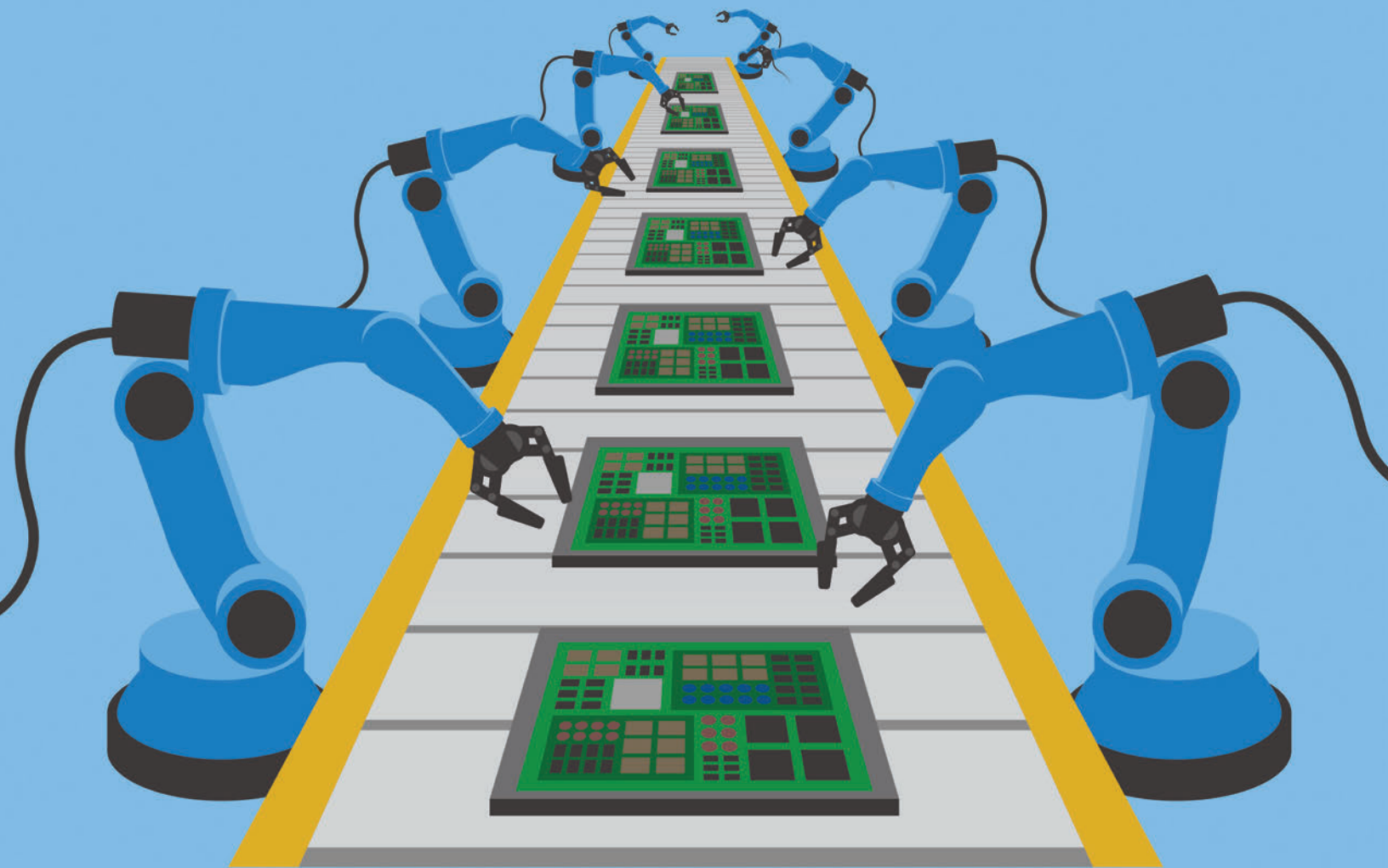


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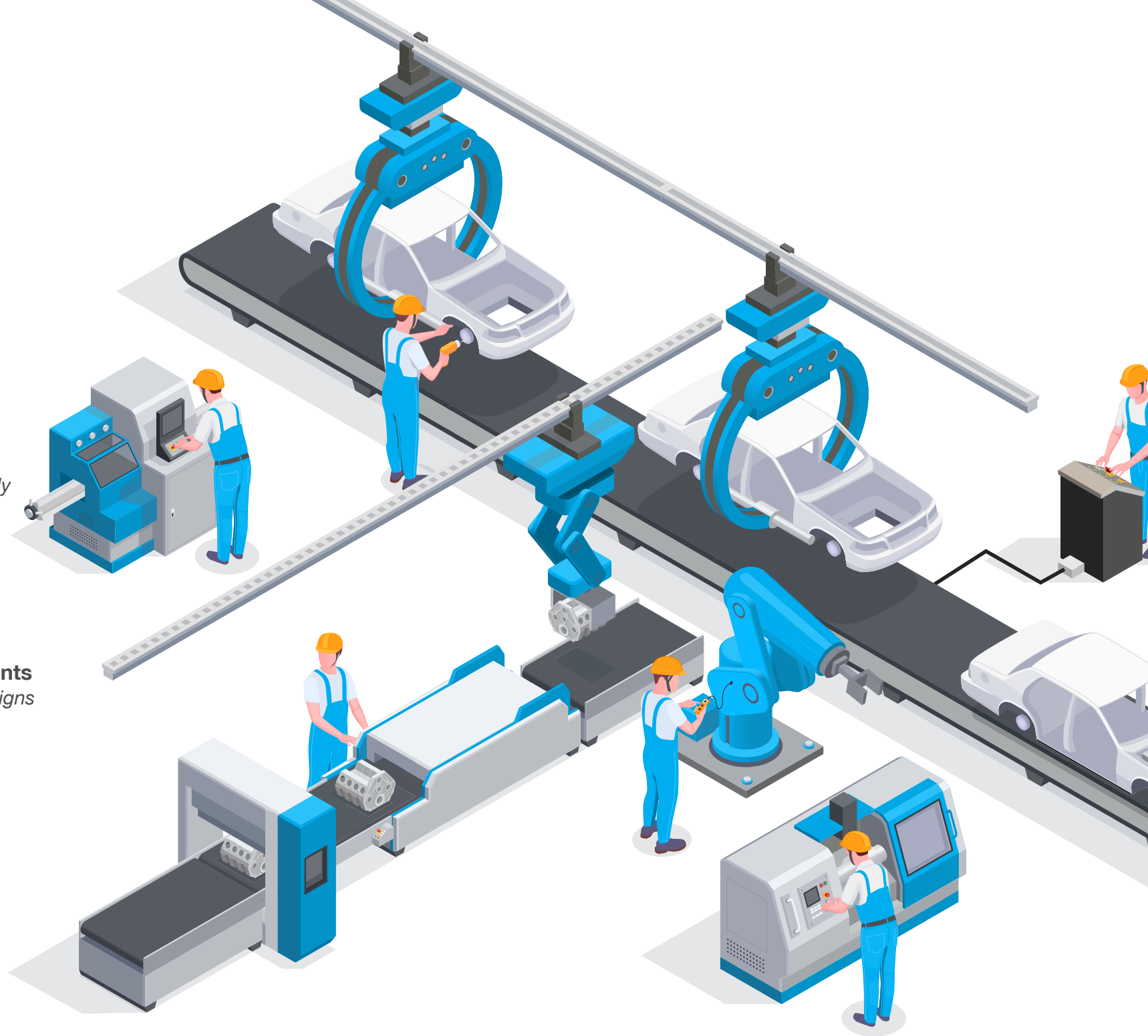
Meeting Certifications and
Regulatory Requirements

Selecting Components
for Manufacturing

Launching Product
Production



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FOREWORD: DESIGN FOR MANUFACTURING

By Mouser Electronics with Josh Lifton, Co-founder and president of Crowd Supply



Josh Lifton is the co-founder and president of Crowd Supply. He received his doctorate from the MIT Media Lab and holds a BA in physics and mathematics from Swarthmore College, which is to say he's devoted a significant amount of his time to learning how to make things that blink. As head of Crowd Supply's project efforts, he is helping others do the same.

Engineers are both excited and motivated by the ideation phase of product design—that period when they are proving they can solve the engineering problem and make a design that works. Once they have a working model, that initial burst of excitement often fades. This is a critical point in product development because proving the feasibility of a design concept is just the beginning of engineering work that needs to happen to turn an idea into a product.

The Design for Manufacture (DFM) Phase

Once an idea is validated, prototypes are built to test the design. However, something else must also happen. Engineers need to begin thinking about designing for manufacturing. Design for manufacture (DFM) is a process of refining the design so that it is suitable for replication in whatever quantities you need. That's important because DFM can be the difference between a successful product and one that loses money.

“DFM addresses all the physical, functional, and cost constraints that must be met for the product to succeed.”

Overview of the DFM Phase

DFM addresses all the physical, functional, and cost constraints that must be met for the product to succeed. Ideally, this happens before manufacturing begins. DFM resolves questions about dimensional constraints and component fit, power and thermal constraints, computational constraints, and total cost. Addressing these issues depends on many things, including

“The earlier you start thinking about DFM the better, as long as you don't fall into that premature optimization trap.”

component availability and selection, supply chain stability, end of life for certain parts, certifications you may not have realized you needed, and many other considerations. Many of the problems encountered when ramping up for manufacturing result from inadequate DFM. Some examples of problems that might arise from inadequate DFM include components that don't fit because of a PCB drilling error or a last minute component change resulting from a late-stage functional change required by backers. Of course, these kinds of problems can be expensive to fix if you are on the eve of a manufacturing run and they can cause product launch delays. Unresolved DFM issues are almost always unexpected, which should not be the case.

When Do You Start the DFM Phase?

DFM is something of an art that requires balancing engineering and business considerations. Most engineers actually begin DFM early in the design cycle, even if they don't call it that. For instance, many good ideas lie dormant for years because there is no practical or cost effective way to build them. Then one day a new part comes along. It might be the exact integrated circuit that has the necessary features at a price the designers know is acceptable. Now it's possible to move forward. A lot of products are born that way, which is a form of DFM.

DFM needs to happen throughout design and prototype testing to really answer questions about how exactly you

will meet design constraints. It's an art because it typically involves many tradeoffs that impact design, function, and cost. There is never an optimum DFM that maximizes every single constraint.

