Providence Enterprise
Full-Service Global Contract Manufacturing

The Makings of a Successful Medical Device Design:

10 Dimensions of Excellence

While far more than just trendy jargon, “Design for Excellence” (DfX) fulfills two common buzzword criteria:

- ☑ A lot of people have heard it, but only a fraction of these really understand what it means.
- ☑ The concept behind it is actually pretty straightforward and based on sound business sense.

WELL-DESERVED **‘BUZZ’**

DfX has been defined in many ways to suit different purposes but basically it means what it says. Designing for excellence means taking a holistic approach to design and produce a device that achieves multiple strategic goals for multiple stakeholders.

Far from a sudden brainwave, DfX has been enhanced and perfected by over the years – decades, really – garnering vital lessons from real-industry insights, experiments, mistakes and successes. It applies practices based on the combined experience and observation of professionals in multiple disciplines who are directly involved at some phase of the product’s lifecycle.

Collaboration between disciplines has been key to the development of the DfX methodology. As such, design for excellence applies expertise to ten key areas or ‘dimensions’ at the earliest stages of development:

1. **Design for Manufacturing**
2. **Design for Cost**
3. **Design for Standardization**
4. **Design for Functionality**
5. **Design for Usability**
6. **Design for Quality**
7. **Design for Reliability**
8. **Design for Safety**
9. **Design for Testability**
10. **Design for Future**

MORE THAN A **CHECKLIST**

Naturally, within the list there are interdependencies. For instance, all 10 dimensions "design for cost" as they improve margins, reduce financial risks or do both. Furthermore, it is not their individual, but their combined benefits that result in a true design for excellence.

This guide examines the 10 dimensions, their benefits and risks of missing critical considerations at the design stage of a product.

10 DIMENSIONS OF **DESIGN FOR EXCELLENCE**

1 DESIGN FOR MANUFACTURING

Before a device can go to market it has to be produced. That may seem exceedingly obvious, and yet, many design fails to take this into account at early enough stages. In such cases a device that looks great on paper may end up being too complicated, too expensive, too slow or downright impossible to produce.

Design for Manufacturing (DFM) ensures feasibility and controls costs from the get-go by optimizing decisions and processes for parts, assembly and tooling.

DFM: Parts

The manufacturability of a product relies heavily on the manufacturability of its parts. If everything else is done correctly but one part of the device fails, cannot be manufactured or is delayed, the knock-on effects can disrupt the entire process and the device itself.

DFM looks at the specifications, functionality and reliability of each part individually that will be incorporated into the device. If the part is to be manufactured in-house, the design will consider production processes, machines and tooling. If the parts are to be acquired, DFM looks at cost, lead-time, quality and alternative sources in case they become necessary.

DFM: Assembly

Getting design for parts right is crucial. Making sure they work together is just as important. If parts are designed in silos without taking into account how they fit in with all other components the result is, once again, a device that cannot perform.

In the past, assembly was perfected (or reached its best attempt) at the prototype phase. In other words, it depended on costly and time-consuming trial and error. Simulation software now allows for design for assembly to occur at, yes, the design phase.
It ensures that the parts, once manufactured, can be put together to make a device of the expected level of quality and performance. The sophistication of this software is such that it can even demonstrate how well assembled pieces withstand stress, extreme temperatures, sound waves and more.

DFM: Tooling

Efficient tooling helps manufacturers to reduce costs, improve production throughput and elevate quality. Sub-par tooling, on the other hand, often leads to higher costs, devices prone to malfunction and wastage as entire batches have to be discarded.

TOOLING FOR MEDICAL DEVICES

Even manufacturers who 'design for tooling' often fail to take into consideration key elements such as a tool's expected lifetime and the time required to replace it. A broken tool means production stops and, in medical device manufacturing, you can't simply acquire a new one. The replacement tool has to go through the entire validation process again.

This can be mitigated at the design phase by:

1. **Considering the annual estimated units (EAU) each tool will be required to handle and;**
2. **Determining proactive maintenance plans for tools to ensure they operate optimally throughout their useful lifetime**

2 DESIGN FOR COST

Design for cost overlaps with every dimension of DfX as all have a positive impact on a project's finances. Design for cost means driving smarter decisions when it comes to device development, materials selection, services, production, packaging and distribution.

Design for cost goes beyond the cost of individual units, it looks at the total cost of ownership (TCO), including bills of material, production costs but also cost of (non)-quality and maintenance costs. By looking at the big picture, design for cost prevents decisions that give short-term returns that are likely to drive up the TCO price tag in the long run. For example, selecting slightly cheaper components that are more likely to break down in favour of more expensive components that guarantee device reliability and vastly reduce risk to your bottom line and reputation.

An experienced DfX team does not restrict itself to the short term and looks at future cost benefits as well. For instance, what it will mean if production volumes go up or if there is a drop in price for your type of product?

