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Springboard

SUSTAINABILITY THROUGHOUT THE SPRINGBOARD DESIGN PROCESS

VALIDATION AND PREPARATION FOR LAUNCH

A BLOG SERIES BY CATRIONA ELDRIDGE

INTRODUCTION

Springboard Pro uses a 5-stage development process:

- 1. Opportunity and Research
- 2. <u>Concept and Feasibility</u>
- 3. <u>Design and Verification</u>
- 4. Validation and Preparation for Launch
- 5. Launch and Post-launch

Like many other companies, we are aware of the growing climate crisis, and the increasing pressures from legislation and consumers to develop sustainable, environmentally friendly products. This article series explores how to design for sustainability at each of our five product development stages.

Increasingly, patients, purchasers, users, government bodies and medical device companies themselves are actively seeking to reduce the climate impact of medical devices, and improve their sustainability.

This 5-part blog series aims to discuss how sustainability can be built into the product development process.

SUSTAINABILITY AT STAGE 4: VALIDATION AND PREPARATION FOR LAUNCH

Stage 4, Validation and preparation for launch, tests whether the manufacturing process is fit for purpose.

During this stage, gauge R&R and verification & validation processes are used to confirm the parts and manufacturing processes meet the requirements. We can also gather objective evidence that the user and business needs are met by the design, including summative human factors studies. The assembly fixtures and standard operating procedures are finalized and a technical file for the device is produced.

For simpler devices, manufacturers may be selected at this stage, and this decision should consider environmental impact; can the transport emissions during manufacture be reduced by bringing manufacturing stages physically closer together, e.g. selecting packaging factories or raw material suppliers near to the production location? Can manufacturers in countries with high renewable energy supplies be used?

At this stage, as most of the design is finalized, much of the sustainability work we can do shifts from guiding design to observing it. The same principles of sustainable design that have been mentioned in Stages 1, 2 and 3 are still useful here, guiding the final details of the device design, but at this point, as so much design work has already been completed, significant changes to the design will be much more costly to make. Once validation and verification testing begins, the design must remain under change control.

Instead, we can focus on producing useful insights into the environmental impact of the device, as it has been designed. This includes an understanding of the embodied carbon dioxide equivalent in the materials of the device, as well as in the manufacturing methods and transport used during the device's journey from raw materials to device in use, to end of life and landfill, reuse or recycling.

Stage 4 switches focus away from design for function and onto preparing for manufacture and validation. Some improvements to sustainability are possible at this stage, e.g. via manufacturer selection, but most of the design itself is fixed.

CONCLUSION

The details have now all been worked out and it's time to focus on testing, verification and validation for a device. This is when you can gain insight into the device as a whole.







COMING NEXT: STAGE 5 -LAUNCH AND POST LAUNCH



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