



IQS Speeds NDI Medical's Time to Market, Eliminating Waste, Errors and Cost as a part of NDI's overall LEAN Initiative

IQS Delivers Risk and Quality Management for FDA Regulated Environments

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IQS, the leading provider of Enterprise Risk and Quality Management Software, announced today that Neurostim Design and Innovation (NDI) Medical has chosen IQS for Advance Quality Management of its implantable and external medical devices. IQS will enable NDI Medical to accelerate time-to-market while ensuring that Class III medical devices meet all FDA regulatory and ISO system standards.

"Medical device companies can't sacrifice quality. Their only choice is how much money to spend on it, and how much risk to take," says Michael Rapaport, CEO of IQS. "IQS provides companies like NDI a centralized fully integrated quality and compliance solution that not only reduces errors and decreases time to market, it allows companies to simultaneously reduce costs."

"IQS stood out from the other options because it was like a carefully woven web," said Michael Haessly, Director of Operations and Quality at NDI Medical. "If we wanted to reduce our time to market and our costs, we couldn't simply look at document management or quality in isolation; we needed a system that addressed cross-functional workflow. Document management for us wasn't simply routing the documents, but providing access to all of the information needed to make sound business decisions, at the click of a mouse. The automated routing of information through IQS drastically shortened our approval times, reduced data entry errors, and has reduced the amount of time needed for issue analysis and resolution. In addition, the centralized data, and user friendly "to do" lists virtually eliminate the time we previously spent tracking down missing documents, such as Nonconformance's and Corrective Actions. IQS has truly made us a much more efficient organization."

IQS Benefit Highlights for NDI Medical;

- Quality has become a value-added tie-in with LEAN initiatives
- Improved manufacturing through-put by increased Change Order processing from 62 to 860 annually
- Improved response time to customers
- Pinpoint quality issues early in the manufacturing process
- Turnkey Compliance
- Reduced audit times from days to hours

"Quality experts know the best way to improve timing and cost without sacrificing quality is to eliminate non-value added tasks, wait time, and waste," says Lori Gipp, VP of Marketing at IQS. "IQS' enterprise approach to quality connects dependent quality processes together to reduce costs and improve product quality – a direct tie-in with an organization's LEAN initiatives."

"IQS gives NDI Medical a tremendous competitive advantage in terms of customer satisfaction and quality improvement: the ability to initiate and approve change orders has dramatically impacted our response-time to the needs of our internal (manufacturing process) and external customers, and for quality issues, we're catching them earlier in the manufacturing process – and in many cases preventing them back in the design cycle before they actually impact production," adds Haessly.

A by-product of IQS' high-level of connectivity and traceability was that by using the product on day to day basis, NDI Medical ended up with turnkey compliance. Audits and validation became events that took hours, not days and weeks," adds Haessly. "In addition, we're able to generate immediate observations and findings, and take immediate action to correct any issues identified."

"We take tremendous pride in the quality of our products because of the improved quality of life our products bring to the individuals who need them," says Geoffrey Thrope, President and CEO of NDI Medical. "Clearly we see IQS as a competitive advantage and a smart investment in the future success of our products and company."

To download the NDI Medical case study, please go to www.iqs.com/downloads.

About NDI Medical

Founded in 2002, Neurostim Design and Innovation (NDI) Medical develops, manufactures and markets implantable neuro-stimulation products including leads and implantable pulse generators (IPG), external devices for patient controllers, and clinician programmers.

NDI Medical's products undergo rigorous quality control throughout design, testing, and manufacturing phases, and are produced in compliance with ISO standards and U.S. Food and Drug Administration regulations. The company is dedicated to continually improving the cost and quality of the products and services it provides by identifying and partnering with qualified suppliers, implementing process improvements and benchmarking industry best practices.

About IQS

IQS – Integrated Quality Systems, helps companies reduce costs and risk by improving quality throughout their enterprise and supply chain. Since its inception in 1988, IQS has been the choice of leading automotive, aerospace, chemical and process, discreet, medical device and recently high-profile manufactures such as those in the pet food industry. IQS reduces risk through a bottom-up verifiable approach to manufacturing. With countless case studies and bottom-line ROI testimonials, IQS is the industry leader in enterprise risk and quality management software. For more information, please visit www.iqs.com.

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