



## Medical Electronics Forum

One of the fastest-growing fields in the electronics industry, medical electronics brings with it a variety of challenges for the electronics designer, including regulatory issues, the ongoing push for miniaturization, and the increasing "consumerization" of medical devices. Recently, we conducted a forum among representatives from a variety of manufacturers involved in the industry to discuss these issues and their impact on the design and development process.

### **The regulatory process**

**EP:** How does the regulatory process impact the design process, and are there ways it can be minimized to allow products to come to the market more quickly?



**Edward Seaman, Globtek:** One of the main things that customers should look for in order to get their product through the medical requirements in the shortest length of time is that the components that they are using already have UL and other safety agencies' recognition or approvals. This way when the system is submitted for approval, it eliminates the safety agency from performing additional individual component tests prior to system testing. This is especially true for power supplies as most of the safety agencies' requirements are resolved at the power part of the system.



**Sean Riley, FCI:** I would echo what Edward mentioned in terms of providing off-the-shelf UL, etc., qualified products. We've found that the connector systems that FCI is selling into the medical industry are products that are already either UL qualified or generally accepted in other markets such as communications or data. So FCI's offerings for the medical market have, by and large, already been tested out, which helps our customers in the medical market shorten their design cycle.



**David Anderson, Precision Inc.:** Because our products are generally custom engineered and designed for a specific device, I think the most important thing that we see is to try to get from the engineers early in the design process what the key requirements are that they're going to need to meet. In other words, really focusing in on not having to redesign something because of some regulatory issue that wasn't brought up early in the process.



**Ed Fullman, Texas Instruments:** The problem that we see with the long design times is that semiconductors are also a long-lead item. The end equipment takes a long time to design as well as the semiconductors that go in them. Then to get through the regulatory process means that we're designing our products several years into the future.

A lot of technology advancements can happen during that time. So the long lead times associated with the regulatory process simply puts more pressure on the semiconductor manufacturer to execute quickly and get the technology to market as quickly as possible.

**EP:** As far as regulatory requirements being a barrier to innovation and slowing down time to market, how serious an issue is this, and is it being addressed?

**Ed F.:** We treat it as more of a boundary condition—it's simply the way the world is and we have to develop our products so that they function and are successful in that environment. It does prevent people from adopting some pretty good ideas that come along, and I think the entire medical industry could progress a little bit faster, and we could get more advanced products to market quicker if the regulatory process was streamlined.



**Wayne Shockloss, Tyco Electronics:** We manufacture custom cable assemblies for a wide variety of medical customers. The way that we try to reduce time to market for them is by looking at all of the industry standards that are out and available in the marketplace, and creating a template of a minimal amount of testing that we will perform on our products to provide them with validation data for flex testing, mate and de-mate retention forces, electrical requirements, and mechanical and environmental requirements. This makes the demands on the OEM shorter and takes some of that work away from them, and will typically cut six months out of their design cycle.

I'm also seeing an increasing trend from the FDA to be very concerned with process controls. I see them performing more audits of suppliers and of customers focusing on process controls and repeatability of processes.

What we can do as suppliers is try to address that with process FMEAs (Failure Mode and Effect Analyses). The process FMEA enables you to review all of the design attributes of the product and look at the potential failure-mode analyses that could occur and try to mitigate those circumstances in your design. When you do that you really will eliminate returns and RMAs and enhance the quality of the product before it goes out.



**Mike Rogen, Maxon Precision Motors:** It seems a lot of customers have the perception that if a component is UL approved it makes the system automatically approved or at least easier to get UL approval. From what I've seen that's really not true. The important point is that to get UL approval for a system you have to get the whole system approved.

Maxon has some of our products that are CE approved•nothing to do with safety, just in terms of electrical noise. That requirement•having a CE mark•seems to be fading. I guess it's really more of a marketing requirement in that it doesn't seem to me to be as important as it was a few years ago.

**Greg Harris, Ault Inc.:** Right now we're finding that one of the quickest ways to market and to get through the regulatory and approval process is to really do design verification testing or go through an FMEA process at the initial design stage, and definitely at the component sourcing stage and the board-level design stage. It's become very critical. I think most of the medical customers find that it really supports their intention of being able to feel very comfortable and confident when they go to the FDA.

