Using Short-Run Manufacturing to Solve Design Transfer Challenges

The fundamental goal of short-run medical devices manufacturing for clinical trials is to test the design integrity. To do this, the manufactured batch must fully represent the planned production version that will enter the market

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The challenges of design transfer are well known in the medical device industry. The innovation process starts by designing and getting the few prototypes of a new device working. However, if an approach has not anticipated the challenges of volume production, then the struggle really starts when that product is sent to a manufacturing partner, often in another country, asking for it to be made in scale.

There are many complexities to consider beyond the device design itself when dealing with high-performance medical devices such as component cost, performance, assembly, and inspection at the high speeds required for serial production. Designers who develop new products from a clean sheet have many issues to consider, and, often, they rely on a manufacturing engineer to sort out production issues later on.

Unfortunately, 'sorting it out' can be a tortuous process because each design change can have many unintended knock-on effects. When the practicalities of making a design work on a production line delays the launch of a product, the direct costs and financial damage can be significant. In the field of medical devices, the window of opportunity in which to sell a product while it is still under patent is likely to be curtailed significantly, causing unforeseen harm to a company's potential income. In these situations, the pressure is on.

In many cases, when a design is handed over to a contract manufacturer, there are challenges with the production processes and equipment the manufacturer uses and is familiar with. To address this, some contract manufacturers offer their own design service so new products are created with the final manufacturing process in mind.

From the medical device companies' point of view, this strategy can leave the contract manufacturer's intellectual property, including know-how, embedded in the product. This can tie in the manufacturer and restrict the ability to control supply chain profit margins in the long term by second sourcing, adding more risk to the supply chain in the future.

The optimum commercial arrangement is to have a complete, self-contained design package that can be manufactured by a number of alternative contract manufacturers in territories close to the intended market. As new markets develop and regulatory authorisations are gained, the product can be rolled out across territories with manufacturing capacity adapted to create the most efficient supply chain. This can pay big dividends when automation is a major cost and optimised manufacturing and logistics strategies become complex.

One company has a product innovation model that aims to achieve this optimum outcome. It is increasingly being found to offer a better solution by developing the new product independently of contract manufacturers, but within an environment where a holistic team of product development and experienced manufacturing engineers work in parallel.

The key step that led to the success of the approach is a robust phase of short-run manufacturing organised by an extended design team that provides both regulated products for clinical trials and verifies the capability of the manufacturing process. This results in a detailed and tested package of manufacturing documentation alongside the completed technical file and clinical trial data, allowing a competitive tender process to identify the most cost-effective volume manufacturing partner.

This approach relies on an array of diverse specialist teams working together closely across the product development and manufacturing disciplines. It starts with a team of researchers (product and regulatory

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strategists identifying the unmet needs and opportunities among the project stakeholders) usually including a complex mix of patients, healthcare providers, regulators, and payers. It then includes technologists and IP specialists developing new concepts and approaches in the laboratory, leading on to the product engineers, manufacturing engineers, usability experts, test engineers, and regulatory teams developing the product in parallel.

Towards the end of product development, the manufacturing team starts to develop and construct the pilot manufacturing process, building up from a thorough plan through process development, tooling, and process qualification. The benefit of having the design and manufacturing teams working closely together is that issues can be fixed quickly by either design or manufacturing changes.

The goal is to manufacture a short run of devices or consumables and qualify them successfully, ready for human trials. This creates a complete technical solution ready for design transfer: a fully detailed pack of production release documentation to hand on to the CMO when the time comes to move up to volume production.

One company recently used this approach on an injector pen system. When the design was passed to a factory in Eastern Europe for volume manufacture, the handover was virtually seamless, with the CMO even commenting that they wished all designs coming to them were so well prepared.

This was because so much of the final manufacturing process had already been developed and tested. The designs were handed over with a quality control plan, standard operating procedures, jigs, and validated test methods. All aspects were in place, had been tested, and were proven to be effective. This meant that all the IP, including the know-how relating to both the design and manufacturing process, were transferred, enabling the medical device company to create more competitive tension in the supply chain and control cost of goods.

Another key advantage is revealed when conducting clinical trials. As trials usually start between design and full manufacture, there is a very real danger that if design transfer reveals significant issues and the product needs to be significantly altered, then elements of the controlled clinical trial may need to be repeated. There are countless examples of pharmaceutical companies needing to repeat or extend clinical trials due to changes during design transfer or to take extra time to perform bridging studies to demonstrate to regulators that changes have not impacted clinical performance. Instead, with the aforementioned approach, a short manufacturing run for clinical trials is integrated into the development process and is made in a manner representative of how the product will be made once it goes into volume manufacture, thus significantly reducing these risks.

All in all, it is being found that in the field of medical device innovation, integrating short-run manufacturing into product development brings with it a raft of advantages to clients, not only saving them both time and money in commercialisation, but bringing forward time to market and vital product revenues.

About the authors

Carl Pullen is a versatile and creative Engineer with extensive experience in a variety of market sectors and a wealth of skills designing components and devices with precision and high quality. He has a strong background of computer-aided drafting design and comprehensive experience of injection-moulding design and manufacture all the way through to commercial production, including process optimisation and validation. Carl focuses on robust production techniques and efficient assembly processes to ensure long-term manufacturing at high-quality standards. He is also an experienced Project Manager and engages fully with all parties in complex projects to ensure cross-functional collaboration.

Wade Tipton has 20 years' experience in the medical device industry, working in product design and development and process engineering. He has been responsible for gaining and maintaining International Organization for Standardization 13485 accreditation and technical file submissions and gaining Conformité Européenne and 510K approval for several Class 2 medical devices. Wade has led successful projects in new product introduction, high-volume manufacturing scale-up, and Lean Six Sigma. He has complete business process experience, from product design and development through design verification and validation and into process validation, product launch, manufacturing scale-up, and process improvement. Wade has a physics degree, a master's degree in applied optics, and an MBA.

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