Advancements in Regulatory Compliance Capabilities for PLM Show Promise

by Sean Klein

Keeping in line with ever-changing regulatory initiatives such as RoHS, WEEE or (FDA) 21 CFR Part 820 can be a daunting task, particularly for manufacturers operating in multiple markets or with large numbers of product variants. Not only do regulations have the potential to derail a new product midway through development, but the consequences for non-compliance are often severe, ranging from hefty fines and brand deterioration to litigation and/or license revocation.

A recent report by Gartner revealed that “During the last five years, many PLM vendors substantially improved their regulatory compliance capabilities…” Additionally, the report stated that the information packaged by these capabilities, “…is starting to play an important role, complementing existing software investments with pertinent product and market-related content for added compliance management and decision support.” In industries with high levels of regulation (life sciences, aerospace, automotive, consumer goods and high tech), firms that make adoption of these PLM capabilities a top priority are achieving accelerated time-to-market and significant improvements to their profit margin.

Within PLM, regulatory compliance ensures that companies maintain an auditable record of product development history, electronic documents and signatures. The product data within PLM allows firms to anticipate future regulations and adapt to regulation changes with limited transitional cost.

Firms seeking to comply with the EU’s RoHS/WEEE or REACH legislations, the U.S. Food and Drug Administration’s Quality System Regulation, or GHS Classification and Labeling of Chemicals should look to regulatory compliance capabilities within PLM to gain a competitive advantage.

Kalypso recommends the following when considering the implementation of regulatory compliance functionality within PLM:

- **Involve experienced, independent PLM experts** in your decision making process.
- **Enable R&D** to design regulatory compliance, quality, sustainability and product safety into product early in the product lifecycle
- **Proactively comply to changes in regulatory environments** with user-defined compliance screenings
- **Implement PLM system solutions in parallel with relevant practices and processes** to maximize system utilization and effectiveness [view whitepaper](#)
- **Measure improvements** using recalls, stopped shipments, and non-compliance reports
- **Explore PLM Vivo solutions** to significantly reduce the cost of regulatory compliance

For more information on Kalypso’s take on PLM capabilities click here.


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Sean has a passion for technology and innovation and enjoys reading, hiking, kayaking, surfing, and playing golf.

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