We spend a lot of time working with the regulatory agencies, and even to a certain extent with the FDA, in understanding what they're doing and what they're seeing in electronic design and what are going to be the changes that they want to see incorporated into the regulatory requirements down the road. And so that gives you a good understanding of what's going on in the market and what the upcoming expectations are.



**Peter Blyth, XPIQ:** One of the ways we find to help design engineers and medical device companies shorten their design cycle is to make sure they use approved power supplies so they already have the UL 60601 approval. Another is to make sure to supply them with documentation up front like the CB test report, a TVUL test report, so basically they have a low-risk solution.

And the other thing that's important is to make sure they have as much flexibility as possible because the design is likely to change going down the road. As long as they know the component power supply can change but still maintain the approvals, then I think that's a big plus for them as well.

On the FMEA, the one thing we're seeing as a company is in the third generation of the IC60601•a big emphasis is being placed on risk management and risk assessment of medical devices. And several customers have pushed back on to us to say they want the components to have an FMEA with them, so when they come through that system analysis they can just say, "Well this power supply has an FMEA and this component does, therefore we're going to feel much happier that our whole system's going to pass this requirement."



**Eric Fage, Fischer Connectors, Inc.:** From a UL standpoint, we make components, and usually if you want to get a listed device, the whole device must be tested. We can get our connectors approved as a recognized component, but that is a different category of listing from UL. Most, if not all, of our connectors used in the medical industry are applied to listed devices so they do pass all the tests•it's just easier if you have a recognized component because then the inspector can just rubber-stamp it.

There is a also a difference from the FDA standpoint, which is quite a change from the late '80s and early '90s when the FDA tended to be adversarial with trying to get things processed. More recently, there's a lot more assistance involved because they're trying to get things through to advance medical technologies.

I agree with someone else who said that it's not so much the product, it's the process. The FDA GMP's (Good Manufacturing Processes) are interested in looking at the process with the assumption that if your process is in order, then your product will be in order.

The biggest mistake as far as trying to shorten the design process or the regulatory approval process is not to involve the UL inspector or the FDA inspector early enough. Usually by the time you think it's time to get them, you've missed many opportunities to shorten the cycle.

**Edward S.:** One thing customers should definitely look for when working with the manufacturer of a medical device that does have a component or power supply that's already UL recognized is that they're able to obtain those safety agency documents. That could really slow down the process for them if they have difficulty in getting those.

**John Brown, Texas Instruments:** From an IC manufacturer's perspective, designers of medical equipment are looking for integrated circuits that pass the UL, CE, and AAMI consensus standards, for example. We see a big industry push toward very low power in single-supply, battery-operated or battery-backup medical systems. For diagnostic-quality ECG applications, it is difficult for us to provide very low analog input noise of say 5 •V peak to peak in amplifiers that draw very low quiescent current of say a few hundred microamps. It puts

a challenge on us because the designer of the equipment can't get approval from the FDA unless they can pass these tests.

And so it behooves the designer of medical equipment to get an IC manufacturer involved as early as possible in what they're trying to do without disclosing their confidentiality. Then we can design ICs that are geared to their regulatory requirements.

**Eric:** It's not so much being UL approved, as being UL approvable. As long as the device has the ability to be approved, it doesn't necessarily need to be preapproved.

## **Miniaturization**

**EP:** Miniaturization is obviously a big issue, no pun intended, involving perhaps in some cases implantable electronic devices, if not just your handheld or portable devices. What sort of issues is it presenting from your perspective?

**Edward S.:** As far as power supplies, everybody wants more power in the smallest package possible. Over the years we've seen power supplies come down in size tremendously, mainly with the advancement of the switch-mode power supply. And we offer some of the smallest external medical power supplies in the market.

But the power that's coming out of the external supply has increased. We're seeing more and more opportunities where people are requesting medical external-type power supplies and a wattage range of 100 to 150 W, which just weren't available 5 or 10 years ago.

**Sean:** FCI has a long history of manufacturing connectors for the consumer market, where miniaturization is one of the driving factors in new product development. Certainly this has positioned us well to address the needs of miniaturization and density within the medical industry. In many product categories, such as flexible circuit connectors and board-to-board connectors, the newer products that we've designed for the consumer marketplace are smaller than some medical customers need, so they have even more options when specifying products for their latest program.

**David:** Well miniaturization of the product lines for implantables is a big issue for us•we see a big drive toward that. Of course with implantables, small is king, so they want smaller telemetry coils, smaller transformers, etc., that will perform. The advances in a lot of the power components•the batteries etc. are helping that.

