

Commanding the Lifecycle Disconnect

How can a medical device manufacturer keep the long, highly regulated lifecycle of their business-critical imaging or diagnostics product aligned with the fast-changing hardware and software at the product's core? Finding the right IT supplier, expert in lifecycle management, is key.

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10 Common Problems and Solutions in IT Lifecycle Management for Medical Devices


Inevitably, the manufacturer of a medical device for human digital imaging or diagnostics will face the challenge of coordinating their device's overall product lifecycle with the useful lives of the device's integrated hardware and software components.

The complete medical machine or device may go essentially unchanged for a decade or more. This is largely due to regulations. A widely used medical device's life will come to a close only after the long process of FDA approval has yielded a proven replacement.

Not so, however, for the device's integrated IT. Mere months may pass between significant upgrades in a particular technology component critical to the device's performance.

This does not need to be a problem – as long as the device maker stays on top of their IT vendors' plans for all relied-upon technology. But if taken by surprise, a genuine disaster can occur. Even if the device's effective performance takes only a temporary hit, the manufacturer will immediately see why attentive IT lifecycle management is so crucial.

This white paper describes ten common IT lifecycle management problems faced by medical device manufacturers – and it prescribes solutions. There is also a real-world case study inside. This tells how a leading U.S. medical device maker learned how to reduce IT risk and optimize IT quality through effective lifecycle management.



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PROBLEM 1: “Our current OEM **doesn’t offer the exact specs** required by our new device.”

SOLUTION: The right supplier should be able to source IT from hundreds of leading OEMs and distributors. The supplier will find the right replacement or add-on product – from the medical device manufacturer’s current provider or another one.

PROBLEM 2: “This product **spec is too granular**. We’ll be stuck with a very short IT lifecycle.”

SOLUTION: The right IT supplier can work with the medical device manufacturer to build a custom product specification. Non-critical items can be specified more generally. This allows for flexibility in future procurement.

PROBLEM 3: “We’re **locked into this OEM**. We don’t always know the other options available.”

SOLUTION: The right supplier can serve as the medical device manufacturer’s eyes and ears in the IT marketplace. Product selection can be vendor-neutral. The device maker chooses from the latest and best technology from hundreds of leading sources.

PROBLEM 4: “Can I **count on this product to be in stock**? Will they still offer it next year? It’s hard to know.”

SOLUTION: The right IT supplier will stay in everyday contact with the major hardware and software providers. They will track and share inventory and end-of-life information for all products offered for direct IT purchasing by the medical device manufacturer.

PROBLEM 5: “This piece is critical. It’s **going end of life**, and a replacement hasn’t been validated.”

SOLUTION: The right IT supplier will work with the medical device manufacturer to calculate the quantity for a last-time buy based on purchase history and forecast. In this way, the device maker maintains IT availability pending the new product’s validation.

PROBLEM 6: “Wait a minute. This new product was **substituted without notice** or validation.”

SOLUTION: The right IT supplier knows the need for consistent specifications for medical devices. The device maker should expect and insist that the IT supplier will never substitute a product – not even a small cable – without verification and/or validation.



PROBLEM 7: “We’ll ship this product globally, but it’s sourced in the U.S. Is it **OK for import?**”

SOLUTION: The right supplier should work with both the medical device manufacturer and the IT providers to ensure that any product sourced for a device’s global use will meet import requirements for each region or country.

PROBLEM 8: “An IT product’s **lifecycle is simply too short** for the longer life of our medical device.”

SOLUTION: The right supplier will know which IT products offer long-life options. For example, with the right choice of laptop computer, the typical 18-month product lifecycle can extend to 30 or even 36 months.

PROBLEM 9: “IT products from multiple OEMs demand **multi-vendor relationships**. What a mess!”

SOLUTION: The right IT supplier can be the medical device manufacturer’s single source for all needed hardware and software products. Device makers should look for their supplier’s expertise in the medical device industry. The right supplier can be more responsive and flexible than the large IT vendors.

