



## Norman Noble Expands Engineering Department to Support Phase Gates *Formalized Steps Ensure Projects Meet Timelines and Objectives*

HIGHLAND HEIGHTS, OHIO – July 2, 2024 – Norman Noble, Inc., the world’s leading contract manufacturer of next-generation medical implants, has established a New Product Implementation (NPI) team of engineers to put a phase gate process into effect to more efficiently develop, qualify, and manufacture customer-designed medical implants and devices.

“We have introduced a phased approach to our manufacturing development process, which enhances our ability to deliver high-quality customer designs with improved time to market. This approach begins with initial process development, followed by process optimization, validation, and finally, production ramp,” said Eric Lehuta, Norman Noble Director of Engineering. “By breaking down the development into these distinct phases, we ensure better planning, more rigorous testing, and faster implementation. Moreover, this phased approach fosters closer collaboration with our customers, providing them with valuable insight into our activities and ensuring their needs are met at every stage. Ultimately, this type of continuous improvement leads to greater customer satisfaction through product quality and on time delivery.”

**Phase 1: Initial Development or Characterization** - Norman Noble engineers collaborate directly with customers on the design for manufacturing new customer designs. For existing commercialized products, the NPI team characterizes the current product against existing specifications and functional performance, even when these items are not fully defined.

**Phase 2: Optimization** - Norman Noble manufacturing process optimization activities involve developing nominal process parameters, process controls, and robust inspection methods. This stage focuses on improving Norman Noble manufacturing process efficiencies and product yield to meet both drawing standards and customer cost targets.

**Phase 3: Validation** – Norman Noble engineers conduct validation to meet regulatory requirements and ensure Norman Noble’s commitment to delivering compliant, repeatable products to customers.

**Phase 4: Production Ramp** - The validated process is scaled to meet customer needs in terms of product launch and volume.

“Norman Noble’s NPI process provides our customers with complete transparency into each stage of their product’s development,” said Sarah Pickens, Norman Noble Engineering Manager. “Throughout each stage of the NPI process, our customers can be confident that their product is being manufactured to their drawing specifications while developing processes that ensure quality and maximum efficiency for long-term commercial success.”

**About Norman Noble, Inc.**

Established over 75 years ago, Norman Noble, Inc. remains a family-owned and -operated company offering the most advanced processes for ultra-precision micromachining of medical implants. The company is known for its exceptional ability to produce nitinol-based implants and to achieve sub-miniature precision beyond the reach of most manufacturers. Norman Noble, Inc. is a supplier to most of the largest OEMs and well-known names in the medical device industry.

Norman Noble manufactures medical devices and implants to customer specifications in compliance with FDA regulations and ISO 13485. State-of-the-art processes include athermal laser machining, laser welding, Swiss turning and milling, conventional and wire EDM, high-speed 7-axis contour milling, electropolishing, nitinol shape setting, and clean room assembly and packaging. Rapid development prototyping services are available in separate and fully dedicated process development centers. FDA Registration #1531050. Virtual tour and more information: [www.nnoble.com](http://www.nnoble.com).

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