

10 Tips for Product Development for Applications that Include Flex Circuits, Flexible Heaters, or Sensors

Chris Eisenberg, Medical Business Development Manager, Minco



Table of Contents

Abstract	Page 3
The Development Process.....	Page 3
Defining the Application	Page 3
Defining the Goals	Page 3
Defining the Team	Page 4
The 10 Tips	Page 4
1. <i>Divide your requirements into "must-haves" and "nice-to-haves"</i>	Page 4
2. <i>Challenge all assumptions</i>	Page 4
3. <i>Provide your vendor with full information on operational and storage conditions</i>	Page 5
4. <i>Design to take advantage of your vendor's core capabilities</i>	Page 5
5. <i>Make components replaceable</i>	Page 5
6. <i>Mistake-proof your assembly process</i>	Page 5
7. <i>Share your assembly process with your vendors</i>	Page 6
8. <i>Get your vendor's buy-in for your use of their product</i>	Page 6
9. <i>Know when your vendor will be discontinuing the product</i>	Page 7
10. <i>Document and share the qualification process with your vendor</i>	Page 7
Conclusion	Page 8

Abstract

In today's competitive world, the success of a product depends on its performance, reliability, speed to market, and price. In order to achieve these goals, products are, more than ever, relying on long, complex supply chains. The more complex the product, the more critical it is that all participants in the supply chain have full knowledge, not just of their own roles, but of how those fit with the overall goals as well.

Success depends on clear understanding of expectations and careful evaluation of assumptions. It requires clear understanding of the real-world conditions under which products and the components that go into them will function. And it requires that this information be shared among participants in the product development process.

The Product Development Process

Electronics and electronic components keep getting smaller, denser, and more complex. Add the fact that they have to bend, in some cases repeatedly, and they become increasingly challenging to design and manufacture. And, in order to compete in today's global markets, they must be reliable and cost effective, both to produce and to own.

Given enough time and money, it would be possible to meet all of these goals by trial and error, fixing problems as they arise. In the real world, however, there's never that much time or money. Fixing problems is always more expensive than heading them off before they occur, and delays in getting a product to market can be costly beyond measure. To overcome these challenges, designers must tap every resource available to them including a clear understanding of the growing variety of available materials, detailed knowledge of best practices, and the assistance of experienced specialists.

We offer here a 10-point checklist you can use as you move through the development process. Many, perhaps most, will not come as news to experienced designers. But, in the face of the pressures and demands of the development process, they may serve as useful reminders of things that help keep a complex process on track. They fall into three basic categories.

Defining the Application

Product development begins with an application. The product is designed to do some specific thing in a specific environment. It will be handled in a particular way, have an expected lifespan, and face particular challenges. Failure to thoroughly understand any aspect of the application will cascade through the entire development process.

Defining the Goals

Goals follow application. If, for example, a circuit passes through a hinge in the finished product and you know the expected product life, you can define a specific goal regarding the flexibility of that part of the circuit. At the same time, you must be careful not to narrow your definition prematurely. (Imagine what would have happened if the early developers of self-powered vehicles had focused on the horse rather than the cart and set out to develop a vehicle that walked instead of one that rolled.)

Defining the Team

There's nothing unusual about teams doing design and engineering. But in today's specialized, often-out-sourced world, it is important to understand that the outside vendors you work with can, and should, be as much a part of your team as anyone within your organization. No quarterback would call a play and withhold information from some of the players, yet organizations often limit the release of information to critical team members, particularly those outside company walls. This might not be a problem if your needs were simple and you were absolutely certain of what was needed, but the development of today's electronic devices is rarely simple.

The 10 Tips

The following guidelines will help you get to market faster by speeding up testing and reducing qualification time. They will help improve manufacturing yield and the reliability of your finished product. They will help you simplify assembly and ensure the accuracy of documentation. And they will help control costs.

1. *Divide your requirements into "must-haves" and "nice-to-haves."*

Engineering is about making choices, and unless your resources are unlimited (and they never are) there will always be sacrifices to be made. If you don't prioritize your requirements, costs will skyrocket or you will run the risk of sacrificing the wrong capabilities.

Must-haves are the features that are essential to the finished product. Unless you have a blank check, cost will be one of them. Nice-to-haves are the features you would be willing to sacrifice, if necessary, to get the must-haves and stay within budget. This is the reality check that helps you separate what you want from what you need, and the earlier in the process you categorize your requirements, the better your chances of getting all of your must-haves and some of your like-to-haves, and getting them on-time and within budget.

