MINNESOTA WIRE
Life Saving Connections

MNWIRE.COM

Solutions For Complex Wire, Cable, and Assembly Projects

Critical Steps for Developing a Successful Medical Device Interconnect Cable

This article was written by ***Steve Pape, Design Engineering Manager, Minnesota Wire.*** *For more information visit our website at mnwire.com.*
This article originally appeared in MEDICAL DESIGN BRIEFS, January, 2016.

The process of launching a new medical technology can be fraught with risks. The development time and cost are daunting, the testing and trials can be unnerving, and the financials can keep everyone on their toes for months—even years. It would seem the task of developing the cabling and interconnects for a new medical device should be "easy" compared to all the other challenges. If you are not careful, however, your brand new device could be late to plan, over cost targets, or worse, judged deficient due to avoidable problems in the 11th hour of development. Following are some useful development-process insights for cables and interconnects that will help keep your medical device launch on track.

KEY STEPS TO SUCCESSFUL MEDICAL DEVICE INTERCONNECTS

Producing a new medical device demands a robust development process. Requirements and constraints should be identified at the start. The Requirements Definition process, which includes identifiable constraints, is the logical place to begin. What many people don't realize is that definition and documentation of requirements may precede the new product by years, especially when an extensive R&D effort is required.

Key Steps in the Product Design Process

INPUTS 7.3.2

- Design Checklist
- Market Analysis
- Customer RFQ
- Specifications

OUTPUTS 7.3.3

- Prints
- Bill of Materials
- Specification Sheet
- Assembly Instructions
- Inspection Requirements
- Test Requirements
- Calculations
- O&M Manuals

REVIEW 7.3.4

- Manufacturing Sign-off
- Purchasing Sign-off
- Customer Sign-off
- Marketing Sign-off
- Engineering
- Program/Project Management
- Manufacturing
- Quality
- Procurement
- Sales/Customer

VERIFY 7.3.5

- Design Checklist
- Calculations

VALIDATE 7.3.6

- Prototype
- Pilot Run
- Customer Testing

MINNESOTA WIRE
Life Saving Connections

The Requirements Definition process includes asking (and documenting) the obvious: What problem are we actually solving with this technology/device? What constraints are we faced with, such as cost, schedule, testing, trials, competitors' products, etc.? The competitive analysis can be an onerous task, but shortcutting the Requirements Definition process is a predictable way to get into difficulties down the road.

This is especially true with cables and interconnects. The time to start defining what is required is as soon as the need for cables and interconnects is identified. The most efficient way to do this is to involve the cable developer as soon as possible. In fact, the developer may be able to help adjust base requirements towards a better, lower-cost solution if they are involved before the constraints are fixed.

Process integration across disciplines and early supplier inclusion will pay huge dividends when the transition to production begins. Some of the keys to getting your cable and interconnection needs met on time, and at the lowest cost hinge on a number of critical design, performance, and production parameters. These include:

1. **Product Requirements Definition and achieving stability of requirements.**
2. **Thorough risk analysis, including FEMA and PFEMA.**
3. **Thorough definition of regulatory requirements and constraints.**
4. **Sound engineering processes and expertise.**
5. **Definition of all testing and performance documentation needed.**
6. **Comprehensive transition to production plan.**
7. **Estimates of manufacturing volumes and ramp-up plans.**
8. **Tooling, processing, configuration control, and quality systems.**
9. **Targeting suppliers who have capability, capacity, and qualifications needed.**
10. **Sound project management including milestone and risk reviews.**

Most of these items will get a knowing nod from any good design engineer, but those same engineers will quickly tell you any number of horror stories about one or more of these process areas skidding off track at some time in their background. Nearly every engineer has been on the receiving end of a project in which the stress levels skyrocketed from decisions made long before their input and support was requested. How do you line up all the key players to achieve great products, delivered on time, and at the lowest achievable cost? We can deduce some common threads for success by reviewing the key process areas listed above.