In our business, really the only way to go smaller is to go with smaller wire, and in that case you have reliability issues that start cropping up. So you have to manage what the customer is looking for•what they want the medical device to do•versus some reliability issues. When you get down to 50-gauge wire, it presents some very, very special issues.

A lot of times it requires a lot of different thinking because the medical industry does have these risk aspects and when you get things smaller, in our business anyway, you may not even understand the risk analysis because you're treading on new ground. You don't know where the breaking points are. So it's very exciting for us, but it

also requires us to work very closely with the customers to try to figure out what their real requirements are and not to over-design.

**Ed F.:** Miniaturization is *wonderful* for semiconductors. This is what we look for and this is what we do well. Semiconductor processes keep advancing; we're able to integrate more and more elements and components in a single design. So while that's very good for our industry because it creates opportunities for us, there's also a down side to it.

We've created, for example, a very-high-speed eight-channel 12-bit 50-Msample ADC with serialized LVDS outputs, and while that's fantastic for ultrasound, it's no longer a general-purpose ADC. The number of customers that can possibly use that part becomes fewer and fewer, and that translates to higher risks and more development costs on a per customer basis.

**Wayne:** We see miniaturization as a core competency that differentiates us from others in the industry. Where I see it applying to our medical business is with miniaturization of connectors and wire.

We're doing more and more work between 46- and 50-gauge wire, and terminating that to connectors that are tiny and can be used for implantable devices and still have very rigorous regulatory controls. And the key to that is to be able to control the tolerances of the product and be able to really terminate it once it gets to be that small.

As far as connectors go, we see packaging getting smaller and smaller and more dense. In terms of ultrasound, you have more and more people trying to pack more conductors into connector sizes that are smaller•more elements and less space.

More and more ultrasound devices need to be more mobile, especially in third-world countries like in Asia. And also more flexible. We see more of a demand for reduced-gauge wire sizes to put more into one package in order to have a lighter, limper cable. So that comes back to ergonomics and healthcare issues to prevent carpal tunnel syndrome in the lab technicians that are performing ultrasound procedures.

**Mike:** To borrow Ed's phrase, miniaturization is wonderful for Maxon. We have motors and gear heads starting at 6 mm in diameter. We have a position controller that's not much bigger than a 9-V battery.

I think some of the issues that miniaturization implies is very often you're going to drive something that's going to be battery powered. And that, in turn, creates the need for efficiency. That's a Maxon strong point.

Likewise, as you miniaturize something, very often the voltage is getting smaller and smaller so therefore electrical noise issues become more and more important.

**John:** Another factor in miniaturization is RFI. The smaller you make a component, the smaller the capacitance usually is around the input stage, particularly of an analog part, and the more it can be susceptible to RFI. Also, tiny parts mounted on a flex cable, floating out there in space somewhere, can be more subject to RFI fields.

This is an issue that we, as IC manufacturers, don't always know how to solve. So miniaturization can create additional RFI problems.

**Greg:** For us the idea of miniaturization really has to do with mobility. A lot of our customers' products are becoming smaller and smaller in the medical environment, as well as ITE (Information Technology Equipment). From a standpoint of power supplies, it's really driven by the ITE market, where the desire—whether it's a handheld PDA or it's a handheld surgical data gathering tool—is to make the product as small as possible. But what we do for the ITE market is different than for the medical market.

And so I may have a power supply and a four-by-five configuration doing 90 W. That's great for an ITE market, but I may end up doing only 65 W for the medical market because of emissions, etc. So for us, the big driver becomes mobile products and products that are going to travel with the patient, and how small you can get the power supply to go with that and still meet all the regulatory requirements.

**Peter:** I agree with everyone else that miniaturization is a great opportunity for all of us. The thing we're seeing that's driving the miniaturization of our power supplies is the drive within hospitals—especially in surgery, operating theaters, and bedside type equipment—to put more and more equipment around a patient, and the space just doesn't get any bigger.

So they're trying to shrink this type of equipment, which is driving us to shrink our power supplies. And the challenge is to get it that small, and to make it as efficient as possible so it doesn't generate that much heat because the more heat you generate the less reliable the electronics around it are.

