MITIGATING DESIGN RISKS

CONSIDERATIONS FOR MEDICAL DEVICE DEVELOPMENT AND MANUFACTURE

Presented by

Celestica™

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A RAPIDLY CHANGING HEALTHCARE LANDSCAPE

Medical original equipment manufacturers (OEMs) are at the forefront of the global effort to empower consumers and their physicians to be more proactive in diagnosing the risk or onset of chronic disease to improve treatment outcomes and lower costs. This effort represents nothing less than the transformation of the world's healthcare systems.

Chronic diseases - conditions such as cancer, heart disease, type 2 diabetes and Alzheimer's that require ongoing medical attention or limit activities of daily living for a year or longer - are the leading causes of rising healthcare costs worldwide[1].

Across the globe, medical OEMs are developing innovative products that make it easier and less costly for people to collect, analyze and share their health data in real-time with their doctors and, in turn, for primary care physicians to collaborate with specialists worldwide. They're capitalizing on innovations in multiple technologies including Big Data analytics, AI, machine learning, the rollout of 5G networks, and the maturation of the hyperscale data center and edge computing. This will ultimately create the products that will serve as the foundation of this next generation of patient care.

Consider the rapid changes in healthcare delivery following the onset of the coronavirus pandemic that forced doctors to use telemedicine platforms to conduct virtual examinations. Beyond the virtual examination room, technologies like remote-operated robotic surgical tools enable surgeons to perform once-risky procedures with incredible precision and less invasively to reduce risk and improve patient outcomes.

"We need to rapidly step up prevention, diagnosis and treatment of noncommunicable diseases. They highlight the urgency of drastically improving primary health care equitably and holistically."

Dr. Tedros Adhanom Ghebreyesus, Director General of the World Health Organization[2]

IT'S AN EXCITING TIME FOR MEDICAL OEMS.

They have the opportunity to produce products that grow their businesses, and contribute to the realization of the industry's goals of reducing global healthcare costs and deliver high quality care to more people.

As medical OEMs innovate and build their products, it is important to consider the complete product lifecycle. The upfront design needs to be robust to help minimize risk in later product life that may impact patient experience.

This white paper explains how a medical OEM, whether a new startup or a large multinational corporation, can seize this opportunity to manage potential risk by addressing four key considerations early in the design process.

Design for Manufacturability

Design for Supply Chain

Design for Quality
Process Failure Mode and Effects Analysis (PFMEA)

Design for Quality
Electronic Device History Record (eDHR)

"Conducting a comprehensive DFx early in the design process and before production begins will reduce risk, lower costs, ensure the highest level of quality and improve speed to market.

These initial steps will also ensure a new product's long-term manufacturability and sustainability as you increase production volumes when entering new markets and expanding your customer base worldwide."

Kevin Walsh, Vice President, HealthTech, Celestica

DESIGN FOR MANUFACTURABILITY

Too often, product development teams commit to a design before seeking input from manufacturing and process engineers because the design team has already invested a considerable amount of effort and time in conducting feasibility studies and testing to ensure robustness.

"At that point, it's really painful to make design changes," says Kevin McFarlin, Engineering Director at Celestica. "If you discover an issue like a single screw interfering with a plastic enclosure after manufacturing has begun, you have to halt production, repeat design verification activities impacted by the change and repeat process qualification activities which will ultimately result in a longer time-to-market."

A comprehensive Design for Manufacturability (DFM) analysis requires following a complex, multi-day process to ensure a product is resistant to a wide array of factors that could cause malfunction or failure. This includes assessing extreme temperatures, electromagnetic discharge failures, constant vibrations, repetitive motions, and fluids.

Conducting DFM analysis after finalizing the functional design is not a nice-to-have. It's critical to reducing the risk of having to perform costly redesigns after manufacturing has begun or in more extreme circumstances, after a product fails in the field.

Manufacturing engineers can contribute substantial value to product design.

"They know where operators might strain specific components, or have ideas on how to streamline production. They should be considered part of the design team."

Kevin McFarlin
Engineering Director, Celestica

Design teams are often under the mistaken impression that manufacturing engineers don't require their input until production begins weeks or months after the designs are finalized. That's understandable. Manufacturing engineers are busy with what's happening on their assembly lines today, and designers are focused on creating the company's next innovative new products. A smaller company may not have personnel dedicated to these specific roles. So they skip DFM and move into production as quickly as possible. But costly and time-consuming delays are the inevitable results.