An example of both under- and over-specifying was a customer who specified a particular thickness of polyimide insulation, but failed to specify a required maximum current leakage for the circuit of 260 amps. When the current leakage requirement was eventually identified, it turned out that the specified insulation would not work and the device would have to be redesigned, including a change in the insulating material. In this case specifying current leakage as a must-have and the specific insulation material as a nice-to-have would have saved two months of development time.

2. *Challenge all assumptions.*

Taiichi Ohno of Toyota introduced the simple practice of asking "why?" five times. This has now become a common tool in the "analyze" phase of the DMAIC methodology of Six Sigma. The goal of this questioning in examining the specification for a component is to fully explore the assumptions upon which the specification is based. Simply put, there may be good reasons for a tight tolerance, but there can be some bad reasons as well: habit, lack of knowledge about alternatives, or an over-large safety margin due to inability to actually determine the requirement. Obviously, time and money invested in meeting an unnecessarily tight tolerance is wasted and may limit your ability to meet other requirements.

For example, Minco was asked to deliver pairs of heaters meeting wattage, resistance, thermal profile, and material specifications developed by a previous vendor, and matched to within a two percent wattage tolerance of one another. When problems arose, it was determined that the two-percent tolerance requirement was causing the problems, had been originally validated through incomplete testing, and was, in fact, unnecessary. In this case, rigorous questioning of the original specification would have led to more thorough validation testing, and a looser, less problematic specification.

3. *Provide your vendor with full information on operational and storage conditions.*

Do not assume that conveying requirements regarding extreme operational conditions will assure performance under all conditions. Customers offer a variety of reasons for providing vendors with limited information regarding their requirements, but incomplete information can result in systems or components that meet the specification but fail to meet unspoken expectations.

For example, Minco was asked to provide a heater that would meet tight temperature specifications across an incubator block at a maximum temperature of 60 C. Minco provided a thermally profiled heater that met the uniformity specification at 60 C, but not at 37 C, a second requirement that had never been specified. In order to meet this new specification, Minco was able to design a two-element heater, which fully met the customer's requirements without adding cost. Stating the full requirement up-front, however, would have shortened the total development time.

4. *Design to take advantage of your vendor's core capabilities.*

Every vendor has core capabilities. These are areas of particular strength, in which the vendor may outperform most, or all, other vendors. If you make sure that your design falls within the vendor's core capabilities, and particularly if you design your subsystem or component to take advantage of those core capabilities, you can improve your product's performance and lower the cost of ownership. Always ask what the vendor's core capabilities are and how they can be applied to your project.

Another way to look at core capabilities is to ask what the key benefits of a vendor's products are. At Minco, for example, flexible heaters are a core capability. Base on experience, we have found that flexible heaters can be thermally profiled to provide a uniformly heated surface, allowing the use of thinner heat sinks. A 50 percent thinner heat sink uses less metal, costs less, and could heat up 25 percent faster with the same wattage as a thicker heat sink.

5. *Make components replaceable.*

Removable components are typically more expensive than those permanently fastened to a circuit, but they may be significantly more cost effective in the long run. In deciding whether to make a component removable, you should consider both the likelihood of failure and the consequences and costs of failure. In short, make those components that are most likely to fail or that would have the greatest consequences if they failed, easiest to replace.

For example, Minco worked with a company that was permanently installing RTD temperature sensors into a heat sink by pressing them into place. While such devices seldom fail in operation, there was a significant risk of damage to the sensor in the installation process. Replacement of a damaged \$15 sensor would require replacement of \$60 heat sink and \$40 heater as well, bringing the total replacement cost to approximately \$115. The solution was replacing the press-in sensor with a slightly more expensive screw-in sensor, allowing easy installation and removal and significantly lowering the total cost of ownership.

6. *Mistake-proof your assembly process.*

In Japanese, it's called "poka yoke" (pronounced "POH-kah YOH-keh"), and it means "mistake proofing." In practice, it is a design step built into a process for the purpose of foreseeing and preventing errors or oversights. Familiar examples are household electric plugs with one wide blade to ensure proper orientation and Internet web sites that check to make sure your information is complete before finalizing an order. When designing a device, take time to consider the assembly process and determine what features are needed on individual components to simplify and mistake-proof assembly.

