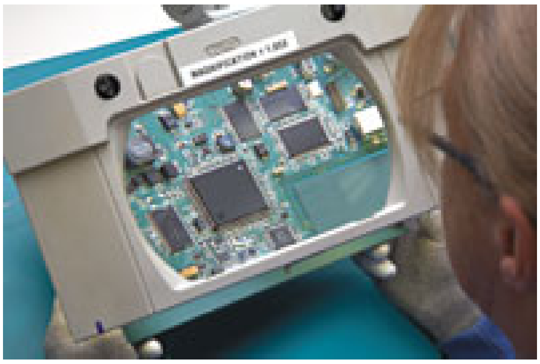
Designing for Obsolescence in Outsourced Product Development

Electronic components used in medical devices can often experience much shorter lifecycles than the products in which they are used. With the additional challenges that come from replacing a part in a finished device, it is best to be as prepared for this inevitable process as possible. This article examines methods to use in order for OEMs to be ready and also provides a case history that illustrates these processes in a real world situation.



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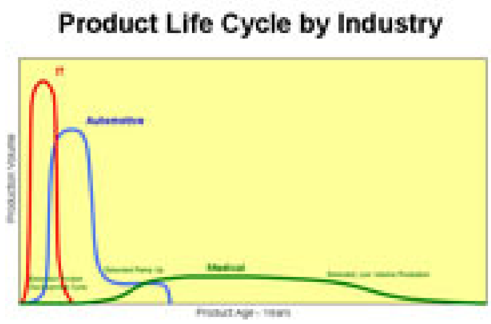


(This chart illustrates medical product lifecycles relative to automotive and IT product life cycles.)

Virtually all medical device manufacturers face the dual challenges of providing the highest quality products and continually finding ways to reduce cost. Medical instrumentation manufacturers have the additional challenge of often supporting long product lifecycles. When product development and manufacturing are outsourced, the end result can be positive or negative, depending on the outsourced team's experience with longer lifecycle products. This article looks at the specific challenges which should be addressed in both the design and sustaining engineering phases of long lifecycle products. For the purposes of this discussion, obsolescence is defined as the unavailability of manufactured sub-components leading to production impairment.

Common Drivers of Obsolescence

Medical instrumentation can see lifecycles of up to 10 years. Most off-the-shelf component lifecycles are driven by higher volume consumer product requirements, which typically run less than three years. Typical healthcare equipment manufacturing requirements further compound the product lifecycle management (PLM) problem. Long design-to-acquisition lead times and increasing cost of validation programs contribute to longer support requirements for healthcare systems. Consequently, even a relatively short medical instrumentation lifecycle can create PLM challenges if off-the-shelf components are selected and become obsolete.

Electronic component manufacturers routinely reserve the right to make product changes without prior notice. Even if the device manufacturer does exercise due diligence and specifies commercial off-the-shelf components with technical data backup adequate for repair or re-procurement, the technical data may no longer apply by the time volume production starts. End-of-life (EOL) status has become the norm rather than the exception. The traditional premise of assuring product continuity through specification control has become outdated.

Another growing area of complexity is driven by RoHS legislation. Although medical devices are exempted from EU RoHS requirements, many component manufacturers are discontinuing leaded parts. In some cases, parts are incorrectly marked as leaded. Additionally, different regions of the world are creating different types of legislation. For instance, China doesn't exempt medical devices sold in country from its RoHS requirements.

Key Considerations in Design Cycle

In mitigating potential component obsolescence, medical device manufacturers often have the choice of either specifying and supporting custom components or managing the inventory costs associated with lifetime buys of critical components as they enter end-of-life. Although obsolescence does affect all component types, the vast majority of obsolescence cases are electronics-related (e.g., passive electronic components, microprocessors, printed circuit board assemblies). Critical subassemblies, such as displays, can also be an issue.

To the average designer, use of commercial off-the-shelf components may appear to be the most cost-effective choice as unit pricing is far less than that of a custom part. While the cost of commercial off-the-shelf components may indeed be less than the cost of equivalent but custom components, the total cost may in fact be higher when considering all sourcing, integration, testing, and support costs over the program's total lifecycle. The cost to reverse engineer, reengineer, develop a

Technical Data Package, manufacture, test and certify, and produce the required stock levels of a single obsolete printed circuit assembly can be significant. The costs to pilot build, test, and validate prototypes and first articles add to that figure.