“DFM is an art is because settling on a manufacturable design too early in the development process can cripple a product, yet waiting too long can result in manufacturing disaster.”

When should engineers begin thinking about DFM? There is no absolute right answer for every product. Another reason DFM is an art is because settling on a manufacturable design too early in the development process can cripple a product, yet waiting too long can result in a manufacturing disaster. The famed computer scientist Donald Knuth once said, “Premature optimization is the root of all evil.” Although he was referring to software development, it is very true for hardware design too. Freezing a design too early can limit its potential, but waiting too long can be a big mistake. Generally speaking, the earlier you start thinking about DFM the better, as long as you don't fall into that premature optimization trap.

The Role of a Manufacturing Partner in the DFM Phase

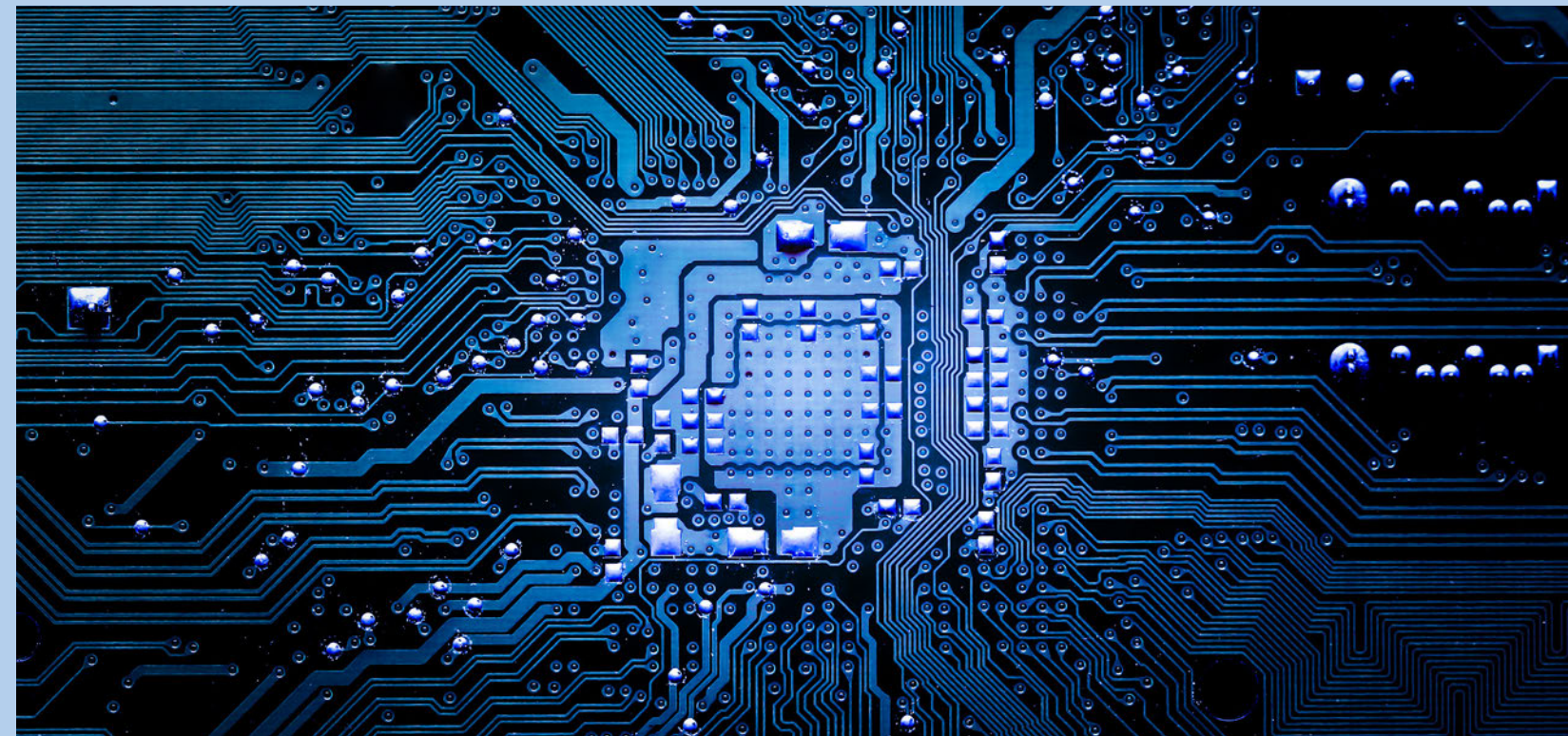
A manufacturing partner can be a big help in resolving DFM questions if you have the right partner. There are

plenty of partners that will do exactly what you tell them to do without telling you that the thing you want to do isn't going to work. It's important to be careful about selecting a partner. Choosing the right manufacturing partner depends on a lot of factors, including the nature of your product, their capabilities and experience in assembling products like yours, and the working rapport you are able to develop with them. You should feel confident about your choices when you are having DFM conversations with your manufacturing partners.

Final Thoughts

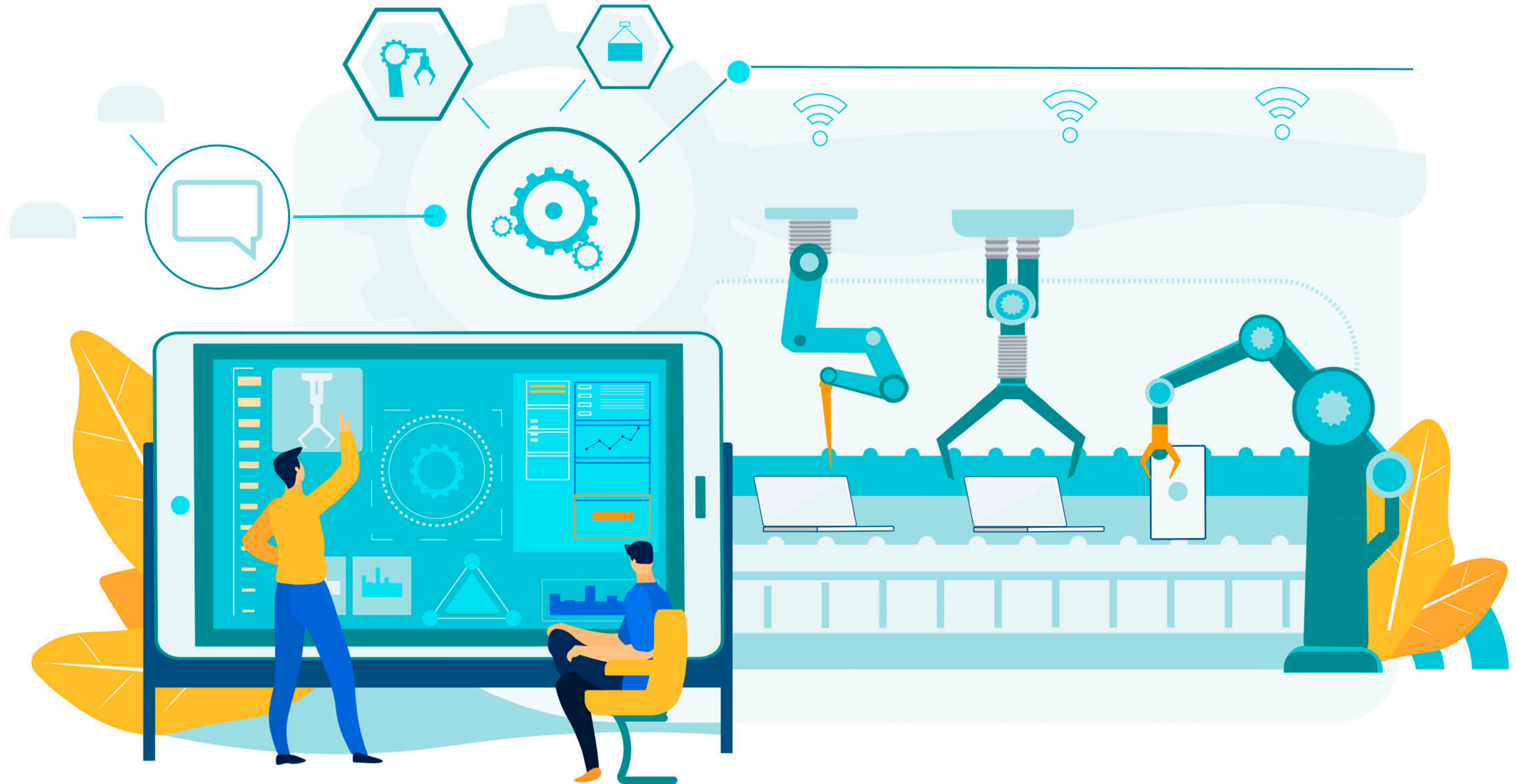
Even the most conscientious approach to DFM can overlook something. When it's time to start manufacturing, begin by manufacturing the absolute minimum number of units that's financially feasible. If you plan building 10,000 units, do a hundred first, even if it means losing money on them. There is always the temptation to go for the larger manufacturing runs because of lower per unit costs, but making 10,000 units that have a high failure rate because of a DFM oversight can be a very costly mistake.

At the end of the day, moving to manufacturing is driven by the practical need to get something out the door. Even if a well-considered DFM process adds some time to the product testing phase, it can save a lot of time and money in the long run. [M](#)



Why Design for Manufacturability?

By Mouser Electronics with Andrew Williams, Electrical Engineer at Berken Energy



WHY DESIGN FOR MANUFACTURABILITY?

By Mouser Electronics with Andrew Williams, Electrical Engineer at Berken Energy



Andrew Williams is an electrical engineer working for a start-up alternative energy company in Fort Collins, Colorado. Andrew received his bachelor's degree in electrical engineer from Purdue University. Andrew currently works with a small team focused on the design and manufacturing of thermoelectrics and provides solutions to quality control and device testing. When not working, Andrew enjoys building and playing modular synthesizers, and is a Wilderness First Responder. He can be found exploring Colorado's mountain biking and backcountry skiing.

Engineers working to turn their great ideas into great products perform two kinds of engineering work. One is designing for development, which focuses on building working models that meet all the device's functional requirements. The second is designing for manufacturability (DFM), which focuses on creating working models that can be manufactured in large volumes. Creating a successful product requires both types of engineering. The difference between the two is really the difference in the problems they are trying to solve.