PROBLEM 10: “Help! We’re **overstocked with IT equipment**, and we’re afraid it will go obsolete.”

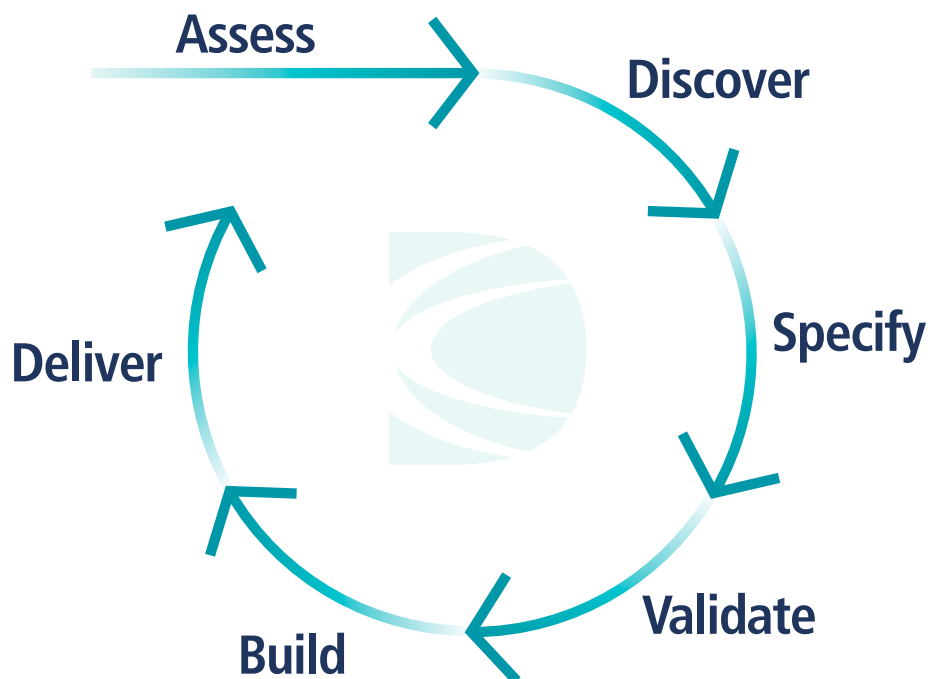
SOLUTION: The right IT supplier can stock products and drop-ship them directly to your customers. This minimizes on-hand inventory. New products can be cut in when validated. The effect can be just-in-time inventory management.