From an electronics manufacturing services (EMS) provider selection standpoint, it can be valuable to understand how the contractor's business model addresses extended PLM requirements. In the design cycle, it can be valuable to tap the EMS provider's expertise relative to best component choices for the likely product lifecycle. As a result, it is important to select a contractor who has a robust procurement system capable of identifying component obsolescence or availability issues early. Similarly, the ability to support RoHS conversions as required may be equally valuable. Even though exemptions exist, many medical device manufacturers are teaming internal and contractor design resources for conversion efforts to ensure that product configuration control is maintained as component availability options change.

The design process plays a key role in controlling lifecycle costs. Lifecycle cost, including potential obsolescence costs, must be considered in conjunction with technical performance. This means that a design fully meeting product performance and manufacturing cost criteria isn't necessarily the best design in terms of obsolescence avoidance and lowest total cost.

The obsolescence cost mitigation tools available to the manufacturer at the onset of a new program to effectively implement the acquisition and lifecycle support concept include:

- DFSM (Design for Sustained Manufacturability) through obsolescence avoidance techniques, including single-source avoidance, design-level contingency planning, and intelligent selection and procurement of commodity components

- Commodity surveys, including component manufacturers product roadmaps, production strategies, and market data aimed at predicting affected components to set the long-term obsolescence management strategy

- Inventory management (including last-time buys and special production runs)

- Sustaining engineering (the reengineering required in response to obsolescence.)

The first two elements represent preventive measures that could be implemented to avoid or mitigate obsolescence, and will be discussed in detail. The latter points represent a more reactive approach which tend to vary by situation. The case study example illustrates typical patterns in these approaches. Achieving the right balance between the cost of prevention and the cost of remediation to minimize total cost should be the goal of obsolescence planning.

Design for Sustained Manufacturability

Front-end planning for obsolescence contingencies can yield significant benefits. The technique involves a Failure Mode and Effects Analysis (FMEA)-like process, where potential obsolescence is defined along with its likelihood, potential functional impact, and avoidance and/or remediation strategies. Design personnel must be trained to recognize good obsolescence avoidance techniques during the entire design process.

Commodity Surveys

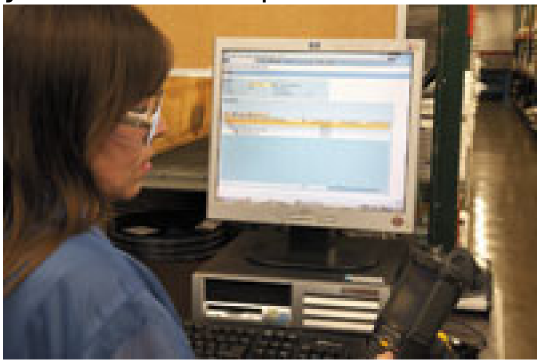
Proactive commodity surveys are key to direct the efforts of commodity managers and design engineers both in EOL replacements and planning for future upgrades. Commodity analysis helps mitigate the effects of the growing obsolescence problem for both in-service and development programs, and produces key data required in planning the technical and support aspects of using commercial off-the-shelf components. In the EMS providers, this activity is often standard practice for product development efforts.

Systematic commodity market surveys for tracking production, technology, and supportability of key vendor components should be done proactively throughout a product's lifecycle. Insight into the vendors of critical system components must be maintained in an attempt to stay abreast of the commercial off-the-shelf component's technology and supportability characteristics. Market resources in this area have increased substantially in recent years, so engineering and procurement teams do not need to spend significant amounts of time compiling this information internally. Web-based tools such as the subscription database maintained by PartMiner Inc. and support services provided through major distributors can be helpful in providing accessible and timely information during initial component selection and in subsequent PLM activities. This information should be reviewed by program, engineering, and supply chain managers on a regular basis for evaluation.

Commodity surveys should be an ongoing requirement and should focus on the critical commodity components as identified during the design phase. Key data that will help gain insight on the components lifecycle include roadmaps, production data, and markets.

Understanding the makeup of components, whether they share subassemblies with other products of the same or a different product family, is key to evaluating lifecycles. Part number structures offer an important starting point. If the component comprises significant subassemblies, they should be identified. For example, all PC assemblies in a subassembly should both be tracked. A revision to one of the assemblies may not change the overall assembly part number yet may cause significant functionality or safety changes.