For example, at Minco, we were asked to produce a flexible heater around a cylindrical warming device. As originally designed, the insertion process for the heater was slowed by the need to ensure which, of many possible alignments, was the correct one (Illustration #1). Our suggestion was that the plastic housing be redesigned to accommodate pins (Illustration #2) on the surface of the heater allowing only one alignment.

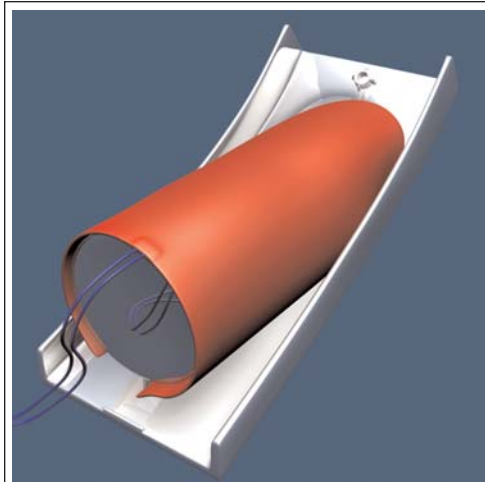


Illustration #1: Design without poka yoke showing improper alignment of heater

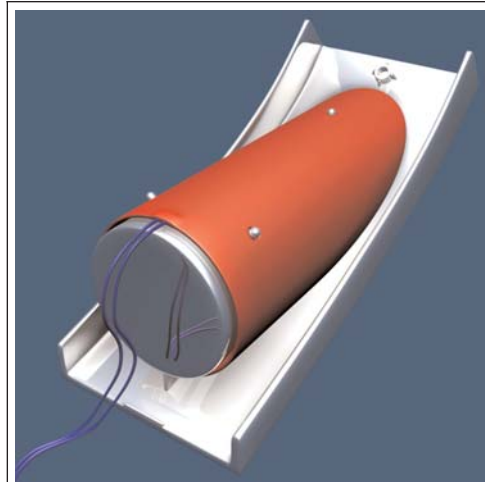


Illustration #2: Poka yoke design showing proper alignment of heater and alignment pins

7. Share your assembly process with your vendors.

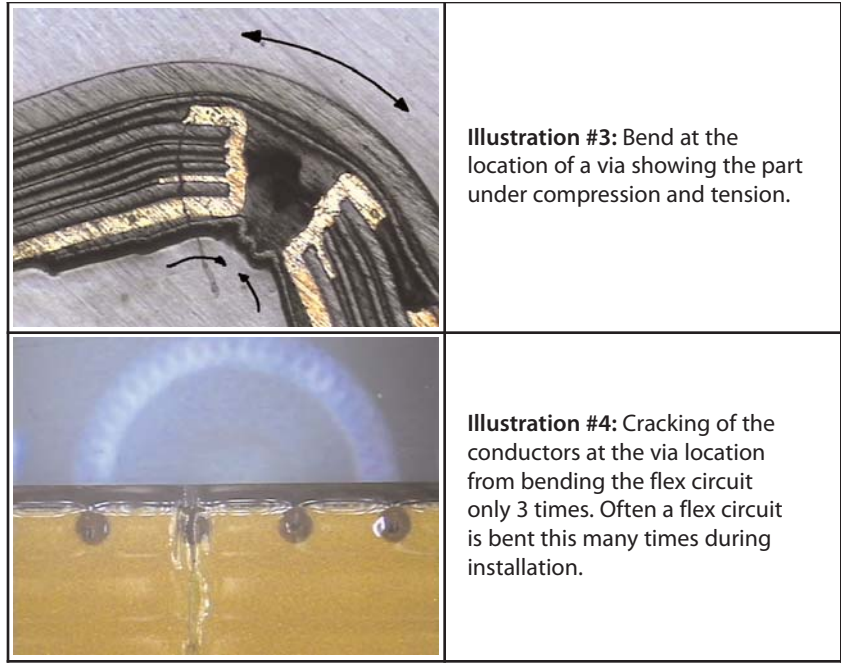
If you limit each vendor's knowledge and participation to the components they are providing, you may miss valuable input on how components can work together or how they can be most effectively assembled. Your vendors have years of experience, not just with the production of components but in how those components are used as well. Tell your vendor about every step of your process, from receipt of the component to final assembly. Include aspects such as whether the component will be bent or folded, and both how and how often that will be done. In many cases, vendors' capabilities or knowledge can simplify or eliminate processes or, at least, eliminate redundant inspections and reduce your cost of ownership.

