ZEPTO™
PRECISION PULSE CAPSULOTOMY

NEOTech

Case Study

Medical Device Commercialization - Mynosys Cellular Devices

Challenge

Commercialization of new medical technology with a short time to market window.

Solution

Choose engineering partner highly experienced in medical product design and connected to the manufacturing environment.

Background and Challenge:

Mynosys Cellular Devices was formed to commercialize technologies developed by a UCSF professor of ophthalmology David Sretavan and Chris Keller PhD. to address a major challenge of cataract treatment – a repeatable, perfect capsulotomy. The other challenge John Hendrick, Mynosys CEO and the team faced was accelerating the commercialization process to give the new technology time to capture market share, becoming the standard of care for capsulotomies.

The Solution

Mynosys realized that to optimize the challenges of a short time-to-market window and commercializing a new technology that they would need a partner with medical product design capabilities and medical product manufacturing expertise. Engaging separate partners for design and manufacturing would involve a knowledge transfer that injected risk and delay into the commercialization process. A single partner with integrated medical device design and manufacturing expertise would reduce knowledge transfer risk and minimize latency in the process.

Having worked in both contract manufacturing and as CEO of several medical device start-ups, John and the Mynosys team knew the attributes a partner must have to successfully take their product from back-of-napkin (literally) to commercial volume production, which is why they chose NEO Tech. The partnership was symbiotic, leveraging both companies' competencies. As a result the company was able to design and develop 4 iterations of its power supply within 2yrs.

The Results

In sixteen months the integrated Mynosys and NEO Tech teams:

- Created the electronic controls system architecture for the device and power sub-system.
- Engineered the pneumatic sub-assembly including the vacuum system and pressure transducers
- Engineered a grey box concept with specialized user interface to enable Mynosys to perfect the technology and have a higher level of control, measurement and data capture in the initial prototype and provide improved feedback for the design process
- Created test system to confirm future production conforms to the design intent
- Delivered full design support documentation to enable Mynosys to submit for FDA compliance in a compressed timeframe
- Were UL approved - IEC 60601 class 3
- Established low cost supply-base in Mexico
- Met unit cost targets sourcing locally
- Designed and implemented custom ICT tester increasing units built/day
- Using a send-receive-team transfer model began volume production of the device

On-time product launch is allowing Mynosys to meet product introduction targets.

Complementary Core Competencies	
Mynosys	***NEO Tech***
Product conceptualization of how to utilize new technology and it's science to create the probe that performs the capsulotomy	Medical product design experience capable of turning a concept into a manufactureable product
Rapid cycles-of-learning, including certification and compliance management	Design, rapid proto-type and flexible documentation to support cycles-of-learning
Sales and Marketing expertise, developing the go to market brand and distribution channel	Manufacturing and supply chain scalability to support market launch

How NEO Tech Product Commercialization Works:

NEO Tech performs product design and engineering service activity and operates as a seamless extension of our customers engineering organizations, adding scale, flexibility and speed to their design process. It is our engineering services strategy to become our customer's engineering partner at any stage of the design cycle to assist in transforming ideas into production ready products.

– Add Engineering Scalability

– Accelerate Time-to-Market

– Add Needed Expertise on Variable Basis

At NEO Tech we deliver these services with a highly skilled and experienced engineering team with decades of experience designing mission critical defense & aerospace, medical and industrial applications. We partner with our customer and design and engineer analog, digital and mixed-signal printed circuit boards and assemblies, which include high-density, high-speed, and RF/wireless designs. In order to provide these services, we have highly trained and expert team members with diverse EMS and OEM backgrounds, who use their various experiences to work together and serve customers with innovative and reliable printed circuit board design solutions. By acting as an extension of your company's engineering team, we are able to provide an efficient and stress-free value to your project's process.

Test Engineering / Test Development

Our test development team has designed test stations and test specifications for parts in the DC range up to 67 GHz. Our test engineering team ensures that quality requirements are met through a wide range of problem solving techniques. Together, NEO Tech engineers work to embed design-for-test thinking to minimize capital and resource investment for mass manufacturing.

Rapid Prototyping Production

NEO Tech offers rapid prototype production services and is staffed by highly trained technicians. This team compliments the development team by building prototypes quickly and enable the design engineers a tool to validate the product performance and support the end customer development schedules.

State-of-the-Art Engineering Toolsets

Our design team uses a robust engineering toolset that allows them to ensure quality and reliability in each printed circuit board design project by using equipment such as MicroWave Office, Altium, Solidworks and Mentor, among others. This toolset helps us provide medical, industrial, and mission critical defense applications with inventive solutions and quality service.

Base Unit Product Development Iterations

NEO Tech Otay Mesa Manufacturing in Tijuana Mexico

Our team of experts in electronic manufacturing work collaboratively with our customers to design and implement tailored supply chains to each customer's individual needs to bring flexibility and speed to meet demanding deadlines. We are able to work with our customers to provide cutting edge technology in our electronics manufacturing services that help to manage costs while increasing durability and component reliability throughout its life cycle.

- Sourcing and Supply Chain Management
- Manufacturing engineering & Test development
- Repair and Refurbishment Services
- Regulatory Support
- Logistics

Conclusions:

The successful alignment of skills and capabilities and the choice of engineering partners are critical to the success of emerging medical technology OEMs as they bring new technology to market. This experience yields several lessons learned that proved critical to the projects timely success. The depth and experience level of the design leadership who oversee the systems architecture cannot be understated. In addition having the design team well connected to manufacturing provides numerous benefits including access to rapid prototypes to aid in speed of design validation, and more seamless transition from engineering into the manufacturing environment.

Otay Mesa Manufacturing Site in Tijuana Mexico

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NEO Tech delivers technology solutions to high-tech OEMs in the Aerospace/Defense, Medical and Diverse Industrial markets.

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