1. Requirements Definition

Defining and stabilizing requirements demands a clear problem statement, and exceptional communication and documentation skills with customers and users. They may not be the same people. This includes regulators, program/project managers, engineers, testers, suppliers, and manufacturers. The greater the integration and communication, the lower the risk becomes and the more predictable the development outcome will be. In the case of cable and interconnect developers, defining basic questions about electrical wiring parameters such as voltage, current, shielding, and materials, as well as connection frequency, environment, and reliability are critical in avoiding late program cost increases and schedule delays.

2. Risk Analysis

The importance of risk analysis, early and often, has made this an industry standard-practice. Conducting risk analysis has been incorporated into many quality standards. This is even true for the new ISO 9001-2015 standard, which has become an accepted minimum standard across many industries. A risk analysis for wires and connectors should include overall product Requirements Definition, stability, design innovations, materials, producibility, testability, quality, reliability, and capability and capacity analysis.

The more innovative the design, the higher the risk tends to be since many new processes and materials will have to be tested. The more that tested and proven processes and materials can be incorporated into the product, the lower the risk and cost will be.

3. Regulatory Requirements and Constraints

Regulators are not likely to be impressed with your new technology or device if it does not map clearly to existing regulatory requirements. This is a burden innovators have always had to deal with. The sooner you include the known constraints into your design and test plans, the faster you can make it through the tests and trials.

For cables and interconnects, factors include the need for bio-compatibility of materials, life cycle and reliability needs, reusable versus disposable designs, configuration and process controls, prohibited materials, and of course, production controls and standards, ISO 13485 for example. Defining the controls and constraints environment over the life of the product is an essential part of the design and risk management process.

4. Engineering Processes and Capability

Virtually any organization that engages in design engineering activity has to recognize the liability that comes with owning a design. This effectively assures that most engineers will be familiar with engineering process controls. Most engineering systems that go through any meaningful process certification must have well-defined design processes and standards. That doesn't mean they are good or efficient, just "compliant" to some minimum standard. For cables and interconnect assemblies, "minimum requirements" might be a risky path to take, since downstream support costs could easily outweigh any cost advantage in design cost savings.

This is where it is critical to ensure that the engineering group has the capability and capacity to execute the design to customer expectations. Problems in this area might come from several peripheral assumptions, such as when an R&D organization is tasked with "innovating" a new technology and demonstrating the product's feasibility. Development engineering is then given a cost and schedule to "productionize" the technology. This is highly risky since R&D may not have considered all regulatory or manufacturing constraints in their work. It rarely works to address these unseen challenges after cost and schedule are defined.

This problem has been so pervasive in Department of Defense technology developments that entire risk and transition protocols were developed to stop the wild cost overruns as developers tried to design amazing new products—products that no one could build for anywhere near the estimated costs or schedules. The same thing can happen, on a smaller scale, with cable and interconnect innovations. The adage here is “fore-warned is fore-armed.” Make sure that development engineering, even if it’s external to your organization, is adequately involved in technology assessments to head off negative outcomes in cable and interconnect designs, including producibility and cost assessments.

Continuous, automated flex testing by an articulated arm checks for signal integrity loss.

5. Testing and Performance

When the design is completed, testing and performance can be a fairly straightforward task, however, the old design adage, “test early and test often” is worth repeating. Money and time spent on product development testing will invariably pay huge dividends if the product heads to production. In fact, test failures should force a hard look into production feasibility. If engineering can’t reliably get the product through test, how will manufacturing be able to build it, especially in volume?

Many organizations are tempted to cut costs and the development schedule by reducing the test program scope. This will rarely yield real savings. It may lead to huge cost “sinkholes” and schedule delays in manufacturing that will make the testing costs saved look like peanuts. Test plans should be developed at the earliest possible design phase. The plan should include thoroughly proving the feasibility of both the design’s capability to meet performance requirements and production’s ability to manufacture the product within projected cost and schedule.

6. Transition to Production Planning

As soon as the design process gets underway, links to manufacturing need to be considered and explored. In a business where the design engineering group works closely with manufacturing, this can happen somewhat informally since the engineers will be familiar with all the necessary manufacturing processes used by that business. In a business where the manufacturing is subcontracted, a more robust transition to the production plan needs to be implemented.

