



MEDICAL PRODUCT OUTSOURCING

### *Custom Motors for Harsh Environments*

Pro-Dex Carson City produces reliable, custom, fractional-horsepower motors for customer's products that operate in harsh or challenging environments in medical and aerospace applications.

Our unsurpassed technical support and customer service assists each customer with solutions for their unique requirements.

Pro-Dex Custom Motors

2950 Arrowhead Dr., Carson City, NV 89706-0488

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### *Medical Device Manufacturing Services*

Pro-Dex's ISO 13485-certified facility gets electro-mechanical devices planned, built and on the shelf quickly with outsourcing excellence.

Customers rely on our proven RA/QA expertise, streamlined documentation and release processes, and lean manufacturing to get their products to market.

Our precision machining capability and high-mix manufacturing flexibility can produce your components to full systems, and everything in between. Our trusted team ensures high quality, reliable and regulatory compliant products delivered on time.

### *Powered Surgical Devices*

Pro-Dex's unique and specialized experience in designing and delivering reliable, powered surgical devices that withstand harsh environments, enables our customers to provide complete medical device systems.

Pro-Dex is your resource for manufacturing capacity overloads, powered surgical device expertise, and for compressing your time to market, enabling your focus to remain on your core business.

Corporate Headquarters: Powered Surgical Devices and

Medical Device Manufacturing Services

2361 McGaw Avenue, Irvine, CA 92614 USA

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### *High Performance Multi-Axis Motion Control*

Pro-Dex OMS provides rock-solid multi-axis motion control with the right combination of standard and customer specified features for general motion application as well as critical applications where failure is not an option. Our customers' count on us when their success depends upon consistent, reliable performance in demanding applications such as Lab Automation, Medical Equipment, Semiconductor Equipment and specialized needs in Research Facilities around the world.

Pro-Dex OMS

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## The Automation Equation

Assembly and automation continue to play a key role in cost reduction and process improvement.

## The Legacy of Lean

Doing more with less is no longer limited to the manufacturing process.

Minimizing Early Stage Risk

Recall Management

Protecting Your IP

## Synergy and Manufacturing Efficiencies: Little Things Make Big Things Happen (or 1 + 1 = 3)

To be competitive in medical device manufacturing, a company needs to run an efficient operation. Many companies talk about a core competency or a new process or technology developed that differentiates them from their competition.



Vic McBenttes, Rick Van Kirk, & Rick Boyd of Pro-Dex Manufacturing

However, as John Wooden (famed Basketball Hall of Fame-inducted coach of the University of California, Los Angeles) said, "It's the little details that are vital. Little things make big things happen."

Manufacturing success is not based on a single factor, such as a unique process or piece of equipment, but rather on performing many good practices well and supporting these practices with a tight culture of teamwork and experience. A combination of collaboration and good practices help companies improve efficiencies in their operations and accelerate performance for their customers. Here are some of the details manufacturing

companies can focus on to realize long-term success.

### Good Manufacturing Flow Starts With the Layout

Although it takes more work up front, it is worth the investment to take a close look at your manufacturing footprint and organize it in a way that reflects your business processes. It is important to foster collaboration in the manufacturing and office settings. For example, it can be highly effective to link series of cubicles in accordance with business process flows. This approach fosters easy communication with typical internal customers and leads to quick resolution of issues. Cubicle walls are tall for privacy but can feature clear windows to promote a sense of connection. Dry-erase white boards in a workspace offer help with scheduling and the sharing of ideas.

A manufacturing area should be laid out to provide a smooth flow of material from the receiving department through the time product ultimately leaves the dock in shipping. Equipment should be situated so associates can work near their teammates and collaborate when necessary. A clear line of sight from one end of the shop to the other fosters communication and a sense of teamwork.

### Include All Teams Early in the Process

But having a well-laid-out facility does not always translate to success. It's important also to create a culture that seamlessly can transition from engineering to manufacturing on new or modified products. When manufacturing is involved early in the design review process, the department can alert the engineers to any future issues and suggest improvements for ultimate manufacturability. Including cross-functional teams from regulatory affairs and quality assurance (RA/QA) to planning in initial meetings allows for op-

timized decisions and builds teamwork. Proof of concepts and prototypes then can be built with confidence that all issues have been addressed early in the development cycle.