When you design for development, you are proving that your idea can work and you are figuring out how to make it work (**Figure 1**). You are thinking about what the hardware and software must do to deliver necessary functionality, as well as how users will interact with your device. As you refine the design, you are working toward creating looks-like-works-like prototypes. You probably start by using familiar components or what you have available, just to get the thing working.

DFM needs to solve a different set of engineering problems. Andrew Williams, Electrical Engineer at Berken Energy, describes DFM in this way: "It is designing the product so that it's easy to manufacture, making assembly as simple as possible, making it so it fits into test jigs, selecting components based on cost and performance, and working out your supply chain. It's like a project management approach to design, with the goal of reducing cost and time to market." Inadequate DFM can result in many issues that will potentially disrupt production, including last minute

design changes, inability to get the parts you need, unexpected lead times for parts or sub-assemblies, and high failure rates of product coming off the assembly line. "It's preparing for anything that can happen," says Williams. "Any issues that come up, if you haven't prepared for them, they are definitely going to increase your project timeline."

DFM focuses on several key areas, including:

- **Component selection** – Many components used in the initial development work are very likely not optimal or even suitable for a manufactured product, so part of the DFM process is selecting the exact components that will be used in manufacturing (**Figure 2**). There are a number of factors that influence component selection, including cost, availability, quality, and how they fit in the finished design. The importance of these factors may vary for the type of product you are designing. For example, Williams' company is designing a product that captures waste heat from industrial processes and converts it to electricity. "For us, cost and the ability to work in industrial environments is important. Our devices will be exposed to high temperatures and possibly fluids like oils or water. So we need components that will work reliably in these conditions." Availability is a big factor too, and it's a good idea to have a contingency plan for what you will do if a key component is phased out by its manufacturer. Second sourcing is another way to ensure component availability by always having another source for a component if one supplier runs out. "I like to get at least three quotations from different vendors," Williams

"When manufacturing begins, you need to be able to test products coming off the assembly line."

explains. "Having that secondary source, cost, and lead times for components is a big part of DFM."

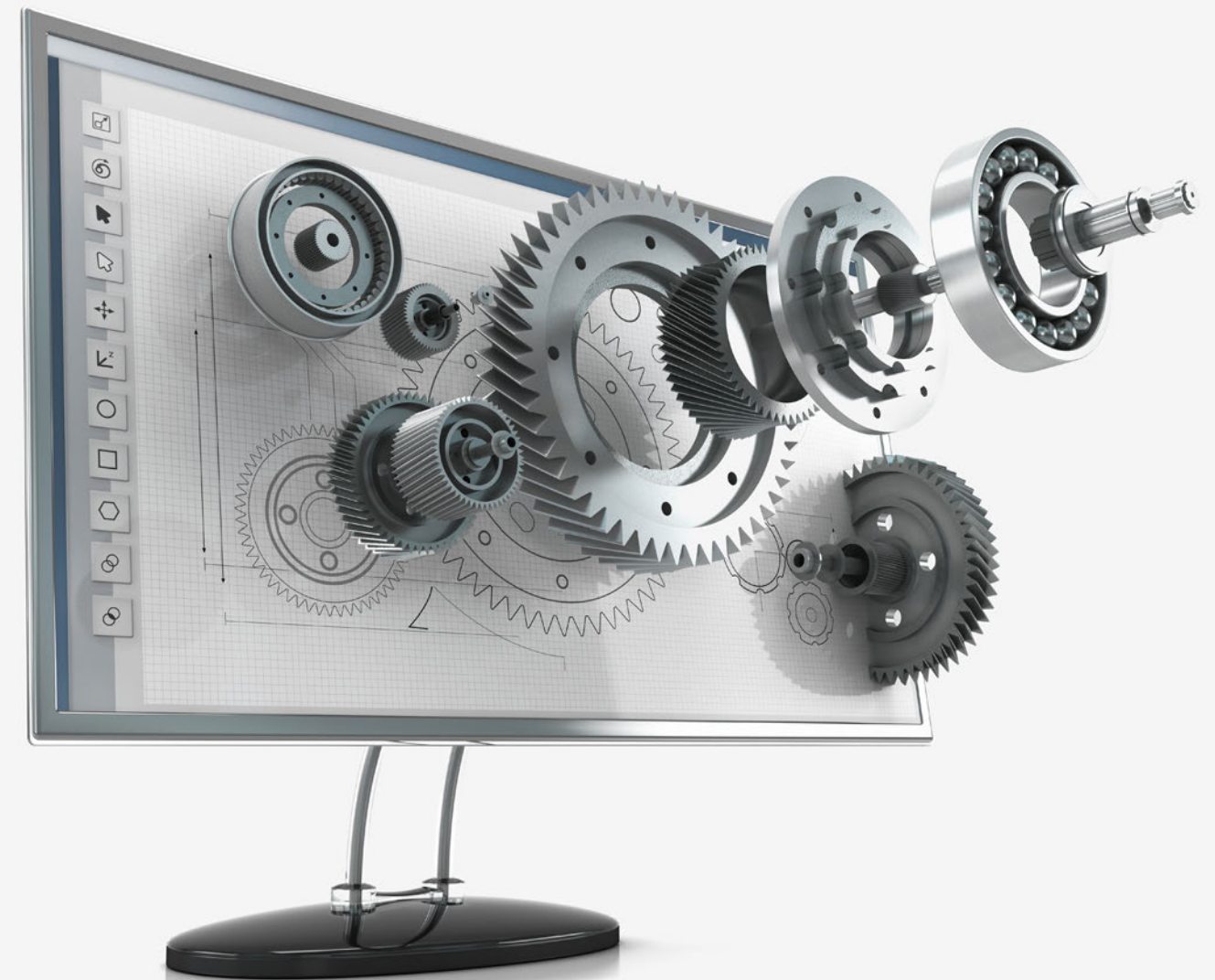
- **Developing testing procedures** – When manufacturing begins, you need to be able to test product coming off the assembly line. This includes creating test procedures and test jigs that work with finished products. "QA is a big aspect of DFM," Williams says. "Not only being able to test product, but also being able to perform statistical analysis on what's working, what's breaking, and how the process is performing. Designing this capability into the product and the manufacturing process is a key part of DFM."
- **Planning for certification** – Most devices require some kind of certification, whether it's basic Underwriter Laboratories (UL) certification, Federal Communications Commission (FCC) certification for wireless devices, or special certifications required by countries where

you plan to sell your product. The certification process can be costly, and it can take months, but it must be completed before you begin manufacturing. Planning for certification is an important part of DFM. It can also influence component selection. For instance, choosing pre-certified components can reduce the time and cost of certification.

- **Choosing a manufacturer** – A key part of DFM is choosing a manufacturer, not only because you need the right manufacturer for your product, but the manufacturer themselves can often make suggestions about component sourcing and design considerations that can streamline the process. One of the most basic considerations is whether you should manufacture overseas or on-shore. Overseas manufacturers offer significant cost advantages, but they come with logistical challenges. It partially depends on the product you

[CONT'D ON NEXT PAGE]

Figure 1: The first design may not be the best design for manufacturability.



are manufacturing and how many you are producing. Williams says, "In our case, being in power generation, we like to keep as much production state-side as possible, so we can keep a close watch on tolerances of our finished product, and it simplifies shipping and tariff management." There are other considerations too. For instance, it's a good idea to select a manufacturer that is familiar with your market space, and Williams likes manufacturers that have additional capabilities they may need in the future. "I like keeping everything in one shop if possible," he says. "Ideally I would like to try to find a shop that can handle multiple tasks if needed." Their ability to be flexible on production runs, especially early on, and their willingness to collaborate on manufacturing decisions are also important considerations.

"DFM is a critical part of product development that is no less important than designing for development."

at what capital equipment might be needed, or what kind of processes will be needed to build it, whether they are going to be labor intensive or if they can be automated. He will be doing that in the context of component selection. "You can't pin everything down too early in the process," he explains. "You want to try to keep things as modular as possible, so if you need to make a design change, you're not starting from scratch."

DFM is a critical part of product development that is no less important than designing for development. It is essential for ensuring that a good product design does not fail because of a poor manufacturing strategy. However, DFM can be tricky. It requires looking at many aspects of a product design, and it requires making decisions that are often trade-offs.

Looking Forward

Balancing the many considerations that go into DFM is the key to product success. The following articles explore some of the more challenging aspects of DFM, including meeting certification requirements, choosing components, choosing a manufacturer, and launching a product. [m](#)

DFM happens in parallel with the design for development, but it becomes increasingly important as prototypes mature and you come closer to beginning production (Figure 3). Williams starts thinking seriously about production considerations after the project concept has solidified. He says, "For me, DFM is an evolving idea as the product progresses throughout its life cycle." As soon as the product concept is well defined, he begins looking

Figure 2: Part of the DFM process is selecting the components that will optimize the manufacturing process.