Adding a manufacturing perspective to the design phase will reduce the risks and costs of surprises and delays that require subsequent redesigns.

A comprehensive DFM process will dramatically increase yield, reduce test escape rates, and ensure the finished product meets all design specifications.

Reduce Risk

Improve Quality

Lower Cost

Speed Time-to-Market

DESIGN FOR MANUFACTURABILITY

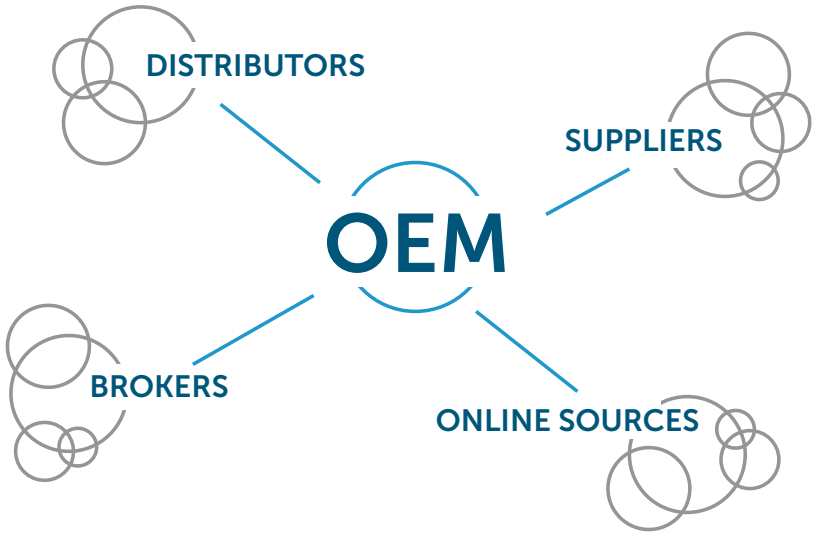
NO ROOM FOR ERROR

A single undiscovered design error can create a domino effect that culminates in costly production and delivery delays. Celestica applies its experience and expertise to avoid any costly surprises that require a re-design.

Celestica's team uses sophisticated analysis tools and guidelines the company has developed to identify all possible component issues. For example, it's not uncommon to identify spacing violations on a circuit board that will cause solder defects during assembly. Identifying and mitigating those violations during the design phase is much simpler and cost-effective than after manufacturing has begun, or worse, if a faulty product fails while a customer is using it.

DESIGN FOR SUPPLY CHAIN

Addressing supply chain management considerations as a product moves through alpha and beta builds to volume builds is a must. The first question to ask is 'Where are we going to get our parts from?' There are many sourcing options and wide variances in lead times and pricing. There is no one-size-fits-all answer, although the primary considerations are always product cost and quality, as well as lead time.



If the need is not urgent, Celestica recommends going to reputable material suppliers who sell directly and usually offer the best prices. However, realize that lead times can stretch from a few weeks to a few months or longer.

Medical OEMs should also consider the following questions: Have we selected the right parts? Are any at risk for extremely long lead times or obsolescence? Do we have a dual source strategy for critical parts?

The right sourcing strategy that takes into account availability, lead times, cost and quality is top priority when it comes to parts for life saving medical devices.

Some material suppliers require buyers to go through their distributors. That's an excellent option, particularly if a distributor can shorten lead times because it has the parts in stock.

Exercise caution when working with brokers who buy and sell componentry. Brokers can be a viable avenue for finding parts if the pressure to shorten lead times is high. But be wary of less scrupulous brokers who try to take advantage of parts shortages by selling counterfeits or do not meet compliance requirements for medical devices.

Another key consideration for many OEMs is the potential for near-term obsolescence, particularly when a customer is designing a large, complex device that incorporates consumer products.

For example, if a product requires a PC, the decision to incorporate a consumer PC into the design may create unnecessary risk. The consumer PC market moves at a lightning pace and PCs can become outdated and inadequate for a medical device designed to work for decades. That forces an OEM to repeat the revalidation process as often as once every six months.