Historically, this approach was called the Concurrent Design approach. Later, the idea of Integrated Product Development Teams evolved to ensure that the transition to production was considered from the earliest possible point in the design. There are a number of methods used to accomplish this, and the only unacceptable method is no plan at all. Ensure that your design teams are fully integrated by whatever method works for your business.

7. Manufacturing Ramp-up Plans

There are few things that will affect a design engineer's early decisions more than telling them the production ramp-up expectations. There is a vast difference between needing ten prototypes next month and needing a million deliverable parts next year. It can be difficult to predict ramp-up volumes for new products. Estimating sales for a new product is not exactly a science because there are so many variables involved. If the engineer is directed to minimize development cost and schedule, and focus on testable prototypes, a distinctly different design will result than if the engineer is given a volume production ramp-up plan.

If volumes are unknown, most engineers will default to existing practices for prototypes and testing. This would imply minimal documentation, tooling, testing, and lots of hands-on engineering oversight. This is where astute program management plays a critical role. It requires a risk assessment to determine the value of designing and building production-ready products, which may or may not ever be ordered again.

Testing a prototype cable for shielding and performance efficiency is a critical step.

If the needed information on volume is unavailable the engineering group will invariably apply sound judgment and experience to estimate the best and worst cases, and do what makes the most sense for the business. Expecting anything different will likely result in unpleasant surprises. It is incumbent on program management and/or the marketing group to take ownership of such estimates—realizing the estimates will impact product development costs.

8. Manufacturing Systems and Processes

Of all the pieces in the product development puzzle, manufacturing systems and processes are generally the most well-developed and stable part. Predictability is the hallmark of a well-run manufacturing organization. That said, the integration of the manufacturing organization into the product development process is often hit-and-miss. This is especially a risk when subcontracted manufacturing is involved. It is imperative that the design team take into account manufacturing capability, capacity, priorities, and preferences. This is so basic to successful product development that it was written into the ISO 9001 Quality Standard decades ago. Still, examples of poor integration abound. For organizations looking for big improvements in performance, manufacturing systems and processes are usually great examples of areas where problems can be easily identified and adressed.

9. Supplier Selection and Integration

This is another area of product development that is often rife with opportunities for improvement; for example, eliminating conflicting priorities. We want the best product delivered on time, and we want it at the lowest possible cost. The problem is, what do you want the most? For instance, setting incentives for purchasing to reduce the cost without proper balance for quality and schedule will yield supplier shakeups, and shake-downs, but not necessarily quality products on time. This is where the idea of partnering with your suppliers needs to be thoroughly explored.

Understanding the whole value stream, and communicating that understanding—from a value perspective—will do more to improve the bottom line than multiple isolated efforts at process improvement. This is a great first step in solving a litany of problems for many businesses.

10. Project/Program Management and Milestone Reviews

Establishing sound Program and Project Management practices, particularly milestone reviews, is one of the best risk-mitigation practices an organization can undertake. There are many approaches to this, but essentially, it amounts to defining what you need, when you need it, and who will do it. This should be complemented with regular reviews to make sure that what everyone signed up for, i.e., tasks (they need to be part of the process to define the plan) are getting accomplished according to the plan.

Milestone reviews should represent logical review points in design and transition to production, and not just weekly meetings or teleconferences, which tend to become unproductive quickly. Review points should include risk analysis completed, orders placed, drawings/models released, materials and tools ordered, etc. The reviews should coincide with key deliverable dates on important programs.

Summary

When developing new products and/or technologies, there is a logical chain of events and tasks to plan and monitor. For cables and interconnections, this often crosses many boundaries, including multiple external suppliers for assemblies and materials. Following these basic design steps will ensure a smoother new-product launch, happier customers, and satisfied business goals. After all, everyone likes the idea of quality products, delivered on time, at the lowest achievable cost.

MINNESOTA WIRE
Life Saving Connections

Minnesota Wire
1835 Energy Park Drive
St. Paul, MN 55108
1-800-258-6922
651-642-1800
mnwire.com

Minnesota Wire
2515 Prospect Drive
Eau Claire, WI 54703
1-800-258-6922
715-874-4580
mnwire.com