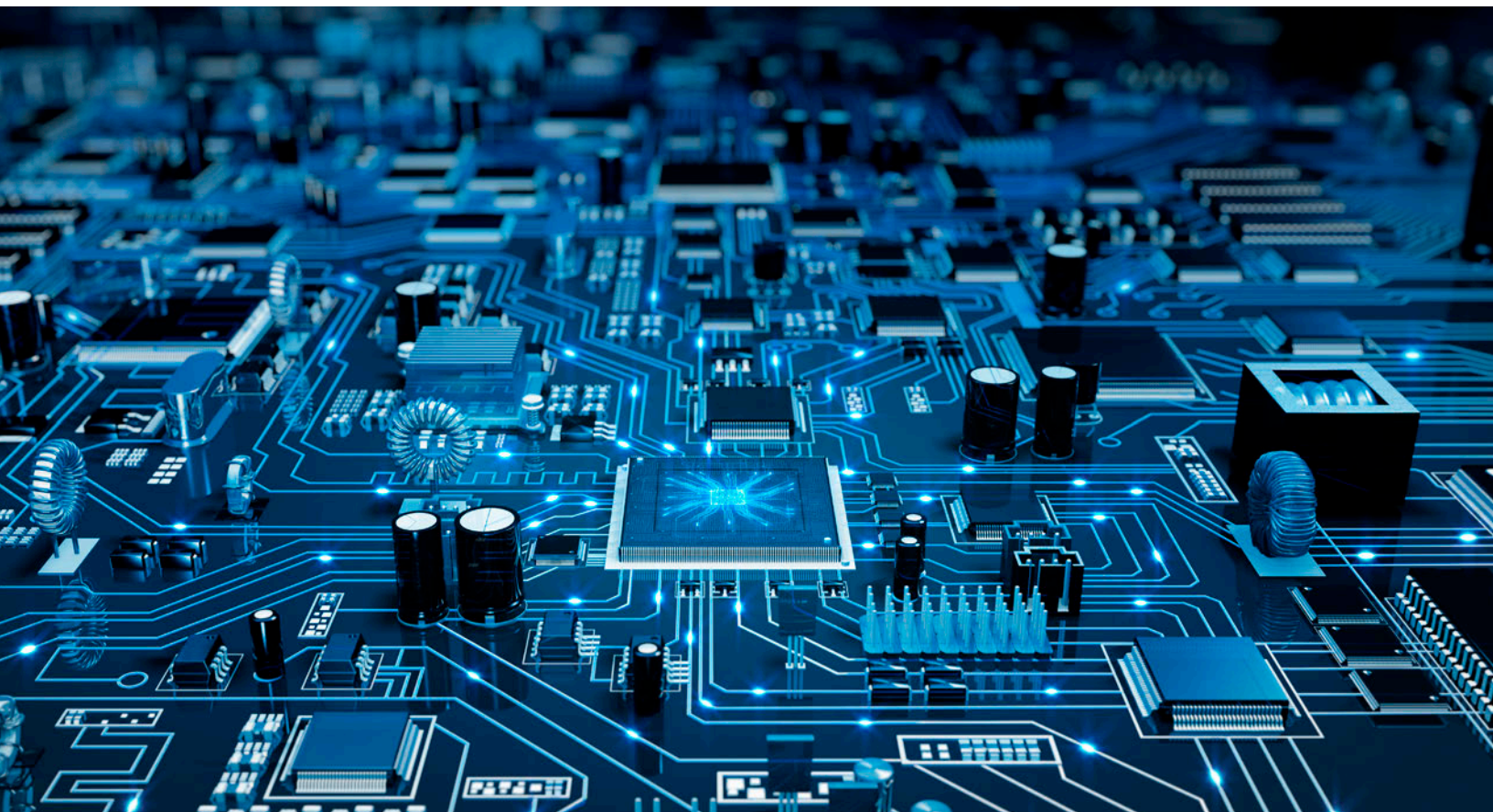
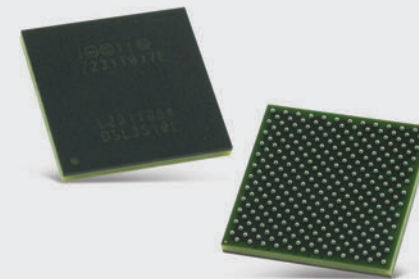


Figure 3: As the prototype design matures, manufacturability becomes increasingly important.



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Meeting Certifications and Regulatory Requirements

By Mouser Electronics with John Teel, Founder and Lead Engineer at Predictable Designs



MEETING CERTIFICATIONS AND REGULATORY REQUIREMENTS

By Mouser Electronics with John Teel, Founder and Lead Engineer at Predictable Designs



John Teel is the founder of Predictable Designs, a company which helps entrepreneurs, startups, makers, inventors, and small companies develop and launch new electronic products. John was formerly a senior design engineer for Texas Instruments where he created circuit designs now used in millions of popular electronic products (including some from Apple). In fact, you probably own a product or two that uses one of his designs. He is also a successful entrepreneur who developed his own hardware product, had it manufactured in Asia, and sold in hundreds of retail locations in three countries.

When preparing a device, product, or component for manufacturing at scale, one essential step you must complete along the way is getting appropriate product certifications. Certification testing provides assurance that the device can operate safely and that its operation will not interfere with other devices in its normal operating environment. Read on to learn about some of the strategies you can employ to ensure your invention meets regulatory requirements and obtains the necessary certifications.

Understanding Regional Certification Requirements

Different countries have different certification requirements. To ensure the success of your product, you need to have certifications that are relevant to the regions where they will be sold and used.

The following section lists some of the key certifications you are likely to encounter. Some certifications are legal requirements, such as

the Federal Communications Commission (FCC) certification in the US for devices that emit radio frequency (RF) signals. Others, such as UL certification, are not legally required, but market expectations make them a necessity.

“...you need to have certifications that are relevant to the regions where they will be sold and used.”

- **UL** – Underwriters Laboratories (UL) test the safety of products that plug directly into AC line power. US retailers will not carry electronic products that do not have UL certification and many businesses have policies that only UL certified equipment can be installed on their premises. “Although UL certification is not a legal requirement, no retailer will carry the product if it doesn’t have that UL certification,” says John Teel, Founder and Lead Engineer at Predictable Designs. “It’s pretty

much forced on manufacturers, and it’s necessary to offset product liability.” Insurance companies may require UL certification as a condition of insurance coverage. Some local electrical codes require UL certified equipment in certain kinds of construction.

- **CSA** – Canadian Standards Association is Canada’s equivalent of UL. CSA and UL certifications are interchangeable in North America. Both Canada and the US recognize each other’s certifications, but neither certification is recognized in Europe.
- **FCC** – Federal Communications Commission sets standards for RF radiation from electronic devices. This includes devices designed to transmit RF signals, such as wireless devices, and devices containing oscillators or microprocessors that radiate ambient RF noise. Meeting FCC standards is a legal requirement. “There are two broad types of FCC certification,” Teel explains. “There’s



intentional radiator certification and non-intentional radiator certification. If the product intentionally radiates RF waves, it has a much stricter certification process that costs more than if it’s a non-intentional radiator. They are two different certification processes.” FCC certification is not recognized in Europe.

- **CE** – Conformité Européenne is a European Union certification that combines elements of UL and FCC. Products sold into the European market must carry the CE certification.
- **RoHS** – Restriction of Hazardous Substances is a standard designed to minimize the use of certain hazardous materials, such as lead, in electrical components. Originally adopted by the European Union, it

has become part of CE certification. RoHS certification is also required for any products sold in California.

Major certifications have many different subtests that must be met to receive overall product certification. Some of these depend on how the equipment is used. For example, medical or industrial equipment will have different standards than consumer devices. There are also UL standards specific to components such as printed circuit boards (PCBs) and batteries. And of course, every country will have its own certification requirements. Qualified global testing labs, such as Intertek, are able to test to any national or regional certification requirements, and they will work with you to determine which tests you need to perform on your device.

Certification testing can be an expensive proposition, but there are things you can do to minimize its cost.

Certification Strategies

Preparing for certification can begin early in the design process, as you think about component choices and make design decisions. However, actual certification testing should not begin until very late in the game when your design is finalized, because any major component changes that happen after certification will likely require you to go through costly certification testing all over again.

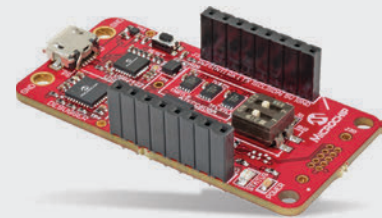
There are a number of decisions you can make during the design process to prevent late-stage changes and even reduce the amount of

certification testing you will need to perform. For example, when building a device that operates on low DC voltage, you could include AC to DC power conversion in the product package so the user simply plugs the device into the wall with a standard power cord. Alternatively, you could leave AC to DC power conversion out of the package and provide an off-the-shelf, UL approved external power supply. “All the AC to DC conversion is done by the certified adaptor,” Teel notes. “It’s an external part. Your product never really sees the AC so you don’t have to have the UL certification in there.” Regardless of how you plan for product usability, the second option using a pre-certified external power supply will result in your product requiring much less UL certification testing.

Another important strategy, especially when building wireless devices, is the use of pre-certified components. For example, let’s say your device has a wireless function. One option is to design the RF section yourself, which means you will have to get the costly intentional radiator FCC certification. On the other hand, you could use a pre-certified wireless module for your RF section. Your product still needs FCC certification, but you will only need to put it through the lower cost unintentional radiator certification testing. Teel says, “Using pre-certified wireless functionality is one of the most common ones because most people want to bypass that intentional radiator certification process. And wireless tends to be really tricky to design anyway, so having a module that’s already tested and working simplifies the design

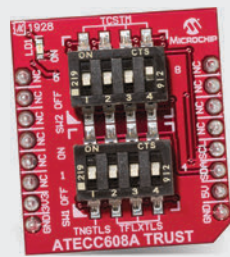
and speeds up time to market.” He also points out that when dealing with pre-certified wireless modules, you need to pay attention to antenna configurations used in their certification process. If you use a module without a built-in antenna, you will have to use the same antenna design and type that was used during the intentional radiator certification testing. “If you make drastic changes to the antenna over what they used when certifying that

“Using pre-certified wireless functionality is one of the most common ones [certification strategies] because most people want to bypass that intentional radiator certification process.”



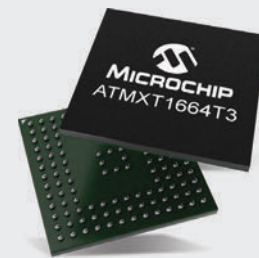
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module, then you will have to have your device re-certified,” says Teel.

In addition to selecting components with certification in mind, a key step for avoiding excessive certification costs is to do a design review before you begin certification testing. If your device fails a costly certification test, you will have to fix the problem and then test it again until it passes. Teel always recommends getting an independent design review. “No matter how good the designer is in designing your product, get someone else’s independent review. That review should be from someone who has experience with certifications. That’s definitely a smart move,” he says.

One other certification strategy is to use testing labs that are able to

provide testing for all the standards and markets you need to meet. In this way you can save through more efficient testing processes. For example, if you plan to sell your product in both North America and Europe and you need UL and FCC certifications, the lab performing those tests may be able to provide CE certification for a nominal additional fee.

Certification Testing in the Design Process

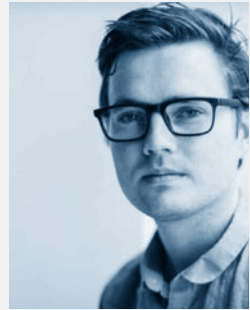
Certification needs to be on your mind from early in the design process so that you can make smart choices about design and component selection. However, you never want to begin certification testing until the design is absolutely final, typically after you have done

many rounds of prototyping. If you receive certification and then change a component that impacts those tests, you will need to re-certify your device.