**Eric:** Our particular product goes both ways because it's a human ergonomic product. It's a connector and it's going to be used by the human hand, so just for ergonomic reasons you can only go so small. What we see more is the trend toward higher density in the same package. In the medical environment in particular you have people in surgery many times wearing gloved hands, or also in the military who are wearing gloved hands, so it can only get so small.

One of our problems is that as we get smaller and smaller you're going to have lower power. Well low power can now be done by the smallest connector—a wireless connector called Bluetooth wireless communication. So when it gets to real miniaturization a lot of those opportunities go away for us because they just use wireless.

**John:** I think there is one additional word to add about miniaturization—it does not necessarily bring lower cost. Smaller ICs usually cost less. However, depending on what it is and how it's actually mounted in a system, total cost could go up. If a system were made slightly larger, it could actually cost less, which is important to the medical consumer, particularly in the home environment.

**Eric:** I completely agree, but since it's counterintuitive, sometimes it's difficult to explain to your customer or the end user that if you want it smaller, you have to pay more. They think smaller should be less expensive, and thus it's a difficult sell in many cases.

**Sean:** One of the miniaturization trends that we've seen is increased use of ball grid arrays, which FCI has a patent on. We've actually seen a great deal of interest in design-in of our ball-grid-array-attached board stacking product where it's used for mounting photodiodes into CT scanners. The density and speed that the product allows provides for a greater amount of photodiode modules able to be placed in the same overall package in terms of a CT or MRI.

## Consumerization

**EP:** Increasingly, medical devices are being used and even directly purchased by average consumers or patients, for use in the home environment. How do you see this consumerization, or commercialization, of medical electronics affecting the design process?

**Edward S.:** What we're seeing now is that medical system manufacturers are starting to move their product into the consumer or the home-use environment. This is mainly due to the rising cost of healthcare. Health insurance companies want the patient moved out of the hospital as quickly as possible and have the after-care monitoring done preferably at home.

Now typically most medical systems designed for hospital use aren't cost effective to the insurance companies for home-use applications. From a power point of view, hospital-use equipment is typically designed with internal power supplies to prevent damage to the power supply during handling or while the system is being pushed around the hospital.

But by going commercial with their products in the consumer market, medical system designers have a little bit of a challenge. They've got to make their system cost less and they've got to make it easy for the consumer to use. So a lot of the power supplies now are being moved out of the medical products and going to lower-cost externals when they're going to the consumer market.

**Sean:** I can echo what Edward said in terms of the pressure to make products smaller, and again, working with the consumer industry, the experience has been there on FCI's part to miniaturize critical connector content. From a cost standpoint, the price pressure has certainly continued to increase.

Fortunately, the products we're seeing price pressure on have been in use in the consumer handheld market for quite some time, so our medical customers are able to take advantage of the cost reductions already enforced by existing customers. So being able to meet target costs from medical equipment manufacturers has been less of a burden by those of us who are active in the consumer industry already.

**David:** I echo Edward's thoughts as well. We see our customers being driven by the insurance companies to provide better diagnostic information without having to drive in to see a doctor.

And also, medical device companies are really competing against the drug companies, so in order to provide devices that will do the same thing as just going to your pharmacist and getting a bottle of pills means that they really need to make those devices consumer friendly and get the insurance companies to buy into the fact that

they're an effective way to provide the service or the treatment that the consumer needs.

**John:** In consumer medical, the user is not as savvy as a trained physician, or technician, or nurse in a hospital. And the pressure on an integrated circuit company such as TI is to supply "easy-to-use" amplifiers, A/D converters, microcontrollers, and digital signal processors.

This allows the equipment designer to create a system that acquires the medical signal quickly and decides whether or not it is connected properly, in addition to alerting the end-user with corrective messages. This is also applies to instrumentation in medical institutions, but for the consumer you've really got to make it friendly.

And we do find a trend in medical electronic designers wanting to offer remotely monitored instruments with diagnostic quality, over telephone, RF, or optical infrared links. But then medically trained personnel need even more reassurance that electrodes are connected properly to the person. So we as IC manufactures are challenged with putting more diagnostics inside our chips.

**Wayne:** We have actually gone so far as to actually market some of our devices to end users to create demand from our medical OEMs. So in other words, trying to promote our products' flexibility and ergonomics to end users to drive medical device manufacturers to incorporate those products into their devices so that the consumer is actually participating in creating the demand. And we've done that through featuring the product's flexibility, ergonomics, and also of mobility and user friendliness.