For example, a Minco customer specified a component with four lead wires that were to be trimmed and attached to a connector prior to installation on a circuit board. Minco suggested an alternate method of termination that would reduce both manufacturing cost and handling time.

8. Get your vendor's buy-in for your use of their product.

If you've chosen your provider well, the vendor is an expert on the use of their components. It is important that you make sure the vendor knows how you plan to use their components and that they buy into that plan. In our experience, customers who are reluctant to act on the vendor's recommendations are risking component failure, lengthened design cycles, qualification problems, and added cost.

For example, a customer was using flex circuitry to reduce packaging size of a device. The customer's design placed a plated via connecting copper circuit layers at a point where the circuit would make a 90 bend (Illustration #3). The customer did not accept our recommendations against that placement, resulting in cracking of the conductor, qualification issues, ongoing design problems, and delays in getting the product to market (Illustration #4).



9. Know when your vendor will be discontinuing the product.

Changing components can be complicated and costly. Depending on the type of product you are producing, component changes can entail re-qualifications, UL updating, or FDA approvals, which can result in out-of-pocket cost and loss of sales while changes are made. There are a variety of reasons-RoHS or miniaturization, for example-for choosing to change components in a planned and controlled way. It's another matter, however, to be forced to make such changes when a vendor discontinues a component or, alternatively, to accept higher costs and longer lead times caused by unanticipated changes in supply.

For example, a Minco customer had specified a particular thermistor when designing a device 15 years ago. To avoid re-qualification, they incorporated the same component into an upgraded model without checking on future availability. Having missed the opportunity to qualify a new component, they now have to cope with a shrinking supply of the original component and are paying twice the original price and enduring six-month lead times.

10. Document and share the qualification process with your vendor.

Medical products require extensive qualification. Ideally, the qualification process should be identified early in the development process and fully communicated to vendors. This helps them ensure that their components will pass, identify possible issues that may affect qualification, and provide any relevant data that can help reduce qualification time. The vendor may also be able to test their components prior to delivery to speed up qualification.

The following excerpt from the FDA's Guideline on General Principles of Process Validation for medical devices highlights the importance of planning for qualification. "The product's end use should be a determining factor in the development of product (and component) characteristics and specifications. All pertinent aspects of the product which impact on safety and effectiveness should be considered. These aspects include performance, reliability and stability. Acceptable ranges or limits should be established for each characteristic to set up allowable variations. These ranges should be expressed in readily measurable terms. The validity of acceptance specifications should be verified through testing and challenge of the product on a sound scientific basis during the initial development and production phase."

10 Tips for Product Development

1. Divide your requirements into "must-haves" and "nice-to-haves."
2. Challenge all assumptions.
3. Provide your vendor with full information on operational and storage conditions.
4. Design to take advantage of your vendor's core capabilities.
5. Make components replaceable.
6. Mistake-proof your assembly process.
7. Share your assembly process with your vendors.
8. Get your vendor's buy-in for your use of their product.
9. Know when your vendor will be discontinuing the product.
10. Document and share the qualification process with your vendor.

Conclusion

Successful product design results in cost-effective, reliable, readily-usable, high-performing products. Achieving these ends requires thorough, goal-oriented design and effective use of all available resources. Among the most valuable of these resources are the vendors in your supply chain.

By working in partnership with your vendors, you add their specialized knowledge to your own understanding of your product, your market, and your goals. You can then prioritize (and share) your requirements, challenge assumptions, and incorporate full knowledge of the product's function, its assembly process, and the conditions under which it will be stored and used to achieve the best possible results as quickly and cost-effectively as possible.

Worldwide Headquarters
7300 Commerce Lane
Minneapolis, MN 55432 USA
Tel: 1.763.571.3121
Fax: 1.763.571.0927
sales@minco.com
www.minco.com

European Headquarters
Usine et Service
Commercial, Z.I.
09310 Aston, France
Tel: (33) 5 61 03 24 01
Fax: (33) 5 61 03 24 09

Asia Pacific Headquarters
20 Science Park Road
#02-31 Teletech Park
Singapore Science Park II
Singapore 117674
Tel: (65) 6511 3388
Fax: (65) 6511 3399

ISO 9001:2000
© Minco 2008


A critical component of your success™

Flex Circuits
Thermofoil™ Heaters
Sensors
Instruments