You do not have to complete certification testing before making small pre-production runs of a hundred or a couple of hundred units that are being produced primarily for your own testing. But once you’re ready to scale up manufacturing and begin selling the product in a big way, you need to have those certifications. It’s when you are at that point of tooling up and preparing for the first large scale manufacturing run that you need to complete your certifications. [▶](#)

SELECTING COMPONENTS FOR MANUFACTURING

By Mouser Electronics with Mike Reed, Mechatronics Engineering Lead at HAX



Mike Reed is an Australian Mechatronics engineer based in Shenzhen, China. As a program director with HAX Accelerator, he helps hardware startups design, manage, and manufacture products ranging from the fields of Medtech, to infrastructural IoT and industrial robotics. His major focus for the last 5 years living and working in Shenzhen has been optimizing the development and prototyping process for local and international startup companies. Having multidisciplinary engineering and business planning experience with ~100 hardware startups paired with proficiency in spoken Mandarin allows him to jump in and add value at any stage of the development of a hardware-based business.

Design for Manufacturing (DFM) is a process of refining product design so it can be manufactured at volume in a way that delivers needed utility, fits unit costing models, and produces a reliable stream of products with a low failure rate. A key part of achieving these goals is component selection.

Choosing components for manufacturing begins with recognizing the difference between designing for development and designing for manufacturing. Mike Reed, Mechatronics Engineering Lead at HAX, explains it this way: “When you’re designing for development, engineers often choose parts they are familiar with. They

use modules and controllers they’ve used before because it makes development easier.” But once you’ve got working prototypes, you often find that those components used in development don’t meet other requirements. It may be that they don’t fit in the final product package size, or that they’re not suitable for the environment

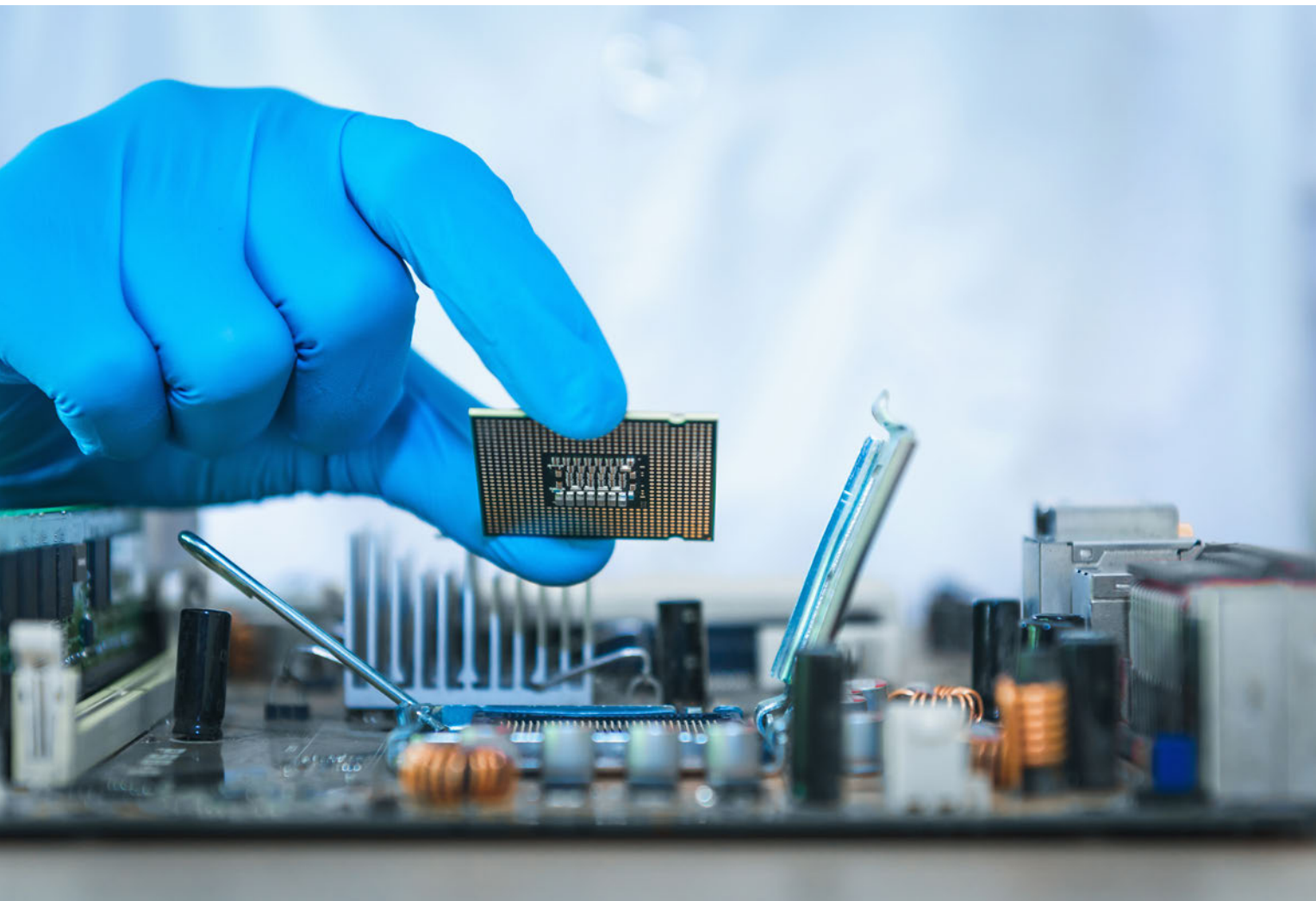
where the product will be used. “That’s when you have to start making decisions,” says Reed. “There may be components that simplify the design, but they cost more, or it’s more difficult to develop with them. Now you have to make compromises.”

Choosing components for manufacturing involves a number of tradeoffs, including the component package, cost, quality, and availability.

- **Cost** – Component cost is always important, and influenced by many factors, including availability, gray market sourcing, and the nature of the parts themselves. You have a lot of choices with a highly commoditized part like an amplifier or a low drop-out regulator. The schematic may not even specify a specific part number. On the other hand, the design may call for a specific branded part that is expensive, though you can look for equivalent lower-cost off-brand parts, comparing specifications and making judgments about their reliability and availability. Reed says, “It comes down to how risky you want to get with these decisions, and how important cost is to you.”
- **Size** – Component size is often dictated by the design. “If you’ve already locked down what you’re using for your charging circuit, what you’re using for your microcontroller, you’re going to have limited options,” Reed explains. In that case, you need to be sure the size that you’re looking for is something that is immediately available in your supply chain, and it is not a package the manufacturer plans to discontinue. Reed cautions against using smaller, surface mount technologies just because they look more professional. Packages like QFP/SOP create assembly and inspection challenges you don’t have with larger packages, which is the tradeoff. If space constraints do not prevent you from using the larger component, then you should go with the larger component package. Reed notes, “It’s not just changing a number on a sheet. It’s changing how someone needs to inspect and assemble this thing, and how difficult it is for them to rework it.”
- **Quality** – Quality and cost often go hand-in-hand. Through their own experience, engineers often have trusted brands. But what if a cheaper option is

available? Choosing alternate parts means digging into their specifications. Sometimes specifications and warranties are not so clear on off-brand parts, and then it comes back to weighing the risk of a potentially lower quality part against the application. Using the component in an inexpensive toy is different than using it in an industrial controller that must be highly reliable. Reed says, “There are times when having and trusting that extra information is just as valuable, if not more so, than reducing component costs.”

- **Using Pre-Certified Components** – Selecting pre-certified components is important, especially for devices that have radio frequency (RF) connectivity. That’s because certification is a costly, time-consuming process. Unless you are designing an unusual device in which no off-the-shelf modules will work, it’s best to use pre-certified components. “It’s almost always the best choice,” says Reed. “Not only will you avoid jumping through the certification hoops, you won’t have to create your own design for that section.” There’s another aspect of pre-certification to consider as well. Once your device is certified, any changes to the bill of materials (BOM) can invalidate the certification. To avoid that, when you submit a device for certification, include a list of alternate components you could swap out without changing the performance characteristics of the device. This doesn’t mean you have to build samples of all the different types, but it does require providing enough information for testers to confidently judge that those component changes would not affect test results. They can certify your device for all the different component options you provide. “This gives you flexibility during manufacturing,” Reed says. “Under those circumstances, swapping approved parts in your BOM is entirely within the scope of your certifications.”
- In addition to balancing these criteria, you must also consider part availability and strategies that minimize the risk of supply problems.



Component Availability and Second Sourcing

One of the most important considerations in component selection is component availability and preventing supply problems that interfere with production. Many factors can disrupt component availability. If you source a product from a foreign country, there can be tax and customs issues that delay delivery. Sometimes a branded part appears to be available because the manufacturer is shipping lots of them, but you might find that only one or two customers are buying them, and as soon as those customers are no longer interested, the part will be phased out. Manufacturers may only produce a certain number of parts a year. When that supply runs out, there won't be more until their next production run. You may start using a critical part and then during production, you receive a product change notification that impacts your design. It is one thing if you are buying a half million or more of the part, but buying the part in quantities of tens of thousands will not give you much leverage over suppliers or manufacturers.

“Manufacturing without second sources can cause production delays and even force costly redesigns.”

