

HOW PRE-PRODUCTION SERVICES REMOVE DOWNSTREAM OBSTACLES



Once a medical device manufacturer has conceptualised a great product, the next major hurdle is determining how to produce it. In the medical device sector, due to stringent safety and efficacy regulatory requirements, along with the escalating complexity of devices and components, this process can be arduous.

Time is of the essence for manufacturers who want to bring their new product and product innovations to consumers and capitalise on their market potential. The key to quicker, smoother commercialisation? Optimising product design for manufacturing and automated assembly in advance.

Mikron's Pre-Production Services are designed to help medical device manufacturers de-risk their production processes before manufacturing begins, enabling a smoother, speedier transition to commercial-scale production. By ensuring that products are well designed for high-speed assembly and automation upfront, Pre-Production Services reduce the chance of costly, time-consuming changes downstream.



Pre-production services, such as proof of principle and design verification builds, mean faster time to market and less risk for medical device manufacturers

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WHAT ARE PRE-PRODUCTION SERVICES?

Mikron Automation, the leading partner for scalable and customisable assembly solutions, offers a full suite of Pre-Production Services, developed to help medical device manufacturers de-risk their programs and accelerate through the manufacturing design phase. Services can range from quick pieces of advice to a full engagement that could include design for manufacturing (DFM) analysis, PFMEAs (process failure modes effects analysis), process range studies, proof of principle feasibility studies, prototype component builds, process characterization and clean room assembly of design verification build or clinical trial builds.

“Customers are, of course, adept at developing their medical devices and understanding what their product needs to do, but they might not be as conversant in what their assembly and manufacturing needs are,” says Bill Jaworski, Sales Director at Mikron Automation. “As their partner, we help them de-risk their programs, enabling them to move more quickly into commercialisation and high-scale manufacturing.”

WHAT IS MIKRON'S PRE-PRODUCTION SERVICES PROCESS?

“We typically start with a high-level risk assessment,” says Jaworski. “We look at the customer’s product and the assembly processes required and then our subject matter experts review areas where there could be challenges. We really allow our customer to use our experience and expertise to gain insight into what will translate well into high-volume manufacturing and where the challenges may lie. It’s really about helping them manage risk.”

When it comes to developing a medical device, there is a plethora of areas which can be optimised for manufacturing. For instance, the early development stage is the perfect time to consider whether a different joining technique, like ultrasonic welding or laser welding, might be more appropriate than adhesive. A manufacturer might be advised to adjust part design to allow components to be more easily fed in bulk to the automation system or more precisely handled in the assembly environment.

Now is also the time to complete process characterisation work to identify and quantify sources that could impact yield or product quality. Mikron subject matter experts can be engaged in the development and execution of these experiments as well as advising on control strategy.

Mikron’s Pre-production Services also offer extensive validation support including, but not limited to, Standard Operating Procedures development, DOEs (Design of Experiments), process development, installation qualification, operational qualification, performance qualification and process validation.

ISO 13485 certification and qualified 2,000 sq ft Class 7 clean room facility in Denver allows Mikron customers to complete design verification builds and clinical trial builds required for regulatory approvals. Mikron is able to produce documentation such as SOPs (standard operating procedures), Batch Records and Inspection Reports to support product builds in the clean room which are transferable to the customer when they are ready for commercial manufacturing. “This is a unique offering by Mikron,” says Jaworski. “Customers may not have the clean room space or bandwidth to perform these types of product builds. This is just another part of how we try to partner with our customers and alleviate that pain point or constraint for them.”

Early engagement with Mikron's services results in a tighter user requirements specification (URS) and mitigated areas of risk. For medical device manufacturers, this means less chance of changes, delays and other obstacles downstream where changes cost more and consume precious time.

THE PRE-PRODUCTION SERVICES STORY

With close to 50 years of experience in high-speed assembly and manufacturing, Mikron Automation's Pre-Production Services are a way of leveraging that knowledge to help its customers during their product development phase.

"When we started Pre-Production Services, we thought it would really help a lot of our newer customers that may not have a lot of history in medical devices," says Jaworski. "Now, we are helping those smaller companies – but we're also helping some of the largest medical device companies in the world, who need to accelerate and don't have the bandwidth to do some of the design for manufacturing and design for assembly analysis."

The suite of Pre-Production Services provides a new way for Mikron to leverage its experience to be a better partner for its customers, Jaworski explains: "We want to be more than just a provider of equipment; we want to be a true resource for our customers to help them deploy their medical devices quicker and successfully into the market."



ABOUT MIKRON AUTOMATION

Mikron Automation, a division of the Mikron Group, is the leading partner for scalable and customized assembly systems – from the first idea to the highest performance solutions. Distinguished by a commitment to innovation, flexibility, unparalleled customer service, and an evolving platform portfolio, Mikron delivers state-of-the-industry solutions to the most complex assembly and testing demands.

To date, Mikron Automation has installed more than 3,900 assembly and testing systems worldwide. Its international customers operate in the following markets: pharmaceutical, medtech, automotive, electrical/industrial and consumer goods. Mikron Automation currently employs around 750 people and is headquartered in Boudry (Switzerland), a region that is regarded as the heart of the Swiss watchmaking industry. It also has sites in Denver (USA), Singapore, Shanghai (China) and Kaunas (Lithuania). It is a member of the Mikron Group, a publicly-traded company with more than 100 years' experience in precision machinery.

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