for driving improvements in product quality, as well as strategic insights from industry leaders who are actively managing C&CM across their product's lifecycle, managing product variations in the field or from concept to global markets. To address key findings and analysis from this research, Axendia is publishing a series of white papers under "The Future of Change and Configuration Management" umbrella. Each white paper addresses one of the following topics:

- Are You a Med-Tech Innovator or Laggard?
- The Continuing Failure of Strategic Leadership in the Med-Tech Industry?
- Drowning in Meaningless Data? Time to fix the DRIP!
- Don't Solve Quality Problems. Avoid Them.
- Does Having a Closed Loop Process and Platforms for Your Business Really Matter?

The first white paper in the series "Are You a Med-Tech Innovator or Laggard?" is attached.

For a complimentary access code to [download](#) the remaining four, please contact: research@axendia.com.

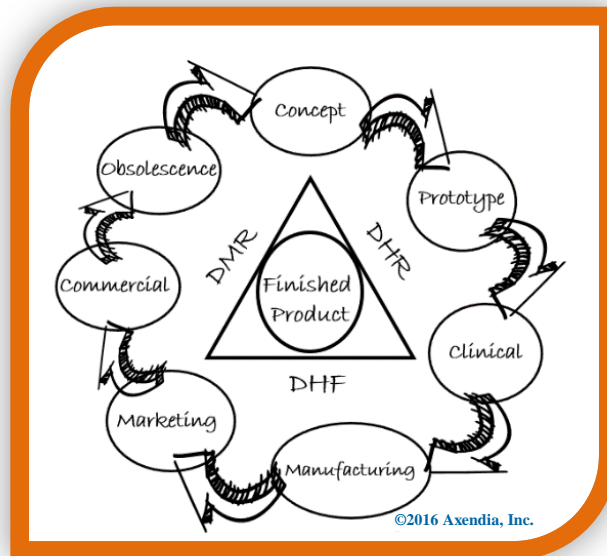
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DEFINITIONS USED THROUGHOUT THE SERIES

Closed Loop Process V. Open Loop Process

When the term **closed loop process** is mentioned, it refers to: a connected control system in which an operation, process, or mechanism is regulated by feedback.

When the term **open loop process** is used, it refers to: a control system in which an operation, process, or mechanism is not regulated by feedback.



NOTE TO EDITORS

Detailed findings from this research study as well as charts and graphs of key findings, will be available for your use with proper attribution in a report entitled, “The Future of Change and Configuration Management in the Med-Tech Industry.” For additional information or to schedule an interview or briefing with the study’s lead researchers, please contact Sandra Rodriguez via email at srodriguez@axendia.com or by phone at +1 (215) 917-4220.

To request a copy of this report, please visit www.axendia.com/wp/research/

METHODOLOGY

Findings are based on a survey of 85 world-wide Med-Tech industry practitioners. Industry thought leaders also provided valuable insight on this topic.

This study was co-sponsored by leading companies active in the Medical Technology sector. They are (in alphabetical order): Camstar Systems Inc. (www.camstar.com), Deloitte (www.deloitte.com) and SiemensPLM (www.siemens.com/plm). These companies supported

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this research to increase the understanding of processes and systems that enable closed loop change and configuration management processes. Axendia retained full editorial control during the execution, analysis, and compilation of this report.

ABOUT AXENDIA

Axendia, Inc. is a leading analyst, and strategic advisory firm focused on the Life-Sciences, and Healthcare markets. We provide trusted advice to Industry Executives on Business, Regulatory, and Technology issues. Axendia professionals offer a unique combination of deep hands-on industry experience coupled with strategic vision. Axendia serves the complete ecosystem including Life-Science, and Healthcare Organizations, Technology & Service Providers, and the Investment community. Our clients range from startups to Fortune 100. We contribute to our client's success by providing long-range visibility, and helping them navigate the increasingly complex landscape in the Life-Sciences, and Healthcare markets.



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