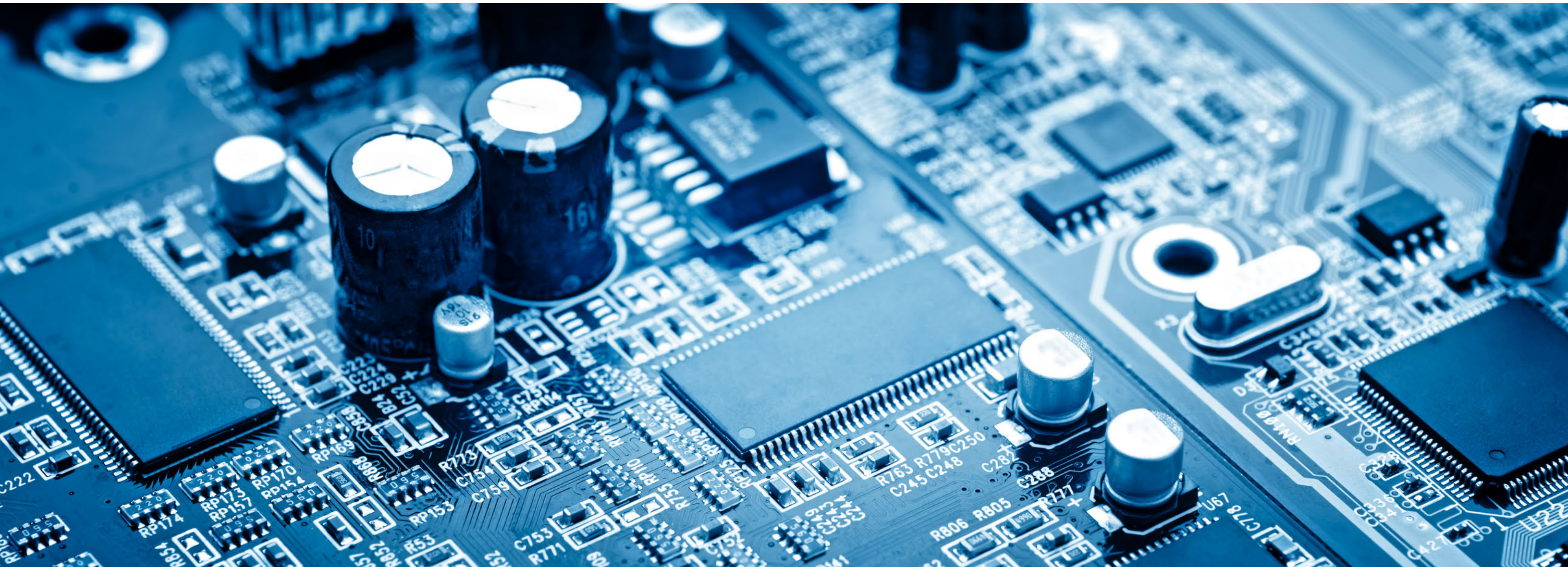
A key strategy for avoiding supply problems is second sourcing, which is assuring that you have a second source for components you use. Manufacturing without second sources can cause production delays and even force costly redesigns. The risk is significant. Reed points this out, saying, “Maybe you have 70 components in your board, which means there are 70 different points of failure. If you're ordering parts from a single source and you're not giving yourself any backups, the lack of one part can shut down production. It happens a lot.” By planning ahead, you can work out second source strategies for critical components. This often involves relinquishing some control over component choice. If you trust your supplier, this is a legitimate option. Good suppliers know

part ordering lead times and they will be aware of supply problems. If you specify components to the exact brand and part number, you limit their ability to solve supply issues. However, giving them flexibility in component selection can keep production going. Reed recommends reviewing your BOM with the supplier's engineers before you start manufacturing to identify potential risks and to work out a schedule for notifying you in advance of supply problems. He says, “This allows them to find secondary choices for components and verify them with you before taking them into production. All of this can be specified in your supplier contract. The important thing is to always have a plan for something going wrong.”

“Learning a new architecture too early just because you want to put that into your design is a bad idea.”

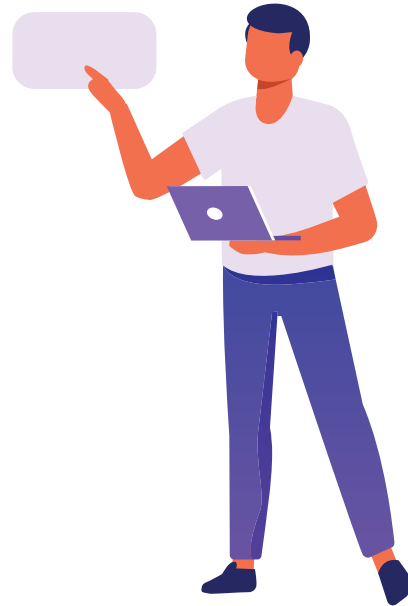
Component Selection as Part of DFM

In the early stages of designing and developing prototypes, it's important to prevent component selection from holding you back or boxing you in. If you know how to use a part, use it to speed the development process. “Learning a new architecture too early just because you want to put that into your design is a bad idea,” Reed advises. “If you're starting with an architecture that you're not familiar with, you can spend a lot of time developing it only to discover later it was a bad choice.” However, at a point when the design is proven and prototypes are working, you need to begin choosing components you will use when you start ramping up manufacturing, which is the time to start balancing cost, quality, footprint, pre-certification, availability, and sourcing. At that point, you should also be working closely with a trusted supplier. ▣



Choosing a Manufacturer

By Mouser Electronics with Michael Morena, Co-Founder of AdhereTech



CHOOSING A MANUFACTURER

By Mouser Electronics with Michael Morena, Co-Founder of AdhereTech



Michael Morena is an entrepreneur and technologist focused on bringing high-value IoT products to market. Starting his career at GE Aviation, Michael then co-founded AdhereTech, a medication adherence company. At AdhereTech, Michael developed an award-winning, cellular-connected, smart pill bottle to measure and improve medication adherence in real time. The bottle is used all around the country by tens of thousands of patients for top specialty medications. As a maker and hardware engineer, Mike enjoys constantly learning about hardware and creating projects at home and with friends.

One of the most important decisions you will make as you prepare your product for volume production is choosing a manufacturer. Many factors influence that choice, including whether the manufacturer has experience with products like yours, whether they are an on-shore or overseas manufacturer, and their overall reputation in your industry. In some cases, your principle customers will have something to say about who manufactures your product.

“When choosing a manufacturer, it’s a good idea to begin as early as possible.”

Choosing the right manufacturer is a key factor in a successful product launch (**Figure 1**). It can also be a difficult choice. Michael Morena, Co-Founder and COO of AdhereTech, likens it to hiring an entire team of employees all at once. If you are a small business suddenly hiring 10 new people, you wouldn’t do so without spending significant time vetting all 10 of them. But when

vetting a contract manufacturer, you may only ever speak to a few people.

involved in making your product successful.”

Figure 1: It can be very important who manufactures your final product.



“You might speak to a salesperson,” says Morena, “and maybe a business owner. You may speak to a technical project manager. Yet there will be a lot more people at that company

When choosing a manufacturer, it’s a good idea to begin as early as possible. This does not mean you have to wait until your design is nearly finalized, but to be taken




Figure 2: Figuring out the initial bill of materials before a final design can springboard negotiations with a manufacturer.

seriously by a manufacturer, you need to provide information about all major parts of your product in a bill of materials (BOM) (Figure 2).

“Everybody is surprised by the high cost when they get a quote back from a contract manufacturer.”

If you are still in the early stages of your product and have not finalized all aspects of your design, Morena advises putting information together based on a similar design, allowing you to move forward. “Many products are heavily leveraged from a reference design,” he says. “Take that reference design, use what you need from it and scrap what you don’t.” This does not require editing the schematic. It’s really about putting together an approximate BOM nicely formatted, doing a simple sketch of an enclosure, and writing up a simple document of how you would test the product. Present that to a prospective manufacturer, and they will either respond to you or not, based on the quality and level of detail that you put together. Morena notes that taking this step as early as possible gives you a reasonable idea of manufacturing costs and begins a dialogue with a manufacturer. “Everybody is surprised by the high cost when they get a quote back from a contract manufacturer,” he says. “If you’re not surprised, you’re missing something. Be surprised as early as you can. Work that into your costing model. If it still makes sense, move forward. If not, you need to change something.”

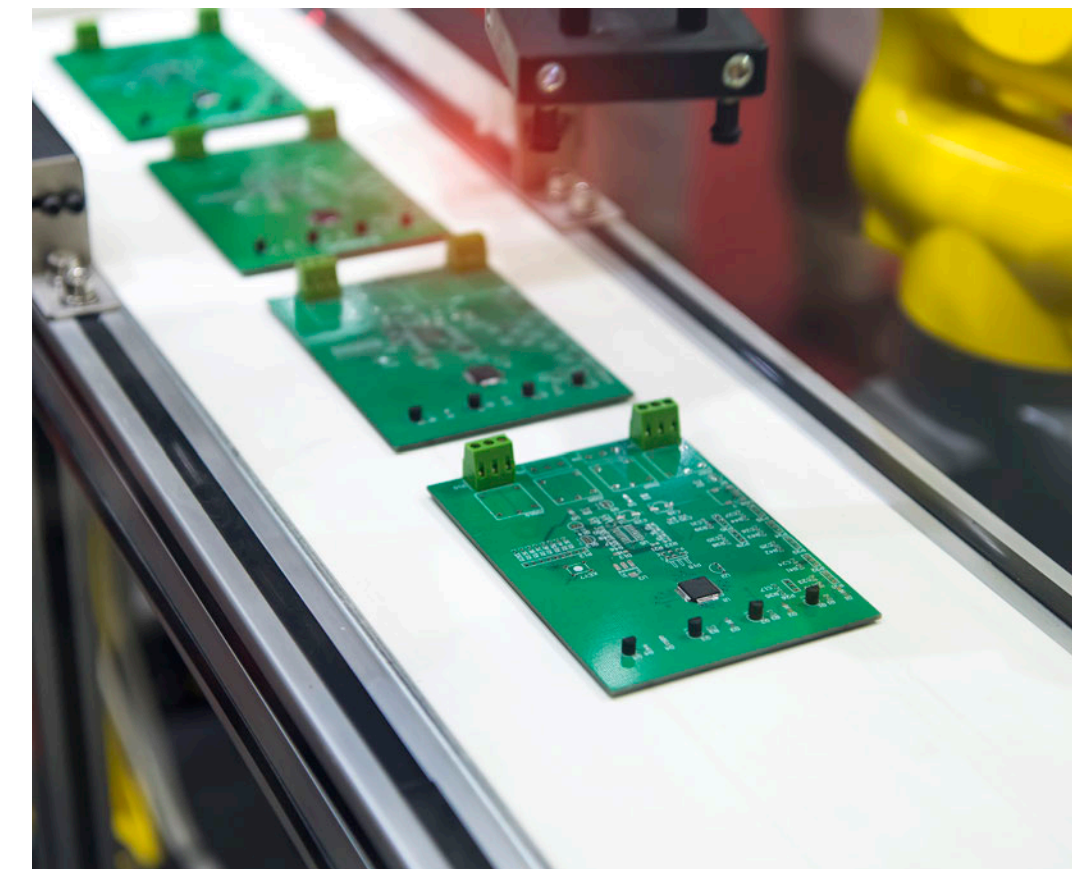
When selecting a manufacturer, there are two fundamental ideas you should keep in mind. First of all, contract manufacturers specialize

in manufacturing things. “You are probably not going to be an expert in all things a contract manufacturer knows,” Morena explains. “They may not be great at designing products, but they are really good at making the same thing over and over tens of thousands of times. You really want to roll that feedback and expertise into your design, if possible.” The second thing to look for in a good manufacturer is their ability to manage a supply chain. Manufacturers know how to maintain inventories of materials they need to keep production going. Morena advises, “You want to find a contract manufacturer who is like a bank for you. You want someone that’s going to give you good payment terms and that’s going to purchase inventory. You don’t want to be consigning materials for them. You want them putting material in inventory and converting it into finished goods.”