Ultimately, design for cost means making the most cost-effective decisions while aligning with product requirements and market expectations. We like to compare it to using a Ferrari to get from point A to point B. Not that there is anything wrong with a Ferrari if you don't mind paying for a luxury sports car to carry out a task that can be as easily by another vehicle at a fraction of the cost. When it comes to people who will use your medical device, designing for cost reminds you that few will prefer a Ferrari and prevent a project from becoming over engineered and overpriced.

3 DESIGN FOR STANDARDIZATION

Consider basic Lego, where blocks of limited dimensions and colors can be used to build almost anything. Design for standardization follows the same principle: Unique products can be built more quickly, reliably and cost-effectively when the design incorporates readily available components, existing products, proven processes and more.

Let's look at just a few additional benefits of standardization:

A stronger starting point

Standardization gives you a whole bag of tricks that have already been tested successfully in the field. The competitive advantages of not having to start from scratch cannot be overstated.

Cost and quality

Not only does your ready toolkit make you faster, when a good number of your components and processes have already been verified, it reduces the costs and risks that comes from making something brand new (read: untested).

Simplified customization

A common problem with devices that have been upgraded but never fully redesigned for standardization is that customizing such products can involve several hundreds of different configurations. Standardization makes you more agile by starting you off with products that can easily be configured to fit a customer's needs.

Buying power

When there are shortages of certain components, suppliers will favour big customers over small. If your standardize designs so multiple devices require the same component or components from the same manufacturer, you become one of the buyers suppliers have to please.

A stronger brand

When you standardize your platform you make global improvements with raise the quality and capabilities of your portfolio. You ensure, for instance, that all connectivity technologies in all products under your name are compliant with privacy laws.

4 DESIGN FOR FUNCTIONALITY

A medical device must perform its intended function. Again, this may seem like a glaringly obvious statement, but, again, when DfX work is not conducted, basic functionality may suffer.

Design for functionality takes into account what the user needs and for which pricing. This allows early input to create a design that will work the way it is meant to, when it is needed and where it will be used. It is the starting point for all other design dimension under the umbrella of designing for quality.

5 DESIGN FOR QUALITY

Quality is the primary strategic goal for any device. If design for functionality asks what a device must do, design for quality ensures it does its job well. No reputable medical device manufacturer would admit to compromising in this particular area. This is an industry in which poor quality can have devastating human repercussions.

It is therefore imperative that quality be addressed as early as the design phase, getting a head start on pouring in the team's combined experience and intelligence. Design for quality pins quality as a priority from the very start of the design and development process, then uses the blueprint to ensuring all initial criteria are fulfilled.

Because of its importance and reach, quality is somewhat of an umbrella term –safety, reliability and compliance are among dimensions that fit under it, all with their specific tools to ensure their DfX effectiveness.

Quality has to be evidenced with specific documentation. This too starts at the design phase, laying the groundwork for supplemental documentation down the road and quality throughout the production process and device's lifecycle.

6 DESIGN FOR TESTING

Medical devices are tested at several points to uncover possible defects and to assure that Critical to Quality (CTQ) parameters are met. If defects are found, production stops until modifications can be made and the product re-tested.

Design for testing takes into account all the ways your product will be assessed for conformance to industry, design and regulatory standards. In addition to preventing interruptions in production, design for testing provides a head start in the lengthy processes of regulatory verification and validation because requirements are spelled out from the earliest stages.

7 DESIGN FOR RELIABILITY

Not only does a device have to function as promised, it has to maintain that level of performance for the duration of its lifecycle.

A device that is inconsistent on when and whether it performs to standard is an unreliable device. Instead of making a promise to its users, it offers the odds and consequences of Russian roulette. Take, for instance the pacemaker which was heralded as revolutionary in part because of its long battery life. It promised to last at least 10 years, and as long as 19. The device would go on to draw even bigger headlines when the same battery failed after three years, gravely endangering its users.

Design for reliability utilizes simulations and other reliability engineering tools to ensure that the components of a device will not malfunction or degrade before the product's promised end-of-life. It uses complex calculations to predict the behaviour of a device in its intended environment, virtually "exposing" it to anything from temperatures, pressure, vibrations, chemicals, electrical surges and anything else it may be expected to withstand.

8 DESIGN FOR SAFETY

A non-functional device does not perform as expected and an unreliable device only performs intermittently. Both of these fall under failures of design for safety. In even grimmer cases, a design that has neglected to consider safety hurt the very users they were meant to help.

The impact of not conducting a DfX analysis in medical devices is far greater than for other products. An investigation into medical records in the U.S. from 2008 to 2017 found that medical devices may have caused or contributed to over 80,000 deaths and 1.7 million injuries.

Design for safety means potential hazard identification happens during design and development planning. In order to receive ISO 1385:2016 certification, medical device companies are further required to conduct safety and risk assessments throughout the design cycle: design input, output, review, verification and validation. The better and more thorough the identification and mitigation of risks at the beginning, the less likely there are to be issues to address later in the cycle.