Typically, the time between the initial design phase and submission to regulatory bodies for large scale product launch would be at least two or three years. But when faced with urgent demand for critical ICU and protective equipment during the pandemic, frontline healthcare workers needed to take delivery quickly. Celestica worked with suppliers to achieve a quick turnaround.

Celestica conducts a design for supply chain (DSC) analysis to accelerate delivery timeframes by breaking down the manufacturing process into distinct phases. The team works with qualified local providers to quickly deliver components for initial qualification units. For the first stages of qualification units all the way to volume production, Celestica negotiates with local and regional suppliers to secure the optimal balance of lead times and costs. The team negotiates with Preferred Suppliers around the world to implement a long term sourcing strategy that delivers on desired cost and speed targets.

DESIGN FOR SUPPLY CHAIN

TIMING IS EVERYTHING

"Match your suppliers to each phase of the product development lifecycle before manufacturing begins. That will enable you to identify local suppliers who can quickly deliver the components you need for the initial production run. Then expand your network to work with volume suppliers around the world who will help lower your costs."

Kevin Walsh
Vice President, HealthTech, Celestica

Celestica recommends breaking DSC into three stages:

1 LOCAL SUPPLY SOURCES

Start with local suppliers and expect to pay a higher premium for "quick turn" suppliers that provide rapid prototyping.

2 NEGOTIATE AND EXPAND

When you're ready to ramp up production, negotiate lower prices for longer lead times and expand the network to low-cost region suppliers.

3 LOW-COST SUPPLIERS

Finally, achieve the right balance of low cost region and local suppliers and negotiate the best prices possible to support mass production.

DESIGN FOR QUALITY

Process Failure Mode and Effects Analysis (PFMEA)

Design errors result in product errors - and there's no room for error when it comes to a person's health. Incorporating quality considerations into the design process will result in far fewer defects, lower costs, and speed the regulatory review process.

A medical OEM and its design and manufacturing partner must gain a clear understanding of the risks before committing tooling, fixturing, and implement layers of controls to mitigate those risks.

Celestica recommends conducting a Process Failure Mode and Effects Analysis (PFMEA) to scrutinize a product design and identify any potential failures that may occur during the manufacturing process resulting from human error or equipment malfunctions.

"If you wait until after releasing a product to manufacturing and discover an error, you have to spend more money and incur delays to retool and restart manufacturing," says Brian Blair, Celestica's HealthTech Global Process Control Leader.

"When a customer makes a purchase, they're not paying for a product - they're paying for its functionality and reliability. Functions deliver value. If a $1 million product fails, its value to the customer falls to zero. And ultimately, this will have a great impact on the brand."

Brian Blair
HealthTech Global Process Control Leader, Celestica

DESIGN FOR QUALITY

ELIMINATE DEFECTS SOONER

"The earlier you identify and fix defects, the better. 95% of the cost of a product is baked into the design - that's where the requirements are cemented. If you discover defects after manufacturing has begun, you'll waste time and money on retooling and remanufacturing, and inevitably suffer delivery delays."

Brian Blair, Health Tech Global Process Control Leader, Celestica

It's not uncommon for medical OEMs, particularly smaller and early stage companies, to want to leverage automated assembly to eliminate manual processes. But many may not have the requisite capabilities in-house. After performing an initial PFMEA, customers contract Celestica to own the automated program from design through delivery. After the product transfer, ideally early in the design process, Celestica performs a comprehensive risk assessment to evaluate the PFMEA and achieve zero defect before committing tooling, fixturing, etc.

Begin by creating a cross-functional team of representatives from design, engineering, manufacturing and quality assurance charged with finding ways to streamline the manufacturing process, such as automating manual processes or eliminating product features that do not deliver value to users.

The PFMEA team requires both information (i.e., users, parts, processes, performance) and time to capture and evaluate all possible issues. A PFMEA is a regimented process that must be followed step-by-step to ensure it captures all possibilities and their probabilities.

The outcome is a set of controls that will make the manufacturing process far more robust and greatly improve the likelihood of delivering a high quality product to customers.

DESIGN FOR QUALITY

Electronic Device History Record (eDHR)

A Design for Quality approach also streamlines the process of creating and submitting device history records (DHR) to regulatory agencies.