Beyond these fundamentals, there are several other key considerations:

- **Local vs. overseas** – There are advantages and disadvantages to both. Costs and lead times for tooling are typically much lower when manufacturing overseas, and specialty services like clean rooms are a fraction of the cost. Some places offer big supply chain advantages such as volume discounts (that can be passed on to their customers in the form of a lower cost of individual components) and access to a wider range of product options. But these advantages can be offset by logistics challenges of working with overseas factories, shipping, and tariffs. The overseas option often design, if possible for large production runs. Tooling costs and lead time can be a big disadvantage in US-based manufacturers, though factory access may be easier. Some big tier-1 manufacturers offer both options. “I’ve worked with manufacturers who have a presence in the United States or the EU, and they also have factories in

[CONT'D ON NEXT PAGE]





to business,” says Morena. “Your customer might be extremely diligent or they may be used to working with certain types of vendors that involves evaluating you as a potential supplier based on who your suppliers are.”

One other aspect of selecting a manufacturer involves negotiating a manufacturing contract (Figure 3). It’s best to keep these contracts as simple, clear, and transparent as possible. Terms need to include:

- **Pricing** – Transparent pricing is best if you can get it, so that you can see what they’re paying for material, labor, and overhead, their profit, and get a clear picture of their value add. This would include both sample pricing and production pricing.

- **Payment terms** – Specify payment terms for both current and future orders.

- **Quality** – Outline clear terms on workmanship, what justifies a return, and what constitutes a defect.

- **Liabilities** – When the product leaves the factory, whose liability is it? Also, the contract should specify how you deal with excess materials

“Creating a schematic is just the beginning of the design process.”

Selecting the right manufacturer can have a big impact on the quality and cost of your finished product. A manufacturer can also play a big role in the success of a product launch, which is the focus of the next article. ■

notes Morena. “They service customers at all those facilities, typically starting them out small in the US. If the day comes when you need a million pieces, they just move all the material to another place and start producing it there.” If you can find a contract manufacturer that’s willing to start you domestically and then move the work overseas when it makes sense to do that, letting them manage the logistics is a great advantage.

- **Familiarity with your technology** – You want a manufacturer that can talk to you about the technical details of manufacturing and assembling your product, and who will work with you closely to get it right. It’s important to choose a manufacturer with capabilities

and experience manufacturing products like yours. Familiarity with your market space is an advantage because they will understand some of the constraints unique

“...choose a manufacturer with capabilities and experience manufacturing products like yours.”

to your product and market. The manufacturer should be in a position to offer you advice about optimizing the manufacturing process for your product. Finding a manufacturer that fits the bill can be difficult if you don’t have a network. There are online directories, but Morena recommends going to manufacturing trade shows where you can talk to people about

manufacturing processes and start building a network. “Reach out early and often, and establish those relationships.” he says.

- **Sometimes it’s your customer’s preference** – In some cases, particularly if you are manufacturing a device that has a critical application like medical equipment or an industrial control device, your primary customer may specify that it be produced by manufacturer they know and accept. “It matters most when you’re selling business



Analog Devices Inc. ADPD4000/1 Multimodal Sensor Front End
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Launching Product Production

By Mouser Electronics with Michael Morena, Co-Founder of AdhereTech



LAUNCHING PRODUCT PRODUCTION

By Mouser Electronics with Michael Morena, Co-Founder of AdhereTech



Michael Morena is an entrepreneur and technologist focused on bringing high-value IoT products to market. Starting his career at GE Aviation, Michael then co-founded AdhereTech, a medication adherence company. At AdhereTech, Michael developed an award-winning, cellular-connected, smart pill bottle to measure and improve medication adherence in real time. The bottle is used all around the country by tens of thousands of patients for top specialty medications. As a maker and hardware engineer, Mike enjoys constantly learning about hardware and creating projects at home and with friends.

Product launch happens after you've perfected an idea, validated it, built and tested it, proven the market for it, and refined the design to a point where it can be cost-effectively manufactured. By this time, stakeholders have invested significant time and money to make the innovation ready for manufacturing, including resources spent on prototyping, tooling for manufacture, and certification testing. Product launch is an important milestone, and it is also a risky one, though only a prelude to what comes next.

As production begins, manufacturing costs rise rapidly, which means you have to generate revenue through

Figure 1: Marketing for your product will be well underway before the manufacturing is complete.

product sales. You started preparing the market early-on during design validation, and you expanded market outreach during prototyping. By the time you are ready to begin manufacturing, sales and marketing initiatives will be well underway, and you may already be taking orders for your product (**Figure 1**).

From a manufacturing perspective, you are ready to begin product production. However, production doesn't just suddenly start. It typically begins with a pilot production run, which some refer to as pre-production or production validation testing. Pilot production is a short production run using the exact tooling, processes, and materials you will use to produce units for sale, though the pilot production units will not be sold. They will be subjected to another round of testing. Once pilot production tests are complete, production begins with one or more limited production runs.

The manufacturer you have selected has a key role to play in ramping up to full production. Michael Morena, Co-Founder and COO of AdhereTech, explains it in this way: "With their understanding and management of supply and materials, your manufacturer can plan for both pilot production and production. They will get you through building and testing those units, and when everyone is happy, they'll be ready to move into production with minimum risk."

[CONT'D ON PAGE 36]






Figure 2: Slight changes will happen after testing the initial production runs.

Pilot Production

Pilot production begins only after you have completed prototyping and design review, validated all the design requirements, tooled up for production, and completed some pre-certification testing.

“Many of the tests you perform on pilot units are technical, for verification and validation.”

In the course of this pre-production work, you will develop checklists that include all the tests you must perform for design and quality validation. “You go through as many of your tests as possible,” Morena says. “Some you can do on your prototype, and some may have to wait for the finished product. You note which tests you have and have not completed. When you get through all the tests and they all pass, with some exceptions, then you’re ready for pilot production.”

The number of units you build in the pilot run depends on the nature of the product. It could be 50, 100, or 1000. It is the number you need to perform all your tests and have some level of statistical process control over test outcomes. “You’re going to practice building the product with every process and tool and fixture as if you’re producing the finished production units,” says Morena. And all those tests you developed before pilot production will now be run again on the pilot units. The goal is to find problems that did not turn up during prototyping. For example, you might find that a subscriber identify module SIM card connector that worked great in the prototypes is failing in 3 out of 100 of the pilot production units. In looking closely at those failed units, you may find it’s a soldering problem that is easily fixed by slightly modifying pad thickness on the connector footprint. This becomes a slight change in the PCB design (**Figure 2**).

Many of the tests you perform on pilot units are technical, for verification and validation. You will also perform user acceptance testing with some of the pilot units to verify the results of earlier prototype testing and see how users respond to final packaging. You will also send off pilot units for compliance and certification testing. You may already have done some pre-certification testing on prototypes to catch problems that would cause the units to fail certification, although that step adds extra cost to the development process. “This is all very expensive,” Morena says, “but if you want to really reduce risk and

if you’re going to be in the volume manufacturing game, \$10,000 testing is not a lot. It’s totally worth it if you’re producing a million dollars’ worth of product.” It’s an important consideration because by the time you have reached pilot production and certification testing, you don’t want to be forced into making changes that affect processes or tooling.

Once your pilot units have passed all their tests, you have received the compliance certifications you require, and both you and your manufacturer are happy with the pilot production process and output, you are ready for production.

Production

One of the toughest decisions you will face when you begin making real production units is knowing how many to produce. The answer is based on the way manufacturers like to manufacture, and it is deeply rooted in the basic assumptions of your business model. First of all, manufacturers like to balance their manufacturing load. In Morena’s experience, people often have a misconception about how manufacturing should go. “A lot of people think of production in fits and starts,” he says. “That’s not the right way to think about it. You should think of production as a regular cadence. No manufacturer wants to work with you to produce 10,000 units. They want to produce X units per month or X units per quarter.”

“Plan your first and second production runs together...”

So the question becomes, how many units is X? The answer goes back to a calculation you should have performed at the very beginning of your project. Morena sees it this way: “Plan your first and second production runs together with the understanding that by the time you sell all those units, you will have recovered all of your capital expenses.” Morena notes that this calculation has nothing to do with marketing or sales. It is a calculation of the number of units you need to produce based on costing and profits.

For example, let’s say that based on the profit you will make from each unit, you need to sell 1000 units to cover all of your capital expenses. You would then plan two production runs (**Figure 3**). The first one would be 200



Figure 3: Plan out production runs to ensure that you generate revenue.

“You need to be comfortable with the amount of throughput you’re going to sell within a certain amount of time.”

units and the second one would be 800 units, with the goal of selling the first 200 units in the time frame it takes to build the next 800. If you look at that plan and say ‘I can’t possibly sell those first 200 units that fast,’ then there is something fundamentally wrong with your model. Either your pricing is not right, or your cost is too high. “You need to be comfortable with the amount of throughput you’re going to sell within a certain amount of time,” says Morena. “If the numbers don’t make sense, even on a napkin sketch, then you need to rethink what you are doing.”

This is a quick and easy calculation that helps you determine the ideal size of your first couple of production runs, but it also works to validate your product concept,

which is why you should perform a calculation like this early before you invest a lot in product development. Morena points out, “If you can’t start a business that covers your capital and costs, then you don’t have a business. If it looks favorable at the beginning, then from that point, you need to develop a product with profitable unit economics.”



