

The Challenge: Avoid Costly Production Delays and Re-Certification Costs

Medical Device - Blood Analyzers

The Client

The Client is a leader in a niche market in the medical industry. This market leader sells a quality, complete blood analyzer product throughout the world.

The company is dedicated to advancements within their market and has a vigorous R&D program. They hold hundreds of patents and continue to make breakthroughs in this field.

This industry leader continues to follow the trends of new technology, incorporating new technology to make their solutions more efficient. They offer a variety of systems to meet their Client's exact needs and requirements.

The Business Problem

Certifying a medical device is costly. Changes in components can affect performance and result in injury or liability for this medical device.

So what happens when a component goes end-of-life and you're not given any advance notification?

Prior to working with ConRes, this company experienced a sudden, unexpected component change. The results were felt throughout the entire company. It caused stockouts. It delayed production and shipping of their bread-and-butter product line by 2 months! It required expensive re-certifications (at \$15,000 each). Even worse, they lost 2 months of revenue.

Every component has a unique life span. Even a minor change to a critical component can mean hours of engineering work or thousands of dollars in re-certification fees.

Potentially disruptive factors must be anticipated, planned for and mitigated to avoid serious repercussions. These factors include component end of life, constrained stock, changes to BIOS on hard drives or motherboards (without a change to the part #), among others.

The Client needed to lock down most components for this particular project – this not only ensures stable performance but avoids recertification delays or costs.

Client Requirements

- ▶ Certified solution for multi-year project
- ▶ Reduced-cost components
- ▶ Locked down, stable platform without changes
- ▶ Rigid processes to ensure changes are not made without notification
- ▶ End of Life notification in time for last time buy option
- ▶ Custom Inventory plan including Inventory stocking and management

The Solution

There are two basic philosophies when approaching the end-of-life issue: Incur the additional expense of using expensive, embedded long life components or effectively manage lower cost, commodity components.

As there was no leeway in the Client's price point, their only option was to choose commodity components. It was decided that an Intel motherboard provided the best combination of features, lifecycle and price. Each component on the bill of materials (down to the cables) was reviewed with the Client to determine the level of flexibility and then optimum inventory levels established. In addition, all documentation was updated to reflect the Client's requirements.

In conformance to its ISO 9001:2008 quality procedures, ConRes uses a Revision Control Sheet (RCS) which lists the critical components on each project and is included with the build instructions. In this Client's case, the firmware level of the hard drive is locked, noted on the RCS and confirmed by production on every system built.

Due to the high sensitivity of components in this case, it was necessary to purchase components in advance to ensure availability through the entire project lifecycle. The ConRes Project Manager secured the inventory necessary to supply the Client's full anticipated project life. In addition, ConRes provides the Client with a regular inventory update which helps monitor the progress of the projects and protects against unwanted surprises.

The result is a configuration that remains stable unless changes are requested by the client.

Benefits

- ▶ Assistance with navigating the certification process.
- ▶ Consistent product throughout the life of the project.
- ▶ Procedures that confirm the stability of the product.
- ▶ Inventory management and upfront stocking to mitigate long lead times and constrained inventory situations.
- ▶ Ongoing End of Life monitoring.

Now that ConRes is tracking the critical needs of the project from beginning to end, the Client is protected from unexpected stockouts and production delays. In some cases the necessary inventory is in stock to cover the entire product production lifecycle.

The Client receives regular notifications on the progress of their projects, including finished goods, work in progress, and component inventory.

Compliance to the project requirements are tracked on an ongoing basis and needs addressed as early as possible to avoid surprises. All of these safeguards are put in place to ensure that projects run smoothly for their duration.

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