IVD Value Engineering

Richard Rubin

When an older instrument requires highly interruptive engineering demands to keep it on the market, some companies may seek engineering resources to support their legacy product line, which can be a viable and highly cost-effective solution. To better understand the feasibility and benefits of strategic partnerships, Celestica HealthTech conducted an IVD instrument refresh project to discover unknown cost reduction options, and alleviate risks within the product lifecycle. For the project, a special task force was assembled, and important findings were established.

Uncovering resources and mitigating risks to extend the value of mature products

Medical device companies are faced with a pressing dilemma between resourcing new product development and deploying their limited resources to extend the life of existing products on the market. The need to deliver innovative products to stay competitive is evident. At the same time, there are many sound business reasons to continue the manufacturing of certain mature products, for example, to meet customers' demands or to dissuade competitors from entering the market. However, few companies today can afford the resources to cater to both needs.

To compete successfully, smart firms today are pursuing a more efficient business model that can transform each stage of the product lifecycle—from design and manufacturing processes to regulatory submission, distribution and after-market service. For these firms, the "strategic partnership" model has become an attractive, viable, even necessary option to streamline operations and bring innovative new products to market more quickly and cost effectively.

By tapping into a strategic partner's manufacturing and supply chain management expertise and resources, medical device companies can focus their own knowledge on research and development, thus remaining highly competitive and responsive to evolving markets.

Many IVD (In-vitro diagnostic) firms, for example, may be facing the scenario in which an older instrument requires highly interruptive engineering demands to keep it on the market. In addition, some companies may not be able to find the necessary engineering resources to support their legacy product line, thus hastening the product's obsolescence.

In these cases and others, outsourcing the engineering and production of legacy technology can be a viable and highly cost-effective solution. What kind of value

can medical device OEMs expect in a strategic partnership?

Understanding and uncovering value through an IVD 'instrument value engineering project'
To better understand the feasibility and benefits of strategic partnerships, Celestica HealthTech [1] conducted an IVD instrument refresh project with the goal to uncover unrealized cost reduction options and to anticipate and mitigate risks within the product lifecycle. For this project, a special task force was assembled, and modeled after an internal engineering team that has been offering teardown analysis services for several years.

The 'teardown team' consisted of: system, mechanical, electrical, and reliability engineers; optics, functional test, and manufacturing technology specialists; metal, plastics, and component supply chain analysts; quality and regulatory management; and a cost engineer.

The team was assigned to analyze a fluorescence-based immunoassay instrument designed for infectious disease diagnostics by small to mid-sized clinical laboratories.

The objectives of the project included:

- Reducing overall system cost;
- Reducing instrument size and complexity;
- Improving ease of use and system reliability;
- Reducing sample processing time;
- Reducing the environmental impact of instrument production.

The teardown was organized primarily around six instrument subsystems identified: Instrument housing; Power supply; Optics bench; Fluidics; Motors; Printed circuit boards/electronics.

Analysis reveals obsolete parts, fragmented supply base, and high risks
A total of 223 parts were documented in the teardown. Analysis of the components identified a large amount—estimated at 73%—as custom, build-to-print mechanical components in the instrument's bill of materials (BOM).

A reduction of hazardous substances (RoHS) analysis reviewed the BOM for instances of components not available in RoHS compliant form. Twelve parts—or 5% of the BOM—were categorized as being at a critical high risk:

- Eight parts were obsolete non-RoHS parts with no RoHS replacements available;
- Two parts were obsolete non-RoHS parts with only obsolete or "not recommended for new design" (NRFND) replacements available;
- Two parts were currently available non-RoHS parts with no RoHS replacement available.

The analysis also found a fragmented supply base of numerous small suppliers, which added to the production cost. An end-of-life analysis of the components revealed about 10% deemed obsolete or nearing end-of-life, which may affect future delivery of the instrument to the market.

In the area of printed circuit board assemblies (PCBA), the team's analysis revealed that more than half of the boards used in the instrument incorporated older, plated-through-hole (PTH) technology. PCBAs produced by surface-mount technology (SMT) offered opportunities for improvement, using fine-pitch parts to reduce size. It was also concluded that a complete rework of most of the board designs, as well as optimizing board layout, could significantly impact overall instrument size, improve supply flexibility, and drive down cost.

In most IVD instruments, critical mechanical subassemblies exist in the optical bench and fluidics path.

In terms of the incident light path, the teardown revealed the opportunity to reduce cost and possibly improve performance by using newer lamps that produce a convergent light beam via an integral reflector. It appeared that the lamp power supply was at end-of-life, thus modification of the light source was viewed as timely. An LED light source, for example, would offer significant improvement in cost and possibly reliability. We envisioned similar opportunities to modernize valves and parts of the fluidics path in the instrument.

Project results point to substantial opportunities for improvement
In conclusion, the teardown project revealed that the instrument OEM could achieve a substantial return on investment for the immunoassay system in terms of improving system design, updating non-RoHS compliant parts, and potentially reducing size in several subassemblies. The project also shows how a strategic partner can help mitigate the risks and lower the costs in continuing the product without taking away precious resources from the OEM for pressing new product development.

By contracting a redesign project to an experienced development partner, the OEM in this case would gain fast access to expertise and resources capable of addressing a necessary redesign effort, while eliminating the dilemma of choosing among competing development priorities.

Richard Rubin *is Technical Director, Celestica HealthTech. He can reached at +1 888-899-9998 or* ContactUs@Celestica.com *[2].*

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