When to begin launch preparations, and what comes next

Product launch may be one of the final stages of a product development cycle, but it is something that innovators need to be thinking about from the beginning. Most engineers are much more comfortable drawing a schematic than doing these kinds of feasibility calculations and market development. But success depends on all these factors.

“If you can’t start a business that covers your capital and costs, then you don’t have a business.”

Once you are in production, you have entered into a new phase, but the engineering work is not yet done. Now begins sustainability engineering, which is the focus of the next article (**Figure 4**). ▣

Figure 4: Launching a product is one of the final stages of the design process.



Product Improvement through Continuous Innovation

*By Mouser Electronics with Michael Parks, Senior Vice President of Engineering Design,
Green Shoe Garage*





PRODUCT IMPROVEMENT THROUGH CONTINUOUS INNOVATION

By Mouser Electronics with Michael Parks, Senior Vice President of Engineering Design, Green Shoe Garage



Michael Parks, P.E. is the owner of Green Shoe Garage, a custom electronics design studio located in Southern Maryland. He blogs and occasionally podcasts at Gears of Resistance, a site dedicated to raising public awareness of technical and scientific matters. Michael is also a licensed Professional Engineer in the state of Maryland and holds a master's degree in systems engineering from Johns Hopkins University. Most importantly, he gets to be a dad to his daughter Hailey.

Does product launch represent the end of the ideation-to-productization cycle? Your innovative idea is validated, designed, and prototyped, it has been readied for manufacture, manufacturing has begun, and it has been launched into the market. With manufacturing underway and sales revenue coming in, you may feel tremendous relief that the hard work is finally finished. Maybe you are already working on a new idea.

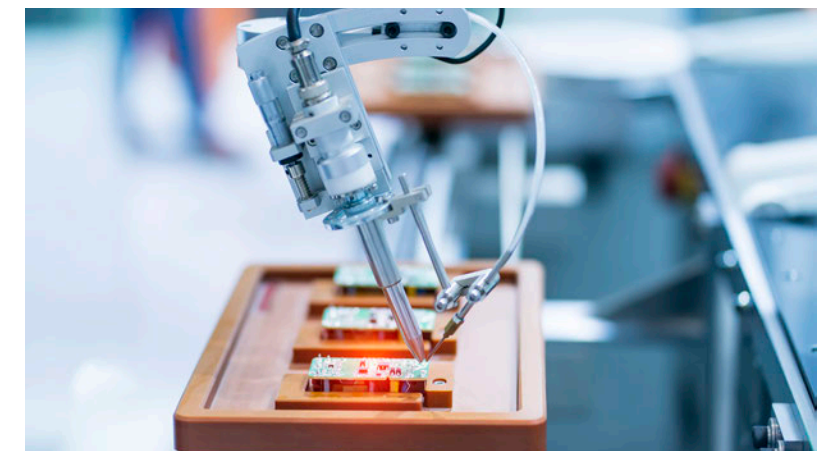
However, the engineering work is not yet done.

Manufacturing Refinement

From a manufacturing perspective, the ultimate success story is a product that launches on time with no quality issues. That is the goal, but it almost never happens that way. "Something always goes wrong on the first production run," says Michael Parks, Senior Vice President of Engineering Design. "You need to have someone on site sitting with the factory personnel to get that first production run correct." Common problems are often basic things, like components getting installed backwards, or a variety of problems that can result in finished products having a high failure rate (**Figure 1**).

Beyond these initial production problems, there will inevitably be fine tuning of the production process itself to increase output and reduce unit costs. Manufacturers

Figure 1: Industrial robot installing electronic components on a production line.



are always measuring themselves in a variety of ways to help drive efficiency. Factors used to grade manufacturing success include product yield, which is the ratio of good units compared to faulting ones coming off the assembly line, manufacturing throughput, percent reduction in manufacturing cycle time, manufacturing capacity utilization rate, and other measurements. Parks notes, "Many companies have a schedule attainment score or production attainment score. They set a goal for making a certain number of widgets in a certain time period, and then they adjust the process to reach this goal."

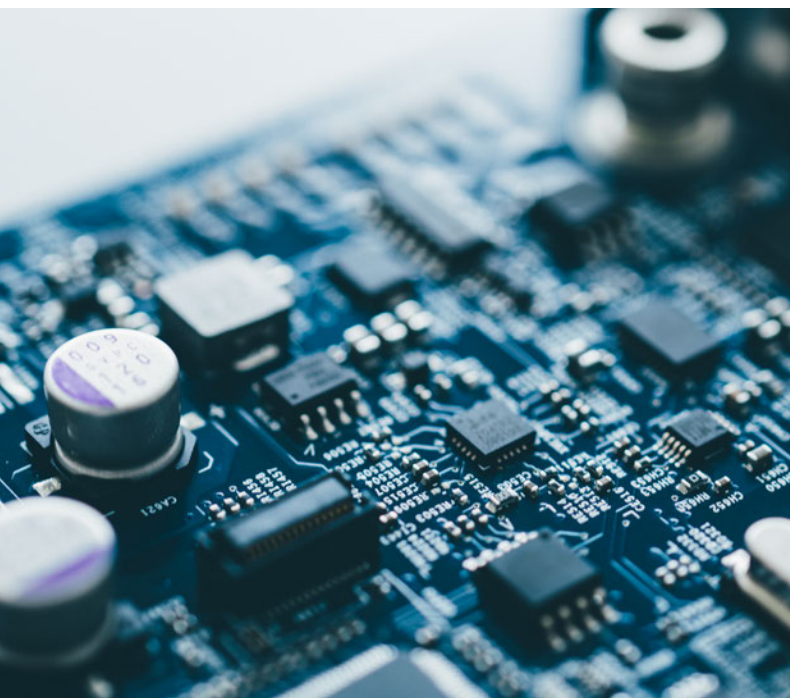
Some minor aspects of a manufacturing process, such as minor part swaps, might happen during a production run. More significant changes, like product revisions that might involve some retooling of the assembly line, happen between production runs. “After a production run, you stand down and then ramp up for another run,” explains Parks. “There are always lessons to be learned about the manufacturing process. You may want to do retooling to make things a little simpler to build. A lot of changes are made to find better ways to build the widget.” Some of these changes depend on the size of the production runs. Parks recommends keeping initial production runs small until issues that affect manufacturing cost, efficiency, and product yield are ironed out.

“There are always lessons to be learned about the manufacturing process.”

Sustaining Engineering

A key role in ongoing product production is that of the sustaining engineer. “The sustaining engineer sits at the intersection of engineering and logistics,” says Parks. “They take the long-term view of product sustainability.” In addition to ensuring that parts are always available for the product they support, sustaining engineers are at the forefront of troubleshooting and understanding

Figure 2: Sustaining engineers provide the technical support for the manufacture, delivery, and ongoing performance of the final product.



“The sustaining engineer sits at the intersection of engineering and logistics.”

issues with products, especially issues that affect product yield. Parks says, “They are responsible for collecting the maintenance and failure data, and performing root cause analysis to understand why there are shortcomings. They may even be required to come up with design changes to address those issues.” For example, widgets in production might suffer from consistent failures of parts. If some of the products exhibit failure caused by the same components, it’s necessary to dig in and find out why that is happening. It might be the failures are caused by bad batch of components. The failures may be localized to devices built with components from that lot. On the other hand, it may be a design flaw in which the part was incorrectly specified in the bill of materials that went to the printed circuit board assembly (PCBA) manufacturer. Or it could be a failure in the PCB layout itself. The sustaining engineer needs to sort through these possibilities to come up with a solution for the problem (Figure 2).

Other problems the sustaining engineers must address are forced hardware changes. For instance, if a component manufacturer changes a component design or discontinues a component, it will be necessary to find a suitable replacement. This is why it is so important to have second sources for components and lists of component substitutions that are acceptable for certification. In addition to hardware changes, the sustaining engineer may need to manage firmware updates.

“...it is so important to have second sources for components and lists of component substitutions that are acceptable for certification.”

Depending on the product and industry you support, the need for sustaining engineering could be measured in months, or in some industrial and defense products, it could last decades.

Continuous Innovation

In addition to refining the manufacturing process and having a mechanism for sustaining engineering, another post-launch activity involves improving the product design. This is effectively an extension of the late-stage prototyping that lead to the first manufacturing-ready

[CONT'D ON PAGE 45]

Figure 3: Engineers analyzing which functions to implement in the next-generation product release.





customer engagement opportunities to understand why features are or aren't used. All of this data is valuable for designing the next version of your product (Figure 4).

“...product launch is not the end of engineering work needed to ensure success.”

Conclusion

A successful product is successful for a lot of reasons. Clearly product launch is not the end of engineering work needed to ensure success. In addition to sustaining engineering that supports ongoing production, there will be design and process adjustments to make manufacturing more efficient, improve yield, and reduce unit manufacturing costs. And of course additional design engineering will be required to make product revisions and specialized versions. A successful product creates its own ecosystem of ongoing engineering and commercial support that can go on for many years. ■

Figure 4: Data can be used to create targeted customer-engagement opportunities.

widget. As soon as a product goes into production and is launched into the market, you will begin collecting information about how it is being used and how it can be improved for customers.

“We look for user interface and user experience feedback.”

Parks explains. “The product might be working as intended by

the designers, but users may have difficulty with some aspects of it. That might require design modifications, like changing the placement of buttons, switches, or ports to make the product more user friendly.” This kind of post-launch product assessment is a continuation of innovation that happened before product launch.

During design and prototyping, you made decisions about which features and capabilities to include in the final product. Some functions may have been too costly to implement or would make the product too complex (Figure 3). During prototype testing, you may have decided to drop features that were part of the original design. After the product is launched, it may become

“During prototype testing, you may have decided to drop features that were part of the original design.”

feasible to add back a feature that was left out of the initial product release. You will also gain new insights about how people are using the product. With that information, engineers can find solutions to its shortcomings so that technology left out of the current generation will be ready for the next-generation product release.

There are many ways to collect user data, but one of the best for connected IoT devices is to build usage monitoring capability into the product itself. Parks says, “The Internet of Things is really going to be a boon for product designers to get actual usage data from their products without the need for customers to fill out a survey or some other manual feedback mechanism. Customer feedback about the user interface and user experience is what I value most.”

With IoT and ubiquitous internet connectivity, it's possible to have near real-time understanding of the features customers are using and the features they aren't. You can take that information and create targeted, data-driven

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