IMPORTANT CONSIDERATIONS IN DESIGNING FOR SUSTAINABILITY

JABIL
HEALTHCARE

In recent years, the international research and consulting firm Deloitte has conducted a series of surveys chronicling consumer attitudes to environmental and ethical sustainability. The consistent message throughout their discovery: sustainability is indeed a vital issue to consumers, and concern is increasing. Deloitte's 2021 report[1] identifies 32% of surveyed consumers as being "highly engaged" toward adopting a more sustainable lifestyle with 28% reporting that they have stopped buying certain products due to ethical or environmental concerns.

Younger generations are seen to be the most apt to adopt sustainable behaviors with 50% saying they have reduced how much they buy and 45% have stopped purchasing certain brands because of ethical or sustainability concerns. The most common way consumers demonstrate their commitment to sustainability is by avoiding single use plastics (61% of people). The single-use medical device reprocessing market was valued at USD 1,858 million in 2018 and is expected to register a CAGR of about 15.24% during the forecast period of 2019-2024[2]. Yet still, approximately 90% of medical device waste comes from disposable, single-use components or products[3].

Regulations and standards such as the Waste Electrical and Electronic Equipment (WEEE); Restriction on Hazardous Substances (RoHS); Registration, Evaluation, and Authorization of Chemicals (REACH); and the Energy Using Products (EuP) have already positively impacted the sustainability of medical devices containing electronics. However, aside from meeting regulatory requirements, medical device manufacturers have typically not led the way in driving sustainability and sustainable product design, citing obvious challenges around cost, safety, functionality, usability, and convenience.

This introduction of new regulations, increased consumer awareness of the environmental impact from medical waste and a sense of responsibility from companies to produce eco-friendly drug delivery devices has driven a rise in sustainability goals and policies in the medical and pharmaceutical industries. There are now programs in place to reduce medical device waste by returning used devices for recycling, repurposing, refurbishing and reuse. These programs present device companies with additional challenges such as establishing a safe means of returning the devices with a low burden on the user and developing infrastructure to introduce the returned devices safely and efficiently into the circular economy.

As medical device manufacturers navigate the many regulatory hurdles to approve a refurbished or multi-user medical device, there is also the obstacle of patients accepting treatment with a refurbished device. For now, it is unlikely that the medical device industry will transfer to a model where refurbished or multi-user medical devices are the norm, but to meet their sustainability goals, there are many small improvements that will make a big difference when introduced to the product lifecycle. A process where design for sustainability is an integral part of the conceptual design process will ensure that environmental and sustainability considerations are elevated to a similar level as regulatory, functional, and business requirements. A design for sustainability process should cover the entire product lifecycle — from design to disposal — and needs input from all stakeholders involved.

The Early-Stage Design Process

At Jabil Healthcare, we have an established early-stage design process that meets regulatory design control requirements and supports optimisation of medical device design for large-volume manufacturing.