UL CERTIFICATION

For a device to obtain FDA or CE approval, it first has to comply with UL protocols. The UL (Underwriter Laboratory) mark is internationally recognized as a sign that a product has met the most stringent safety standards. In the medical device industry, certification is earned by passing tests in:

- **Electrical safety**
- **Electromagnetic compatibility (EMC)**
- **Cybersecurity**
- **Biological evaluation, microbiological tests and sterilization**
- **Interoperability**

A design for safety is checked for all UL requirements and selected parts must also comply with UL standards.

9 DESIGN FOR USABILITY

In 2016, a Johns Hopkins study created a stir when it estimated that medical errors accounted for a quarter of a million deaths in the United States every year. That is nearly one hundred thousand deaths more than those caused by respiratory disease or accidents, making medical error the third leading cause of death in the U.S. before Covid-19. One estimate suggests that 15 percent (approximately 40,000 per year) are due to a poor device user interface.

In other words, a device does not have to malfunction in order to cause damage. Incorrect usage is just as dangerous.

Manufacturers tend to blame use error on users. However, the case has been made that when a device is used improperly over and over, there is likely a problem with the design, the instructions or the training.

Design for usability, also known as “Human Factor Engineering” (HFE), strives to prevent incorrect usage of a quality product. Only very recently has it received due attention for the medical device industry. As late as 2011, the FDA released Applying Human Factors and Usability Engineering to Medical Devices “to support manufacturers in improving the design of devices to minimize potential use errors and resulting harm.”

HFE looks at the long-term use of a device from the end user’s perspective. Is it the person who needs the device or a carer/healthcare provider? Is the end user likely to have difficulties with coordination, strength or vision? Are daily tasks or behaviours likely to interfere with using the device safely? What is the likely level of user’s technological maturity?

Not considering usability at the design stage means errors are only likely to be caught at human testing phase, when going back to the drawing board has become way too expensive. The result is band-aid solutions that do not address fundamental issues and an unacceptable number of use errors.

10 DESIGN FOR FUTURE

Designing for future presents as many challenges as opportunities. It involves accurate forecasting and observation of trends. Designing for future examines multiple scenarios in near, mid- and far horizons. Production-wise, what will happen to per device cost if there is a significant increase or decrease in production volume? What if components become obsolete or unavailable?

What disruptions and changes can you expect in your product’s lifecycle? Deloitte found that 88% of MedTech companies manufacturers consider advances in technology as their top challenge. At the same time, only half of these manufacturers consider cyber-readiness as an immediate priority. A further 20 percent intend to make it a priority sometime in the next five years.

How is consumer behaviour changing? Lockdowns during the first year of the Covid-19 pandemic accelerated a trend for users to keep and operate their own medical devices instead of making regular appointments at health care facilities.

There is also a clear move towards customizing wearable devices to make them more fashion-friendly, thereby reducing the stigma of clinical-looking attachments.

Design for future asks these questions to spearhead innovation, without compromising on the other DfX dimensions.

WHY DFX IS **TOO COMPLEX** TO GO AT IT ALONE

A design for excellence moves a device swiftly through the development and production process, avoiding surprises, minimizing issues and staying well within budget. It ensures the device passes tests for quality and fulfils expectations for functionality, timeliness and customer satisfaction. It ends up as a reliable, safe and easy-to-use quality-of-health or even lifesaving solution to the end user.

For the list to achieve result in an excellent product, two things have to happen:

- ☑ **ALL 10 dimensions have to be covered – it's an all or nothing deal**
- ☑ **ALL 10 dimensions must be considered at the earliest stages of the development process – nothing should be treated as an afterthought.**

If this sounds complicated it's because it is, and many manufacturers are unequipped to cover all dimensions.

AN EVOLUTION, **NOT A TREND**

The tools and thinking behind DfX is the culmination of decades of experience, of keen observation and analysis of mistakes, failures, experiments, insights and successes. The observations come from a range of perspectives and the approach is continuously refined by interdisciplinary teams – both individually and cohesively – to optimize the 10 dimensions of DfX.

Providence Enterprise has expertise in all DfX dimensions, including mechanical, electrical, software and quality engineers. Our extensive supply chain network includes trustworthy and reliable suppliers who work with our in-house team, sharing the most up-to-date trends in product offerings, capabilities and technologies.

DfX is not a one-off exercise, any more than a strong start guarantees you will win a race. While Providence Enterprise applies DfX to ensure that strong start and a clearer path, we also continuously monitor, address challenges and seize opportunities that present themselves throughout the process.

About Providence Enterprise

Providence Enterprise is a Hong Kong medical device contract manufacturer of Class I and II medical devices with manufacturing in China & Vietnam.

We specialize in electro-mechanical assemblies and high-volume disposables. We are FDA registered and ISO 13485, ISO 14971, ISO 14001, ISO 27001 certified. Our capabilities include fabricating tooling for silicone rubber and injection molded plastics, clean room injection molding, electronics, clean room assembly, and sterilization.

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