

TEN (10) REASONS TO WORK WITH AMERICAN ENGINEERING GROUP (AEG) ON DEVELOPMENT AND MANUFACTURING ON MEDICAL DEVICES

SHOULD I OUTSOURCE DEVELOPMENT TO AEG?

How can device manufacturers determine whether their product development and manufacturing processes will benefit from outsourced engineering? If any of the following statements are true, outsourcing product development and manufacturing may be the solution.

- ◆ Internal resources are stretched thin
- ◆ Medical device development projects often run over budget
- ◆ Product launches are often delayed, costing the company lost sales and additional expenses
- ◆ The company has not released a market-dominating product in several years
- ◆ The company's engineering staff's expertise is concentrated in a few core competencies
- ◆ The R&D department has several new ideas, but it cannot develop cost-effective manufacturing
- ◆ processes to produce these concepts
- ◆ It is difficult to keep up with the competition in terms of new product development

There are many factors that must be considered to determine whether outsourcing product development and manufacturing is a strategic fit for a company. Here are 10 key benefits that medical device manufacturers may be able to realize by contracting product development and manufacturing with AEG.

1. LEVERAGE MULTIDISCIPLINARY EXPERTISE

Two heads are better than one, as the adage goes. This is particularly true for product development and manufacturing. Truly innovative products rely on multiple concepts and theories for differentiation and leadership in the market. A design team made up of customer and AEG engineers with industry- spanning expertise can apply the best possible technology to the product concept. Design for manufacturability is a key area that AEG can make a significant contribution due to our many capabilities and experienced medical products engineers.

2. EXPAND INTERNAL ENGINEERING CAPABILITIES

Some projects require rapid staffing scale-ups for short-term assignments, and not all OEMs are equipped to do so. Hiring full-time employees is not always economical, and adding temporary help is time-consuming and can present confidentiality risks. Outsourcing to AEG allows OEMs to leverage AEG full-time staff to device development projects quickly and cost-effectively. Then, the proper amount of the targeted customer

and AEG expertise can be applied at the right time. Companies can therefore avoid paying for excess labor and engineering costs.

3. CAPITALIZE ON STATE-OF-THE-ART TECHNOLOGY

AEG experience and ability to be knowledgeable about state-of-the-art manufacturing techniques and equipment can play a significant role in medical product development. Application of this knowledge, especially in the area of micro-machining, precision machining, laser processing and assembly, is critical in today's market as all implantable products become more complex and miniature.

4. MANAGE PROJECT TIMELINE

Many design projects fall victim to unmanaged timelines. With internal engineering and management resources stretched thin, it is often difficult for OEMs to fully commit resources to product development projects. Outsourcing partnerships can offer an advantage because AEG assumes project time management responsibilities. It is a good idea for both parties to agree on a program timeline up front and schedule periodic meetings for status updates. A contract with established deadlines and deliverables for each party helps to keep projects on schedule.

5. CONTROL PROJECT COSTS

Similar to providing project timeline management, AEG can help device OEMs keep product development costs within budgeted goals. At contract signing, the project budget should be set and resources allocated, with written approval required at milestones and for any changes. Reports should be developed and delivered on an agreed – upon periodic basis to keep all parties abreast of current expenditures versus budgeted amounts and how well milestones are being met.

Compared with internal product development, during which it can be difficult to account for time and resources, outsourcing relationships set costs for each project stage. In this way, OEMs can clearly identify the areas in which resources are invested and prevent costs from spiraling out of control.

Outsourcing product development can have a positive effect on the bottom line, even if budget control is not an issue. Device manufacturers can often reduce project costs by working with AEG because we rely on innovation and years of medical experience to optimize designs and manufacturability.

6. REDUCE TIME TO MARKET

AEG can speed time to market. We can provide end-to-end solutions, providing input and solutions from product development through manufacturing. Having one point of contact for all aspects of a project lends efficiency to it. Additionally, AEG can apply knowledge from our wide range of experiences and technologies thereby enhancing productivity. We are aggressive at overcoming technical obstacles that can delay product introductions.

7. MAINTAIN CONFIDENTIALITY

One of the major misconceptions about outsourcing product development and manufacturing is that it compromises corporate trade secrets. However, confidentiality can be protected through nondisclosure agreements. AEG non-disclosure procedure protects the confidentiality of all related information.

8. CREATE A PROPRIETARY MARKET POSITION

To gain market ownership, a medical device must provide an innovative solution to an unsatisfied need. Complete and lengthy market ownership also depends on a company's products being difficult to replicate. AEG can assist in developing innovative products because we bring novel ideas and wide- ranging expertise to the table.

9. PROTECT INTELLECTUAL PROPERTY RIGHTS

Device manufacturers can outsource upstream product development functions without compromising IP. AEG agrees to assign IP rights after the program's completion. This means that AEG either cooperates in preparing patent applications or maintains the IP as a customer owned trade secret.

10. KEEP UP WITH THE COMPETITION

Device manufacturers are increasingly allocating funds to outsource product development and manufacturing functions. This trend is supported by the growing budget percentages allocated to R&D. For example, in 2008 the medical industry spent 11.4% of its sales on R&D, higher than any industry except for pharmaceuticals and in 2007 medical companies increased the R&D portion of their budgets by an average of 8%. Whether their strategy is to maintain or gain market leadership, an increasing number of medical device companies are recognizing that outsourcing product development and manufacturing is a critical strategic tool. Companies that expect to compete in the device market may find that they have to outsource.