Medical devices today•just like cell phones•are sort of changing the world here. Everybody wants to be more mobile and so whatever we can do to make medical devices more mobile and smaller and user friendly really helps sell products.

Another issue is the increasing concerns about sterilization and the cross contamination of various diseases•HIV, mad cow disease, SARS, what have you. Whatever we can do to commercialize our products to meet new requirements that allow us to claim that the products can withstand certain sterilization is a significant benefit.

**Mike:** I think it's almost an oxymoron to talk about the consumerization of medical devices. When I think of consumerization in the medical field, I think of something like a disposable item and there are some products like that. We don't sell very many motors that are actually disposed of after being used once or a few times. Believe it or not we do have a few of them.

When I think of consumerization it's not so much that we're designing it for the consumer per se, it's just that it's a high-quantity item that another medical company has designed. A good example would be ambulatory pumps, drug infusion pumps, or feeding pumps, or even portable respirators.

Consumerization is just making something so it will more easily fit in with other, complementary products. That could be as simple as for instance a computer interface. For instance I see CANopen becoming more and more widespread in the United States, and as more devices get that they become able to have an across-the-board

functionality between multiple devices.

**Greg:** I don't think it's an oxymoron at all, but I do think that it is very similar to the consumerization we saw of PCs, and once again it's driven by ITE. And it's also a matter of what the baby boomers want•things that are easy to use, that are portable and convenient. And it's not going to go away as a trend.

We design products for our medical customers that they can use on multiple products. Most of these products are going to be portable. Some of them are going to be standalone in the hospital, some of them are going to be standalone in the HMO clinic, but they're also going to be portable. So we design for them a suite of products that allows them to match up for the applications that are going to be consumerized.

**Peter:** I'd to look at it as more of the home healthcare type products increasing, and I think it comes back to what everyone else has said, that I see it driven really by the insurance companies wanting to get people out of hospitals quicker so it's less costly. My personal experience in the UK is with the healthcare system there, and the lack of space in hospitals•that's a big drive as well to treat people at home more than in hospitals.

But I think one thing nobody's really mentioned is that for a product going from a hospital environment to a domestic environment there are RFI, EMC, and safety-related issues that have to be taken into account as well. For instance, UL are requiring that home healthcare electrical products have to be double insulated. And that's one thing that we are seeing as a manufacturer of power supplies•that type of drive on a safety standard.

**Eric:** From a design standpoint, commercialization or consumerization shifts the emphasis from a skilled *user*, as in a typical OR or clinical environment, to a skilled *designer* because you don't have a skilled user. So this means the user interface has to be much simpler.

And a lot of that is being driven by marketing departments. Especially in pharmaceuticals, where in the past the pharmaceutical company would market their products to the doctors who would then prescribe them to the patient. Now on TV and magazines everywhere they're marketing directly to the end user so the end user goes into the doctor and says, "Hey, I want to try the purple pill." That's a major shift and it's starting to also occur with devices.

**John:** Well there's a phrase that I use when a consumer medical sales effort becomes the dominant end-goal. I call it the salesman's approach to healthcare. From our point of view, this means that some companies seek an integrated circuit that does everything, so they can promise nearly anything to their customers.

They want to advertise that a consumer medical product will make you healthier. And so the integrated circuit manufacturer sometimes tries to include everything in an IC that allows the end-system to be completely automatic•you don't have to touch anything or do anything. That we find puts the pressure on us to become an IC design resource, or just an extension of some consumer companies.

**Greg:** We just started seeing some of our customers selling products to pharmaceutical companies through drug stores to the different chains that are responsible for medical products that used to be canes and walkers.

Now they're selling small respirators and devices for the home that would have been in the HMO or the hospital.

So it's very much a consumerization. It's not necessarily being driven to me at least by the HMOs as much as by the convenience that we as users really want.

**David:** Portable defibrillators are another good example where you see that as the price gets driven down, more and more municipalities can afford to put them into police cars, EMT's, etc. Even corporations are including them as safety devices on the floor, so if somebody has a heart attack they can deal with it right then instead of waiting for an ambulance. Consumers are going to demand more of that and we'll be better off for it.

**Eric:** Because you have the commercialization or consumerization and the quantities going up, you have the advantage or the opportunity with disposables due to economies of scale. But in Europe where disposing of things is not looked at very highly, I believe there's a new law that makes it the OEM's responsibility to take back the product and dispose of it properly. That could cause some big issues in the future if one is not aware of that.