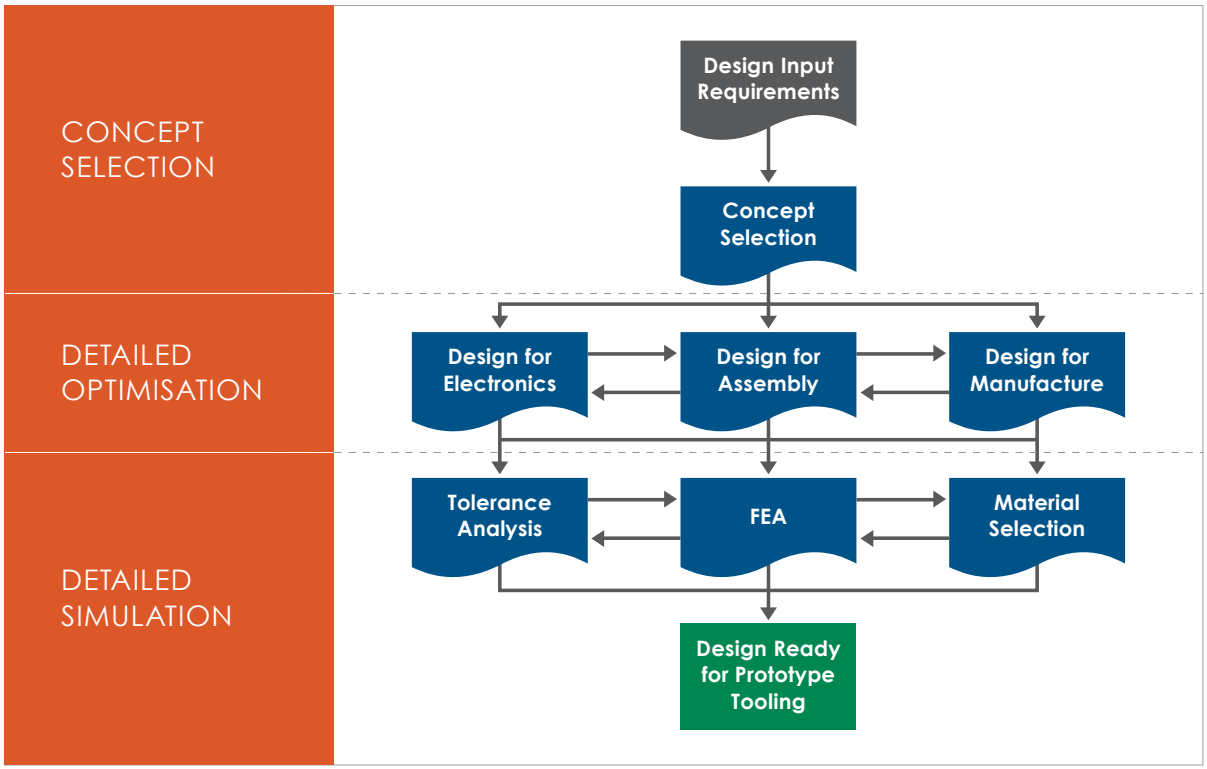

Figure 1: Early Design Stage Process Elements

This process commences with concept selection, where all potential concepts are reviewed and optimised into one selected design. The selected concept is then brought forward to the detailed optimisation stage, where subject matter experts from a range of disciplines (e.g. manufacturing, assembly and electronics) work with the design team to further improve the device design for each area. Following implementation of these optimisations, analytical tools such as mold flow, tolerance analysis and FEA (Finite Element Analysis) simulations, along with final material selection are conducted prior to the design being released for prototype manufacture. By integrating design for sustainability into our established early-stage design process, we can have maximum impact on the sustainability of the device with minimal impact on project timeline and cost. However, this decision-making process for optimising sustainability needs to be informed and data driven, as we will discuss here.

Stage 1: Concept Selection

At concept selection stage, the opportunity to optimise a device design for sustainability is at its peak. Conversely, if you do not consider sustainability at this stage, then your chance to consider it at later stages is much reduced, becomes more complicated, and adds significant time and cost to the development lifecycle.

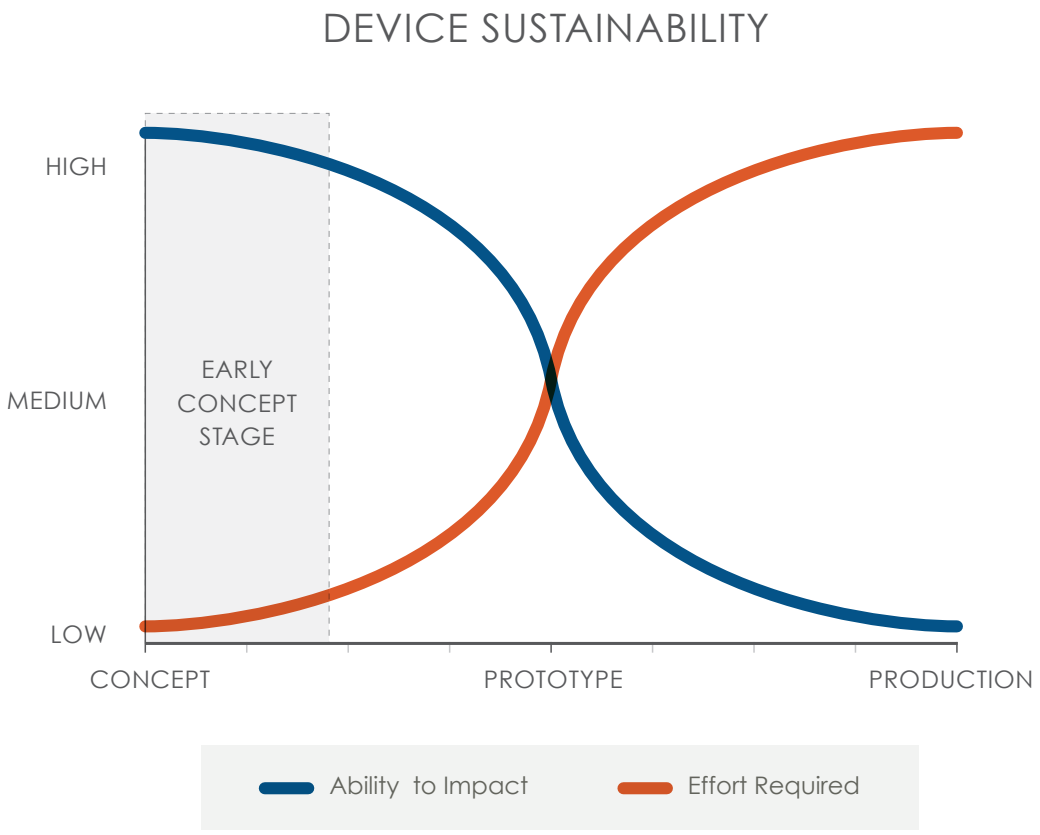

Figure 2: Device Sustainability: Ability to Impact vs. Effort Required

Design requirements are crucial input to the concept selection stage, as all proposed concepts will ultimately be assessed against these. Therefore, establishing specific, measurable and attainable sustainability goals within the device requirements is a key contributor to success.

