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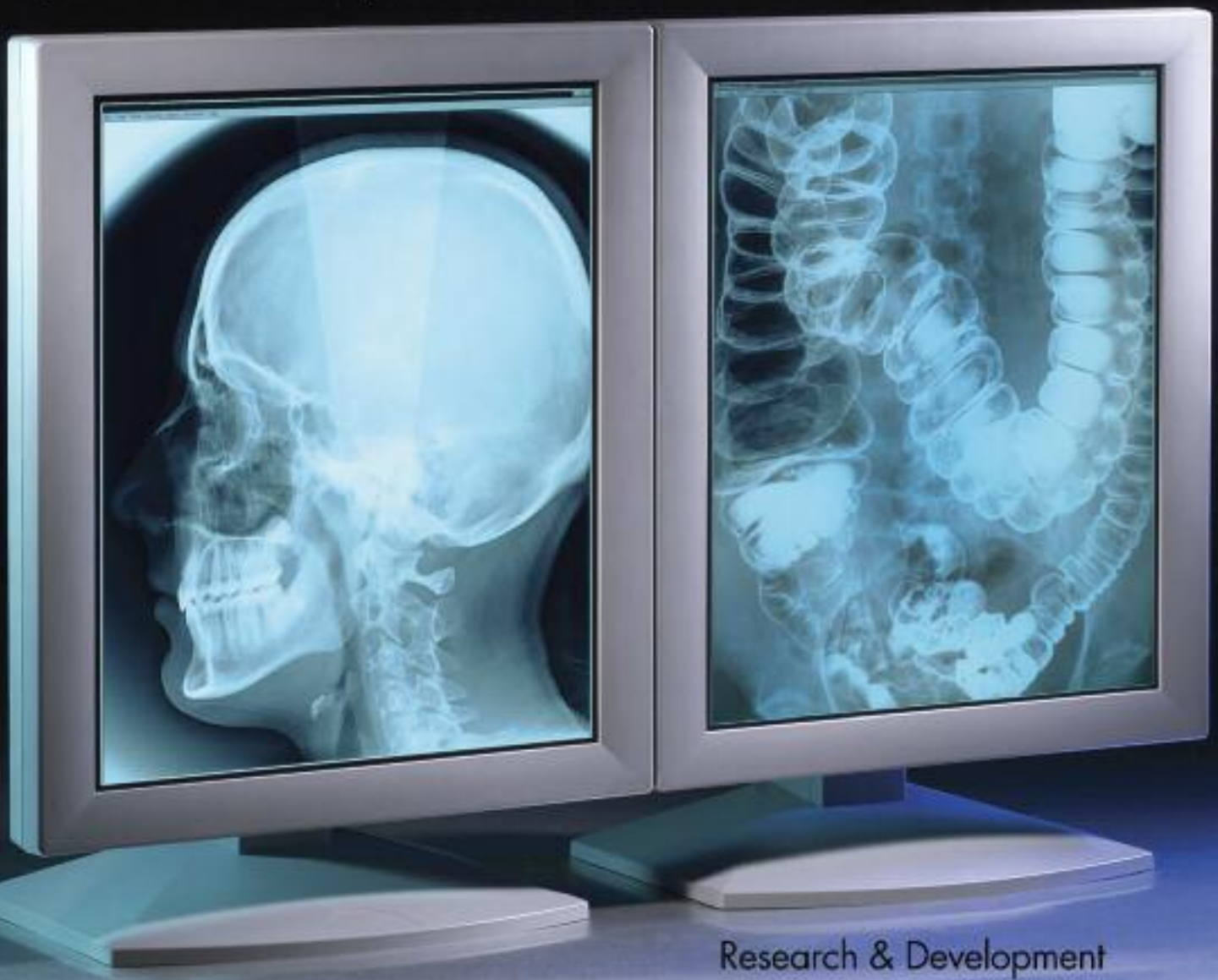
# MPO

MEDICAL PRODUCT OUTSOURCING

## A Strategic Charge

Device firms continue to screen EMS partners for additional capabilities and services, but at lower costs.



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# Outsourcing Efficiencies

## Beyond Inventory Adequacy

Accurate counts and proper parts handling are key elements of an effective inventory control program.

Cesar Morales and Rick Boyd

Effective management of inventory is an integral element of efficient manufacturing. Accurate counts, real-time transaction tracking, and proper parts handling are among the key inventory practices medical device manufacturers follow. Manufacturers performing accurate cycle counts on a regular basis can compress time spent on physical audits. Many medical device manufacturers consider this practice a cornerstone in effective inventory management, ultimately playing a role in the manufacture of safe and reliable products.