**Peter:** The standard and directive in Europe is called the WEEE directive•Waste Electrical and Electronic Equipment. That's the one that basically puts the onus back on the OEM's to dispose of disposable items when it comes to the end of their service life.

## Communication

**EP:** What about communication within the industry•for example among medical device engineers, manufacturers, and the regulatory agencies? What sort of issues are you seeing here?

**Edward S.:** One of the things that I'm hearing, especially from my engineering team here at Globtek, is that a lot of the regulatory agencies have different interpretations of the specification. UL has a different interpretation then, say, TUV or CSA.

Many times it's outside of what the specifications were supposed to be about, which is keeping the patient safe. And sometimes that does cause delays when you're trying to get a product approved.

**Sean:** Because of the type of connectors that we provide to the medical industry, we seem to be luckily a step removed from most of the regulatory issues, so in all honesty we haven't really experienced the effects of a lack of communication. We make a point to maintain close contact with our customers' engineering teams and haven't experienced any major issues.

**David:** We do have a number of communication issues from time to time with our medical customers. Part of it I think is the need to overcome their homegrown brilliance. In other words, this is the way they want it done, and this is the way you just have to do it when in fact that may not be the best solution.

I think that's the biggest issue•getting our expertise across in terms of what can we do for you. Maybe you need to take a look and think outside the box a little bit and say, "You know, 130°C wire works very well in this application versus 200°C wire." And the cost differential is there.

**John:** Communication issues can be challenging with some medical device companies. Sometimes they generate a business plan based upon a medical product approach that contradicts semiconductor physics.

For example, it's not always practical for us to offer a medical instrumentation amplifier that acquires a 1-mV peak-to-peak electrocardiographic signal that consumes 200  $\mu$ A of quiescent current and has 5  $\mu$ V of peak to peak input noise in a 0.05 to 100-Hz bandwidth. It's not that we admit defeat, but we try to offer another approach•not necessarily of their first choice•that will work. It's often a matter of offering the best of the analog in combination with the best of the digital circuits•not just "magic" from one of them. Fortunately, many companies understand this, and strive to work with us in seeking an application solution.

**Wayne:** I think one of the biggest issues in the medical industry is the manufacturers' nonacceptance of industry standards or the lack thereof. I see more and more customers wanting to put unique features into their products to differentiate themselves and secure aftermarket business that goes against more-or-less industry-wide standards.

A perfect example of that is trying to get people to agree on a wireless standard, or on Infiniband, or on the AME ECG cable standards. These are standards that a lot of people are trying to drive in the industry and nobody seems to agree on. They all seem to be pretty important, yet they're being slow to be adopted. It's also got to do with different agendas driven by everybody trying to protect their own interests.

Another issue is more of a practical nature•the scope of projects changing. Once you start a project with many customers, the scope of that project has a tendency to migrate, and what is expected sometimes appears to be assumed rather than specified. And all of a sudden you get down the path of designing a product and the customer says "well I wanted it to perform to these requirements" and the scope of the project has just changed.

**Greg:** It would be nice if we could somehow pull together a forum or meeting between manufacturers, our customers, and the regulatory agencies to talk a little bit about the direction of design efforts, and the direction of regulatory requirements so that everyone could be on a somewhat similar footing. I've been to Medical West, Medical East, Medical Minnesota, and I've never really seen any sort of meeting ground or forum that allows for that sort of dialogue.

**Peter:** I think somebody else mentioned gray areas in the standards•the interpretation from one test laboratory to another. One lab will interpret one requirement one way and another lab will interpret it another way, and one product will pass at one lab, and fail at another. It's important just to make sure that they are on the same page and they understand it the same way and interpret it the same way.

**Eric:** One of the purposes of the ISO trend of quality control and FDA GMPs is to ensure the requirements are addressed. That's generally what we try to do•ask the customers. Don't assume anything. A lot of manufacturers make the mistake of assuming they know more than the customer and they forget to ask them and they come out with a product that's blue and the customer says, "Why is this blue? We want it red." Because they never asked.

That usually happens to inexperienced manufacturers or designers. Generally after you design your first or second, you don't make those same mistakes. So it's based more on experience. If you're new to the industry and you don't realize the issues associated with regulatory agencies you're going to be in trouble down the road.