At Jabil Healthcare, we use a Concept Selection Matrix that accommodates a data-driven approach to assessing each device against its design requirements. Applying a weight to each requirement and scoring each concept provides a holistic approach to assessing the sustainability of a concept in the context of other requirements such as functionality, manufacturability, usability and cost.

The three important sustainability factors to consider during the concept selection stage include:

1. Modular Design

Modular design is particularly important for the more complex connected or electronic medical devices that are increasing in the market today. It's crucial to consider how elements of the device that have specific medical waste disposal requirements (i.e. drug cartridges) can be separated from the overall device.

Modular design was a principal focus for Jabil in the conception and development of our Qfinity™ Autoinjector platform. The device features a reusable drive unit and a small single-use, pre-filled cassette. The cassette is comprised of only four plastic parts, which significantly reduces the disposable plastic parts when compared to traditional single-use autoinjectors that are discarded in their totality after each dosage event. Furthermore, the electronic hardware (PCBA and rechargeable battery) of the smart, connected version is housed within the reusable drive unit, reducing the consumption of electronic components.

Figure 3: Qfinity™ Cassette, Reusable Autoinjector and Connected Charging Hub

2. Component Reduction

Reduction in the component count or the amount of different material types in a device can have a large impact on how readily the device components can be introduced into the circular economy and the cost effectiveness of doing so. Reducing the size and amount of material in a device can have a positive impact on carbon emissions during transport, manufacture and assembly. With increased use of 3D-printed materials in medical devices, additive manufacturing can be assessed at the concept-selection stage as a means to reduce component count and optimise material usage. This can be achieved through the use of lattice structures and organic features only possible in a 3D-printed design. Thus, the mechanical requirements of each component can be met with the optimal material efficiency.

3. Device Disassembly

Advancing concepts that optimise the device for disassembly should be a key sustainability requirement assessed at the concept-selection stage. An important factor to consider here is at what point does disassembly of the device to recover the constituent components for the circular economy become less sustainable than shredding the device and sorting the material via mechanical or chemical means. This assessment will have a big impact on the optimal design concept selected and should be determined at the design requirements or concept selection stage in consultation with subject matter experts in device recycling.

Stage 2: Detailed Optimisation

Once a device concept is chosen, the next stage is a detailed optimisation of that design for the chosen manufacturing and assembly methods. For plastic medical devices that are produced at high volumes, a key area for improvement is the injection molding process for plastic components. Reducing the overall amount of material in the component by coring out features while maintaining part functionality is an important consideration. For manufacture of the molded components, optimising runner systems to reduce material waste and selecting resins that have lower processing temperatures can also greatly enhance the sustainability. Understanding the disassembly of the device is also key during this stage as we will discuss in further detail now.

Design for Assembly

A standard approach to Design for Assembly (DfA) is to develop an assembly process flow and then optimise the part design to meet the assembly equipment, fixtures, feeding systems, vision systems and other interactions at each stage in the process flow. In the past, little consideration has been given to what happens to the assembled device after it is used.

When device sustainability is considered only after the device has entered production, it can bring many challenges. The device manufacturer is then swimming against the tide, attempting to separate out materials from a device that is not designed to be disassembled.

The sustainable approach is to understand the post-use economy for the device and design it so that materials can be easily separated and recovered for the chosen recycling method. This might necessitate a move away from assembly processes that chemically bond the materials together such as ultrasonic welding or laser welding. These processes also have high energy requirements that can contribute to a larger manufacturing carbon footprint.

We recommend:

- Avoiding the use of lubricants or solvents that can contaminate waste streams and reduce the value of the device as a circular asset.
- Reducing the use of screws or bolts that will make disassembly more time consuming. If screws are required, ferrous materials are optimal so they can be magnetically separated during recycling.
- Avoiding the use of inks or painting of parts that can contaminate whole plastic batches. Consider processes such as in-molded marking or laser marking as alternatives.
- Considering the use of shape memory resins in device clipping mechanisms. These can be designed in such a way to secure the device enclosure during use but also facilitate easy disassembly by heating the device post-use.