One solution for developing a rapid transfer from engineering to production is the development of a "bridge cell." The concept is to "bridge" the transition from a prototype or engineering build to a production build. A bridge cell should be staffed with senior operators and set-up people skilled in medical device machining. It is used to build 15 to 50 validation units and offers a chance to develop programs, tooling and fixturing for a job prior to it being handed over to full production. By the time the initial builds are complete, the job is ready for production.

For long-term success, it is important that an organization remain open to new ways of doing things. Extensive cross training also is a sound practice contributing to flexibility. Training multiple associates to handle several tasks allows a manufacturing organization the luxury of extending its resources and multiple options to move quickly on critical jobs.

If your manufacturing organization also includes assembly, setting up a lean, one-piece flow process is especially important. Creating "cells" for complete assembly and cross-training associates to assemble a variety of products means greater dexterity in the long term.

Similarly, developing dedicated tooling and flexible work holding allows companies to run the same job on multiple machines at reduced setup times. The combination of versatile human and equipment resources provides several permutations of potential solutions when expediting work through a facility. It also helps if an organization has a seasoned, experienced team. Creating an environment that fosters mentoring and training and allows for a career path helps retain important resources and guarantees that there are not too many manufacturing challenges a team encounters that have not been seen before.

### Provide Tools for Success

As is the case with many global manufac-

turing operations, associates may be employed outside the United States or if in the United States, English may not be their primary language. In this case, it always is more effective to provide detailed visual aids in addition to written instruction for the assembly and manufacture of the medical devices you produce.

In addition, providing a climate-controlled work area ensures the same temperature in all areas of the building and helps to build a "one for all, and all for one" culture. The result is that associates working in the stock room enjoy the same temperature as the executive team and are able to perform at a higher level.

### Implement a Reliable ERP System

Sourcing and implementing a reliable enterprise resource planning (ERP) system is vital and allows an organization to baseline each process and qualify each improvement made to the production process. In addition to procurement and job order management, detailed bar coded tracking of all jobs and a robust cycle count program ensure no surprise shortages.

### Create a Culture Based on Collaboration

A culture of powerful teamwork and collaboration will serve to enhance these practices. Many companies claim they have good teamwork, and many do, but there must be an unyielding commitment from the top down in order for open, direct and collaborative communication to get the results needed. The contributions of everyone working together will then exceed the sum of its parts.

Creating a culture such as this does not happen by accident. It requires a management team that is committed to a foundation of trust and empowerment. This environment instills confidence in associates, encourages them to speak freely, and fosters the generation of new ideas and quick resolution of issues.

Recruiting like-minded associates and providing training for everyone in productive interaction skills helps strengthen the culture even more.

### Little Details Add Up to Collective Success

So how do all these small details translate to collective success? As with most challenging endeavors, it's the collective effort that yields the greatest progress.

To recap, important tips include:

1. Reviewing the flow of your operation to ensure maximum throughput. Consider workspaces, aligning teams, temperature control for creating the best environment for success.
2. Include all teams early in the process. Make sure to alert teams such as marketing, sales, RA/QA, planning, engineering, manufacturing, assembly, and shipping of any new projects to identify issues or challenges early on.
3. Provide the tools for the team's success. Visual aides, cross training, communication and team building all are good long-term investments.
4. Implement a reliable ERP system.
5. Create and cultivate a culture based on collaboration. Gathering input from all levels of an organization can lead to a more flexible and open environment and speed up your processes.

A disciplined, daily focus on good practices, in concert with a culture of collaboration, allows for continual improvement of operations and continues to meet the increasingly stringent requirements of the medical device industry. Applying a razor-like focus to the small details in manufacturing excellence will prepare an organization for the increasingly stringent requirements they face in medical device manufacturing. The added benefit it will create is a better work environment for its associates. Balancing solid work practices and improving communication may not appear to be cutting edge, but as Coach Wooden reminded us, "Little things make big things happen." ♦

*Rick Van Kirk is vice president of operations; Vic McBenttes is manager of manufacturing; and Rick Boyd is manager of planning for Pro-Dex, Inc. Pro-Dex designs, develops, and manufactures powered medical devices for some of the world's leading medical device OEMs.*