



Selecting Computer Systems Integrators for Medical Device Manufacturing Success

The makers of medical devices, ranging from ultrasound machines to diagnostic laboratory equipment, are experts in their technological specialties. However, many of those manufacturers are not, and do not wish to become experts in PC selection, qualification, support and integration.

Instead, many medical device manufacturers (MDMs) seek out reliable partners who can provide, configure, certify and ensure continuing availability of computing systems, so they can focus their own resources on optimizing the capabilities of their tests and modalities. These companies act as the MDM's system integration partner in obtaining, customizing and documenting computing systems. They give device manufactures the cachet of a leading computer manufacturer's nameplate on the system, combined with the upgrades and modifications necessary to satisfy compliance requirements.

Selecting a partner can be daunting though. Because regulators consider the computer to be a part of the larger device, it is subject to certification requirements. It must also remain available and supported for the lifetime of the device, and it must be supportable – meaning that warranty or contract service and repair must be available reasonably close to anywhere the device might be deployed.

Through more than 18 years of experience in supplying computers to the medical device manufacturing industry, Momentum Microsystems, Inc. (Momentum) has discovered that most MDMs follow a strategy that considers three aspects of their product's lifecycle:

- 1. Development Phase:** identifying processing requirements, determining costs, and ensuring quality
- 2. Manufacturing Lifetime:** assurance of continuing availability and planning for end-of-life
- 3. Deployment Support and Service :** reliable long-term service relationships and rapid problem resolution

The balance of this white paper examines each area in greater detail.

1. Development Phase

During development, the first consideration is identifying the computing technology necessary for the medical device. In most cases, MDMs seek the "latest and greatest" technology as a means of ensuring the longest lifetime before obsolescence.

Most MDMs also need customization options to ensure compliance with medical device regulations, but don't command sufficient volume to obtain affordable customization support from the largest computer makers. These customizations can range from replacing components that contain mercury, to ensuring that parts as simple as power cords meet proper certifications.

Fortunately, companies exist that specialize in bridging MDMs and OEMs. These companies act as the MDM's system integration partner in obtaining, customizing, validating and documenting computing systems, and they provide assurance that these systems will continue to support their applications throughout an extended product lifetime.

Quality considerations go hand-in-hand with technology issues. Just as MDMs strive for top ISO certifications, they prefer partners with similar processes in place. Certifications such as ISO 13485 and others can facilitate device certification in the United States and Europe, while others can yield unexpected benefits. For example, CCFP certification by the US Transportation Security Administration enables manufacturers to reduce shipping costs by as much as \$1 per pound and reduce pre-flight screening requirements so shipments avoid unnecessary delays.

MDMs also seek insulation from unpleasant surprises such as computing system price increases. Most look to their computing solution partners to establish guaranteed maximum prices, and then pass along savings as prices fall during the base computer's lifecycle. Doing so enables the MDM to increase its profit margins over the lifetime of their device model.

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2. Manufacturing Lifetime

Once the computer system is selected, MDMs prefer to use it as long as they build the device, without revisiting their selection. As the migration from PCI to PCI Express has shown, some computing system changes can defeat that expectation, so MDMs seek OEMs that offer configuration guarantees ensuring any computing product changes will comply with existing certifications. Many also seek computing system partners who possess visibility into the computer manufacturers' engineering pipeline, advise MDMs about upcoming changes, and safeguard them against lifecycle and end-of-life disruptions.

As one example, Momentum utilizes a formal, documented process for obtaining end-of-life, Engineering Change Notifications and Product Change Notifications from suppliers and communicating them to customers. Momentum's relationships with leading computer vendors can also provide access to parts that other system integrators cannot obtain. Momentum also maintains a comprehensive record of equipment in the field, allowing our engineers to trace which systems will be impacted by configuration changes or parts replacements.

When parts availability changes, personnel from support through senior management are able to work with part suppliers to allocate additional inventory, and even delay the end-of-life until sufficient quantities can be provided. When a last time buy (LTB) is needed, Momentum facilitates procuring this material on behalf of the customer and guides the customer through the needed steps for insuring there is enough of a particular component to bridge the design cycle for the next generation of component or system.

3. Deployment Support and Service

In the medical device industry, quick and reliable field support is essential to ensuring continuous, accurate and reliable operation of life-critical equipment, promoting customer satisfaction and maximizing return on customer investment. MDMs and OEMs seek out computer system partners with a proven record of quality manufacturing and a global service infrastructure.

Reliability begins in the manufacturing process, both through selecting parts and utilizing manufacturing processes that maximize mean time between failure, and in front-to-back order processing and manufacturing administration that includes multiple quality checks and redundancies that help ensure the right product reaches the right customer at the right time. It continues through testing by "burning in" components and systems to accurately predict mean time between failures and replacing those that perform inadequately.

Sustainability means supporting MDM products for their entire lifecycle, with ample parts for manufacturing demand and spare parts stocked near the customer for seven years or longer. Computer system integrators frequently achieve this by partnering with global manufacturers such as HP to leverage their logistical capabilities. This includes stocking spare parts at strategic facilities around the world, and ensuring partner support and service personnel are trained and equipped to maintain their equipment.

Companies such as Momentum take logistics one step further, by also purchasing, stocking and configuring all the parts in the customer's original bill of materials, and shipping them to customers worldwide. Momentum also maintains a library of system images deployed in each product family, allowing the company to replace hardware in the field with exact duplicates of their original systems.

Continuing support can also be as subtle, but important, as ensuring the computer system is registered in the OEM's warranty database. This helps avoid any last minute confusion when end users need a service call.

Partnerships for Success

Leading MDMs have long understood that partnering with a reliable systems integrator results in faster product development, greater product quality and lifetime product support. A trusted partner enables MDMs to focus on maximizing the value of their core technology without the distraction of dealing with computer OEMs and supporting customized PCs and workstations.

For the best assurance of success, MDMs must ensure potential computer system partners utilize quality processes and maintain comprehensive relationships with OEMs that protect MDMs from disruptions due to product changes or end-of-life, as well as ensure fast access to services for device customers, wherever those devices are deployed and for the lifetime of the device.