A 'Global Returns' system is also key here, so that devices can be received back to the manufacturer post-use and they can then become a circular asset than can be re-used, recycled or refurbished. Of course, there is a point reached where the time, effort and energy required to disassemble a device becomes too high and focus should be diverted to optimal design for a device that will be recycled via shredding and separation. In this instance the material selection during the detailed simulation stage will be the higher priority, as we will discuss now.

Stage 3: Detailed Simulation

Material Selection

Optimising component material selection is an established means for achieving sustainable designs, however, determining the most sustainable material to progress forward at early design stages can be challenging. At Jabil Healthcare, we work with partners to develop a database that compares different material options and allows us to select the most sustainable material for each component in the early design stage. This assessment includes:

- Recycling method
- Environmental impact of the material production
- Carbon Footprint of the supply chain for the material
- The material supplier's sustainability credentials
- The predicted post-use outcome for the material (i.e. landfill, waste to energy, circular economy)

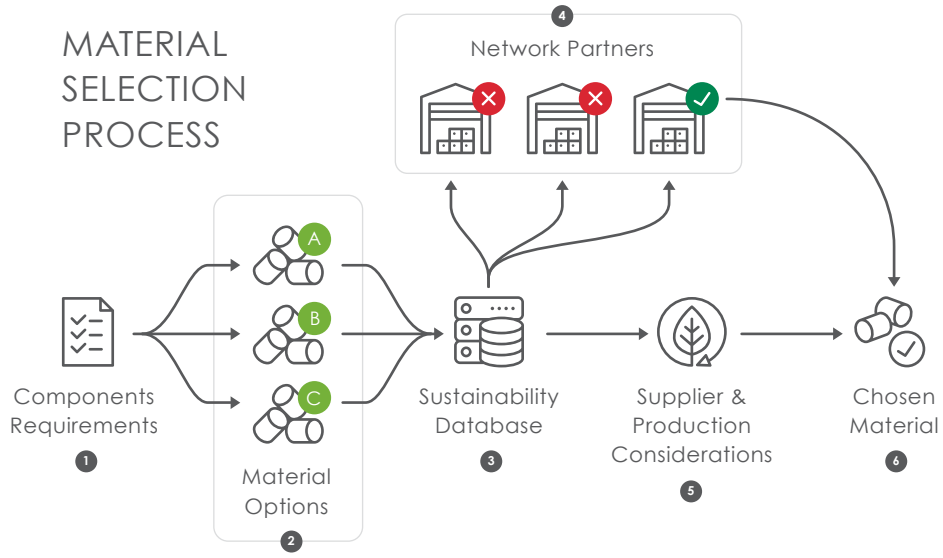

Figure 4: Jabil Healthcare Material Selection Process

Shown here is the step-by-step process in action:

1. The component requirements are compiled
2. A list of materials that meet all component requirements is generated
3. Datasheets from these materials are uploaded to the sustainability database
4. This information is disseminated to network partners in the circular economy
5. The sustainability credentials of material production and material suppliers are assessed
6. Feedback from network partners and material suppliers is reviewed and the most sustainable material choice for the component is approved to move forward

For single-use plastic devices, understanding the environmental impact of the resin production is also important to consider. Use of recycled material continues to be challenging due to the risks of contamination and material traceability. Companies such as Borealis are working on operations in advanced recycling to return plastics back to their basic monomers, which would be suitable for medical device manufacture but there are economies of scale required that make this challenging in the short term.[4]

For resins in particular, the feedstock used is critical. One way of transitioning away from fossil fuel feedstocks is to use a mass balance approach. The mass balance approach is a method of linking sustainable feedstocks to end products[5]. It enables a shift away from fossil fuel feedstocks to a more sustainable circular economy. This system requires resin manufacturers to gradually use more and more bio based or circular feedstocks in products. It is a similar process to how "green energy" initiatives work with some of the electricity in the grid coming from renewable sources and some from fossil fuels. For example, Celanese has developed Hostaform® MT® POM ECO-B, a sustainable medical grade material which is almost identical to their existing POM product but is made up of around 97% bio-content (biogas). This material has less than 50% of the carbon footprint as the original POM produced from fossil fuels[6], thus giving the medical device designer the option to select more sustainable materials that meet the same performance criteria.

Conclusion

Producing a sustainable medical device is not without its challenges. By tackling this problem at the early design stage, there is maximum flexibility to optimise a device's sustainability with minimal impact on project timelines and cost. In order to do this effectively, we recommend integrating sustainability into all aspects of the early-stage design process to deliver a best practice approach for sustainable design. We use this approach at Jabil Healthcare and through our concept selection process, only the most sustainable concepts are progressed. We also follow a Design for Assembly process where the device is optimised for disassembly and component segregation post-use. Lastly, our material selection process ensures that the most sustainably produced and recyclable materials are used for each component. By implementing a thoughtful Design for Sustainability process, product developers can ensure that future medical devices not only improve patients' lives but are also kinder to our environment.

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