Understanding where components are produced or whether they are assembled from commercially off-the-shelf available subcomponents again increases visibility into obsolescence risk. For example, display monitors manufactured in different locations under the same part numbers often will have subtle makeup differences depending on the local supply chains. Consequently, a subset of a part numbers production may become obsolete without warning.



(In a best-in-class teaming relationship, an EMS provider can mitigate obsolescence risk through a combination of market trends knowledge, shared supply base information resources, and robust internal inventory management processes.)

Finally, understanding quantities and market segments where the products are sold provides some insight. Some markets (e.g., medical, defense, aerospace, security, etc.) are often more stable than consumer markets. It may also provide clues as to how well a vendor understands and handles issues such as safety, component lifecycle stability, backwards compatibility, subcomponent obsolescence, etc.

Specifications

Besides technical and functional specifications, the detail level of specifications defines the part number stability. Other key data include serviceable life and warranty. Along the same lines, secondary or after-market sources can extend a component lifecycle if they are sold new.

In a best-in-class teaming relationship, an EMS provider can mitigate obsolescence risk through a combination of market trends knowledge, shared supply base information resources, and robust internal inventory management processes. Properly structured, this type of resource adds value through both proactive recommendations in product development and early identification and support of obsolescence issues which develop over time. When repair depot support is also part of the equation, proactive approaches which maintain some legacy inventory during the early years of a product lifecycle can ensure continued support of product as it nears end-of-life.

Obsolescence Mitigation Case Study

Even with a proactive approach to design, obsolescence can occur. This example looks at an actual sustaining engineering project and discusses both what was done in the actual approach, along with potential options that should be considered if a more proactive approach is desired.

In this example, the end product is an intravenous ultrasound imaging system for which Kimball Electronic Group's Fremont, CA facility performs assembly of intelligent data acquisition and display subsystems.

The EMS provider's initial role in the end product lifecycle was to support the customer in redesign of the display subsystem, which included conversion of the original off-the-shelf CRT monitor to a 17 SXGA LCD display. Industrial design (aesthetic blending with the end product), electrical and mechanical compatibility with the original monitor, and best-in-class image quality were the key project requirements.

This resulted in a compatible LCD monitor in a cast aluminum housing with a unique tilt/swivel mechanism. This solution also provided the customer with extended lifecycle for the end product and design control of the display subsystem.

When the graphics interface board became unavailable a few years later, the contractor's engineering team identified the boards' OEM offshore manufacturer and secured the limited number of the boards remaining directly from the factory to keep customer production deliveries on schedule. While the offshore boards were being depleted, the engineering team designed and qualified a custom replacement featuring improved image quality and in-house hardware/firmware control, thus minimizing the impact of future LCD panel obsolescence. The team also assumed responsibility for agency re-certifications, minimizing the involvement of the customer's engineering staff who was engaged in next generation product development. Migrating to a custom, domestic board design minimized costs and provided a reliable, long-term component supply line for the life of the customer's end product.

The facility continues to supply the customer's final assembly operation with three-piece subassembly kits on demand. Although the associated computer assemblies were originally build-to-print, the contractor's engineering team now assumes the sustaining engineering role to address proactively periodic component end-of-life situations with critical supply line management and engineering support. This includes identifying possible replacement components, qualifying supplier sources, qualifying component performance and compatibility, securing inventory, and managing engineering change processes both internally and with the customer.

The integrated lifecycle planning carried out as part of a next generation project has yielded a vastly more obsolescence-robust display system. By design, the unit has a high probability of four years built-in life. The status of the components that could potentially prematurely bring about obsolescence have been placed on a monitoring list. The system's optimized custom design content has met its expectations and withstood the test of time and obsolescence at a fraction of the costs incurred in the aforementioned example despite a more volatile LCD and semiconductor marketplace, RoHS-induced part shortages, and a more sophisticated design basis.

Conclusion

Focusing on proactive obsolescence planning during the design process can significantly lower PLM-related costs, contribute to improved product quality over time and ensure that supply meets demand even in extended lifecycles. Strong teaming relationships with supply chain partners help broaden the pool of resources and available options, and may help to offset hidden costs which develop over time.

References

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