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THE LAZARUS REPORT

Product End-of-Life News and Insights

In the News

Microsoft releases <u>list</u> of products scheduled for end of support in 2023

Windows 8.1, Visual Studio 2012, and Office 2013 are among the Microsoft products for which there will no longer be new security updates, non-security updates, free or paid assisted support options, or online technical content updates.

Intel introduces 13th-Gen Raptor Lake processors

Intel claims that Raptor Lake, with more cores, more connectivity, and a revamped core architecture, will have a 15% gain in single-threaded performance and a 41% gain in multi-threaded compared to Alder Lake.

Dell launches <u>Project Frontier</u> initiative to advance edge computing

The company's new initiative will help customers simplify, optimize, and scale their edge applications in a secure way, tying it to a design program through which it will collaborate with customers to further advance edge computing solutions.

OpenSSL <u>update</u> to fix critical vulnerability for versions 3.0.0+

For the first time since 2016, OpenSSL has issued a critical vulnerability patch for its open-source security library—a commandline toolkit used to generate private keys, create certificate signing requests, install SSL/TLS certificates, and identify certificate information.

Vital TSMC supplier warns of chip material price hikes into 2023

Showa Denko K.K., a major chemicals supplier to such chip manufacturers as TSMC, says it expects to raise prices in 2023 and to cut back unprofitable product lines. Among the factors driving these expectations: a weak yen.

Global supply chain is "still not <u>stable</u>," says HPE CFO

Pointing out that "historically 40% of global manufacturing capacity was based in China," Tarek Robbiati, CFO of Hewlett Packard Enterprise Co., told investors that it is critical to "be a lot more distributed across various countries in the globe, in Europe, and also in Asia."

The Art & Science of Product Lifecycle Management for Medical Devices

How medical device manufacturers can adapt product development and management disciplines to keep up with technological change

The rapid growth of digitization, combined with the increased sophistication of the Internet of Things (IOT), continues to have a significant impact on the design, commercialization, and frequency of modifications to complex medical devices. Notably, any medical device that integrates IT components or systems now has considerably more modifications and changes, which means it's more complex to manage than ever, given the length of the validation process.

Many medical device manufacturers, however, do not have quick and responsive internal process disciplines in place to proactively manage the rapidity of change. Or they have not updated their methodologies to address the increased rate of technological advancement. In either case, given the growing disconnect between the lifecycle of the medical device itself, and the lifecycles of the various IT components it requires, companies must create a more robust process for tracking and managing those components.

Effective management of a medical device's lifecycle begins with:

- Asking your IT systems/components supplier to provide lifecycle information to you at the beginning of the product design phase, including end of life dates.
- Creating a comprehensive list of IT systems/components deployed within your company for all products, with details including vendor or manufacturer, installation sites, uses, upgrade schedules, etc.
- Designing a formal change management process that is triggered by the EOL dates of each of your IT systems/components.

There are numerous elements that make up an effective change management system, according to a recent article by <u>Greenlight Guru</u>, including: documented processes, clear communication and coordination, traceability, and accountability. "Each element of the change management process should work in tandem to provide full visibility of all related activities for the quality team, product managers, and executive level stakeholders," Greenlight Guru notes.

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Successful navigation of change management is especially nuanced for the life sciences and medical device manufacturing industries, according to electronic quality management system experts **Dot Compliance**, which wrote that "in order to do it right, communication is key to streamlining implementation for employees, managers, and customers. A clear strategy is required, with realistic timelines for everyone to work toward."

Here are key questions that need to be addressed within a change management process:

1. How early should we be notified of EOL dates?

Receiving EOL notifications well in advance for the various IT systems/components that are critical for your product helps ensures the ability to act in a timely manner to manage product functionality and lifespan. Work with suppliers to set a goal for proactive EOL notifications. As the EOL date approaches, a change management plan should be created that provides an estimated timeline and information about replacement options.

2. What steps are required to test and validate a new component?

If a product goes EOL without advance notification, it can disrupt a company's supply chain, negatively impact revenue, and reduce customer loyalty. Monitoring EOL status for IT systems/components will help prevent unwanted surprises and provide time to validate new parts.

A change management plan should identify any direct replacements or next-generation options available for the item going EOL. If a direct replacement isn't available, new options must be identified, which might require a new round of testing and a revalidation process. For products such as medical devices, a change to a critical IT system/ component may also require notification and recertification with regulatory agencies.

3. Who is responsible for identifying replacement options?

To minimize EOL interruptions when developing a new product, design not only the current version but also look ahead to the next one. For example, if a product is expected to have a five-year lifecycle but incorporates an IT system/component that has only a two-year lifecycle, the product design team should be working to identify what will replace that system/component in the next product version.

Adding alternative options to product design means that if any IT system/component goes EOL, it may be possible to integrate that option without having to go through the entire change management process. By working with suppliers to identify replacement options, a sourcing team can stay ahead of product or system/component obsolescence, so your company remains competitive.

4. Can the change management process be outsourced to a supplier?

At most companies, in-house change managers are responsible for IT systems/component changes. Having a plan in place is especially important in the design and development of complex products such as medical devices, and the plan should be shared by company leadership and the internal change management team.

However, outsourcing certain aspects of your product lifecycle management and the change management process to your supplier can help free up time and resources to focus on developing new products and bringing them to market. Some suppliers can help mitigate supply chain disruptions during the process.

Medical device manufacturers that wait until end-of-life issues occur before creating a plan always risk delays in getting product to market, meeting demand, and maintaining their brand reputation.

Finally, it's important for product designers to communicate and partner with internal supply chain/sourcing teams, as they may already have some of the change management processes in place and can facilitate closer working relationships with suppliers.

This is especially important at a time when rapid technological change requires medical device companies to continually reassess the ways in which they approach the design, commercialization, and lifecycle management of their products. For more information, review Dynamic's <u>4 Best Practices for</u> <u>Effective Product End-of-Life Management</u>.

Dynamic Technology Solutions maintains partnerships with more than 800 leading technology providers and relies on those sources for product End-of-Life information. Dynamic makes every effort to ensure that the EOL information presented in this publication is timely and accurate but cannot guarantee the accuracy of information obtained from any third party, or any information that has not been provided to us.