Medical devices must meet certain requirements and validations that are more stringent than in other industries, so a DHR plays an important role in the quality management system. It conveys to regulatory agencies a product's entire history, including who built it and when, who performed testing and when, and details on the calibration and maintenance of testing equipment.

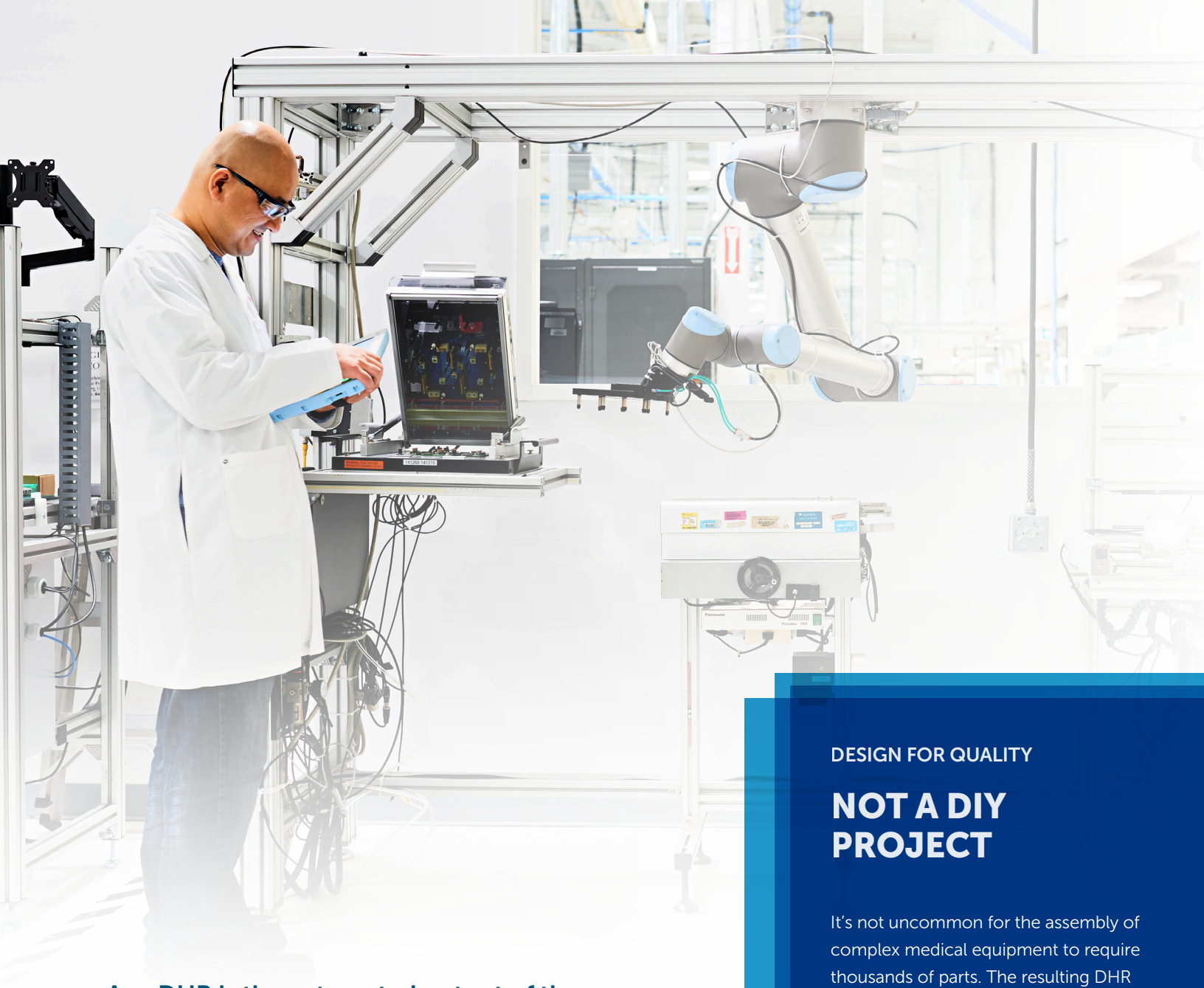
"A typical DHR can run between dozens, even hundreds, of pages depending on the complexity of the product," says Paul Min, Celestica's Senior Director of IT Risk and Cybersecurity. "It's traditionally been a person-dependent, intensive process that is prone to inconsistent results - a recipe for failure to meet FDA requirements."