Inventory management can affect manufacturing efficiency in several ways, both good and bad. Poor inventory control quickly can shut down an assembly line and impact profitability. Therefore, it is imperative that parts are handled, stored and tracked through the production process in order to maintain consistency, improve efficiency and keep the line moving at all times.

Accuracy is one of the most important aspects of effective inventory management. Device manufacturers must maintain accurate counts at all times. Thorough and effective systems for tracking and counting parts not only save time and money, they ensure efficient production. Without accurate counts, companies spend more money than necessary for inventory, ultimately leading to cost increases and lower profits. Implementing a process that incorporates daily cycle counts avoids surprises, keeps inventory low, and assures a smooth-running assembly line.

In addition, the mishandling of parts, particularly electrical components, quickly can affect an assembly line and ultimately the safety and reliability of a product. Mishandled parts placed in inventory and then used in assembly increase failure rates in the field. To eliminate this problem, device manufacturers immediately should identify defects in components and then isolate them in a separate area or Materials Review Board room so that all parts in the stockroom are 100 percent defect-free. In addition, proper storage of components and parts in a clean, dry, electrostatic discharge-free area ensures that they stay damage-free before reaching the assembly line.

Because of regulatory requirements, medical device manufacturers need to ensure that traceability extends to inventory control. Traceability is one of six important practices for effective inventory management. As a medical device manufacturer or supplier, it is critical to:

- Implement quality systems that allow for traceability that is specific to the medical technology industry;
- Monitor vendors actively to make sure that their policies and procedures support the manufacturing process. This is part of a good internal quality system;
- Dedicate man-hours to consistent cycle counts;
- Use tools to facilitate inventory management. As an example, consider using special scales to weigh very small parts. This practice improves overall accuracy and speeds the process;
- Maintain all inventory in a clean, well-lit, temperature-controlled environment; and
- Store super-precision parts in a climate-controlled environment. This helps to maintain the tolerances required in the assembly of metal-machined parts.

For example, regarding cycle counts and man-hours, we were able to reduce our company's annual inventory schedule from one week to one-and-a-half days by having a dedicated employee conducting daily cycle counts. This process involves a five-week cycle during which the employee counts a part of the entire inventory each day. At the end of five weeks, the process begins again. Currently, this technique ensures a variance of less than 0.1 percent. Far more important than the 70 percent reduction in time taken to complete annual physical inventory counts is the operating efficiency that occurs all year long from having 99.9 percent inventory accuracy.

Elaborating further on the storage environment, it is important to note that our stockroom was built with lowered ceilings in order to minimize dust particles. The airflow

in the building also cuts down on dust and dirt. The building's design ensures that the area remains clean and free of clutter at all times. Bins are used to store parts, and very small parts are packaged in units, weighed, and counted.

To help illustrate the process, here is the path a typical part may take as it makes its way through the manufacturing process—from initial order through assembly and shipping:

1. Order received.
2. Order loaded into the enterprise resources planning system.
3. Materials requirement planning system triggered.
4. Purchasing/planning employees order and pull parts from inventory.
5. Scheduling occurs by software program.
6. Product is manufactured.
7. Product is shipped.

In order to be effective, all levels of the organization should be aligned on proper inventory management. The executive team should embrace and understand the integral role that inventory plays in manufacturing reliable and safe medical devices. It is recommended that associates collaborate in a disciplined approach that is tied to the understanding of the importance of controlling and managing the company's parts supply. A new system of increased time spent on cycle counts will result in inventory counts that take days versus weeks to reconcile. At Pro-Dex, for example, the resulting degree of accuracy in the cycle count process has made physical inventory audits optional. A made-to-order process is offered in order to ensure flexibility and to meet customers' immediate needs. This preferred method allows the company to keep limited inventory on hand in order to retain the flexibility needed to meet customer requirements.

Of course, a good inventory manager is an equally essential component to any effective inventory control program. The responsibilities of the employee in this position include: Proper parts handling; completing work orders to ensure traceability; following all guidelines and processes in the manufacturer's quality system; following first-in, first-out procedures; placing transactions into the system in real-time as parts are pulled; and cross-training all team members to follow all procedures and familiarize themselves with all inventory management roles. Any engineering change orders need to be processed immediately in order to keep the assembly process moving.

Efficient manufacturing relies on a well-managed stockroom. Taking care of the "nuts and bolts" of manufacturing through accurate counts, proper parts handling, real-time tracking, and similar essential practices will ultimately ensure that the devices leaving the shipping dock are safe and reliable. ❖

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