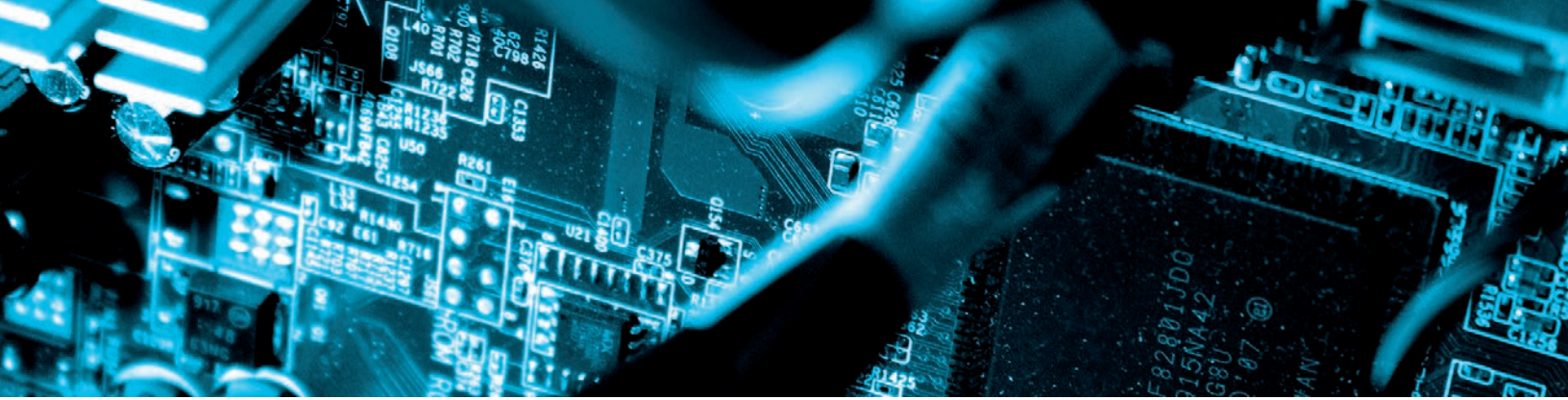


End-to-End IT Lifecycle Management for Medical Devices

The lifecycle disconnect makes it hard for the medical device manufacturer to keep a product's support in sync with its integrated IT. But the right IT supplier can help.

The supplier will track and share inventory and end-of-life information for all IT products offered for direct purchasing. They will know which products offer long-life options. And they will help the device maker make strategic last-time buys to ensure IT availability when a key hardware or software product comes up for replacement.





CASE STUDY

“Communications Are Key”

How a Leading Medical Device Manufacturer Has Reduced Risk and Optimized Quality by Entrusting IT Lifecycle Management to a Specialized Supplier

Need proof of the value of effective IT lifecycle management for medical devices? Consider this recent real-world example. It is the story of how a leading U.S. medical device manufacturer had to swiftly scramble when the life spans of one of their most important products and its integrated IT were suddenly thrown out of sync.

No Easy Way Out

The problem occurred in 2012. The device manufacturer learned, without advance warning from their IT supplier at the time, that the power supply driving one of their flagship products for pathology labs was soon to reach its end of life. Worse, the replacement power supply, as it turned out, was incompatible with the overall device.

The device maker had no easy way out of this hole. They special-ordered renewed production of the discontinued power supply from the OEM in China. But three months passed before they could get their hands back onto the needed component. In the meantime, the device manufacturer was unable to ship their market-leading product.

Consequences were severe: lost sales and disappointed customers. Even if the harm to the device maker's reputation was only temporary, it hurt more than enough.

Since then, the device company has shifted the supply of their integrated IT for this prime product platform to Dynamic Computer Corporation, the Farmington Hills, Michigan-based IT solutions provider. Dynamic specializes in end-to-end IT lifecycle management for medical device manufacturers. From project management through process automation, Dynamic works tightly with device makers to be sure that their products' critical hardware and software components keep working right for life.



Ensuring IT Availability

Looking ahead to ensure IT product availability, and keeping customers informed of changes to IT product lines, are standard operating procedures at Dynamic. For the particular device manufacturer and product platform profiled here, Dynamic continues to order custom builds of the original power supply – always with at least a 20-week lead time – to ensure consistent availability.

In other ways, Dynamic's approach to IT lifecycle management is even more proactive. Now, for all product platforms, the device maker gets ample warning when an essential piece of IT is to go EOL. Dynamic then coordinates with the customer to place a strategic last-time buy. Meanwhile, replacement products are thoroughly tested and validated for compatibility.

"Communications are key," says Farida Ali, Dynamic's president and CEO. "A medical device manufacturer must trust that their primary suppliers are giving them plenty of time to react to changes in features, functions, and availability. Being the device maker's eyes and ears in the technology marketplace – that's the hallmark of a quality IT supplier."

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About the Author



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Farida Ali has led Dynamic's growth and success since 1994. She oversees the company's day-to-day operations, manages key customer relationships, and provides guidance and counsel to Dynamic's leadership team. Ms. Ali holds a Bachelor of Arts degree in Political Science from the University of Michigan. She also earned a Juris Doctor degree and is a member of the State Bar of Michigan.

About Dynamic Computer Corporation

- A quality IT solutions provider since 1979
- Services include custom software imaging, testing, validating, cross-platform hardware integration, virtualization, cloud computing, and IT lifecycle management
- On-time, on-spec, on-budget delivery
- High customer satisfaction has produced 98% repeat business
- Two locations: Michigan (HQ) and Arizona
- ISO 9001:2008 and ISO 13485:2003 certified



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