80% **of all warning letters the FDA issued in 2016 included data integrity deficiencies.**

Just one typo or a seemingly minor paperwork error such as a missing signature, correction initials or date on a page can delay the regulatory approval process.

Creating the DHR can be particularly difficult for startups or other companies that do not have much experience in manufacturing or in navigating the regulatory review and approval process. It requires ensuring that all manufacturing operators working on the product follow strict procedures and provide accurate records at the appropriate times.

"It is really a daunting task that requires a lot of training, and it's ultimately fallible because it relies on human input and behavior to ensure consistent, accurate results," says Min. "Transitioning from paper to electronic DHR (eDHR) eliminates the reliance on manual processes to ensure reliability and verification."



An eDHR is the automated output of the enormous volumes of data that manufacturing systems generate to improve the analysis of potential issues, generate consistent results, and substantially reduce the risk of FDA review.

Once the desired output and outcome is achieved, the manufacturer has a process for building the product correctly that will make it easier to scale up volume production in the future. This also facilitates Corrective and Preventive Action (CAPA) and Complaint Investigations to demonstrate prompt and effective completion of actions and reduce product liabilities and impact to patient safety, compliance, and business risk when conducting field actions (recalls).

DESIGN FOR QUALITY

NOT A DIY PROJECT

It's not uncommon for the assembly of complex medical equipment to require thousands of parts. The resulting DHR can run dozens, hundreds, or even thousands of pages with several entries on each page. That requires completing, inspecting and approving thousands and thousands of entries.

A single data entry error - even one that would not affect the quality or performance of the device - could lead to FDA rejection. Leveraging the automation capabilities of an eDHR process eliminates that risk.

ENABLING HEALTHTECH MANUFACTURING'S PRESENT AND FUTURE

The need for healthtech innovation is urgent. The solutions that medical OEMs are developing today will play critical roles in combating the global crisis of chronic diseases that cause healthcare costs to continue rising and leave populations more vulnerable to acute health emergencies such as COVID-19.

But skipping a comprehensive design analysis in the rush to begin production too often leads to costly delays, or worse, product malfunction or failure in the field.

OEMs should consider the product design process as a key component in their overall risk mitigation strategy. Prioritizing Design for Manufacturability, Design for Supply Chain, and Design for Quality will enable the manufacturer to strike the right balance of speed to market with scalability, cost and the highest level of quality that any product designed to improve a person's health must achieve.

For more than 25 years, Celestica has helped its customers across multiple high-volume industries design, test, build and deliver their products to market. The medical device sector is growing as more start-ups and early-stage companies unveil their innovative product designs and prepare to begin manufacturing in low volumes.

Celestica has developed a Design for Manufacturability playbook to help these companies, in particular early stage, identify common pitfalls or mistakes that make a design more difficult to produce at high volumes. Celestica has the technology to manage all product design testing documentation, all necessary testing, and certification protocols and systems in place at our facilities around the world.

Celestica also works with a number of large multinational manufacturers who have a good understanding of the front-end of product development. They know what they need in a partner to augment their teams or get to market more quickly. Celestica is an invaluable partner in helping them scale quickly when needed or collaborate to lower product development risk so that OEM's internal teams can prioritize innovation.

Customers partner with Celestica to help them turn their visions for new products into reality to meet market or patient demand. Celestica helps them achieve cost and delivery targets, ensure regulatory compliance, and manufacture at the desired scale to stay in lockstep with company growth.

For more information on how Celestica can help you bring your innovative medical devices to market, please visit www.celestica.com/healthtech

ABOUT CELESTICA

A global provider of product lifecycle solutions, we have extensive experience working with the world's leading healthcare companies. We build and sustain strong relationships by offering innovative manufacturing and supply chain solutions, a commitment to quality and compliance, and a heritage of technology leadership.

We specialize in providing advanced solutions for surgical instruments, patient monitoring devices, diagnostic imaging, in-vitro diagnostics, and other medical devices.

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[1] https://www.cdc.gov/chronicdisease/about/index.htm
[2] https://www.who.int/news/item/09-12-2020-who-reveals-leading-causes-of-death-and-disability-worldwide-2000-2019