CASE STUDY

Life Sciences Manufacturing

Product Resources finalizes prototype and manufactures bio-bank extraction device

PRODUCT RESOURCES
DESIGN – BUILD – SERVICE

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Product Resources provides turnkey product development solutions to the biotechnology and life sciences industry.

In many cases, clients come to us with a product idea – outlined with a rough sketch or sometimes with a more detailed schematic.

But assignments also come from clients who have a working prototype, but need help getting that product ready for manufacturing. Very often, these prototypes are developed by another design shop.

That's where this project started.

Background

Bio-Banking is a growing industry segment serving the needs of researchers, medical facilities and educational institutions.

One of the most frustrating challenges bio-banks face is the extraction of individual samples (called aliquots) from a cryovial of frozen tissue or fluid stored in liquid nitrogen with temperatures of minus 150° C.

Until recently, samples needed to be thawed to allow for extraction, then refrozen after the extraction. This repeated thaw-refreeze process would eventually cause the remaining samples to lose their integrity.

Our client, a leading developer of instrumentation for the bio-banking industry, came to us looking for a product that would allow users to extract samples without thawing the original tray.

The Challenge

When we were first called into the project, the client had already developed an engineering prototype with another design firm.

Product Resources has a reputation for working with engineering and industrial design firms to take a working prototype and produce a more finished design suitable for manufacturing.

Although the prototype did demonstrate overall product viability and proof of concept, it was far from ready for manufacturing. This is often the case with initial prototypes where the priority is getting the product to work as intended.

Preparing for Manufacturing

Our Design for Manufacturing (DFM) team immediately went to work to prepare the prototype for the manufacturing phase. The team identified several preliminary steps to provide a manufacturing-ready prototype.

First, they needed to reconfigure all the wiring and electrical boards so they would be easily accessible for repair and maintenance.

Second, they needed to develop an air-cooling system to protect the unit during extended use. The initial prototype would routinely overheat after a short period of time.

Third, while the prototype was able to perform the desired function, it was not designed for compliance. The Product Resources team was able to revise the design to meet all relevant regulatory requirements.

Finally, the team needed to confront various thermal engineering challenges that typically occur when working with liquid nitrogen at temperatures of minus 150° C. Both operators and equipment needed to be protected from the extreme temperatures. Frost buildup was a significant design hurdle that required mitigation.

The Manufacturing Phase

To the surprise of laymen, the manufacturing phase is much more than the physical assembly of the product.

There are detailed drawings, specifications and procedures that need to be developed for every aspect of the project – parts, assemblies, schematics, piping, instruments, testing and risk assessment.

These documents are essential to ensure the product can be reproduced reliably and repeatedly throughout the manufacturing process.

With the paperwork complete, product parts are sourced to the supply chain, and work stations are created for product assembly and testing.

The Finished Product

In the end, our manufacturing team delivered both the design and the product on the client's schedule and budget. This was a complex, evolving project that required multiple specification changes over time.

Since the production of this stand-up floor model, Product Resources has participated in the design and manufacturing of a lower cost desktop model to extend the product line and expand the company's presence in the marketplace.

Post-Manufacturing

With finished products coming offline, additional documents and plans had to be developed for product shipping, Installation and Operational Qualifications (IQ/OQ), maintenance and repair.

Product Resources has also been responsible for the packing and shipping to customers.

A Focus on Quality

Product Resources has an outstanding reputation of maintaining the highest levels of quality both in house and in the field. This includes ISO 9001 (for design and manufacturing) and ISO 13485 (for medical device manufacturing).

"This was a fascinating project for us," said John Erickson, Partner and CEO at Product Resources. "It is very satisfying to be able to take a working prototype and get it ready for manufacturing. This was no small task given its multiple challenges."

Learn More

Find out more about Product Resources and how our design, engineering and manufacturing services could fit into your product development process.

To request a quote or schedule an initial discussion, contact John Erickson at 978-225-4994 or jerickson@prodres.com.

About Product Resources

Product Resources is a product development and contract manufacturing company specializing in complex products for the scientific, medical and industrial markets.

Product Resources provides a full range of design and manufacturing services that include:

- Industrial Design
- Prototype Development
- Design for Manufacturability (DFM)
- Manufacturing Assembly and Supply Chain Management
- Post-Manufacturing Support & Service
- Product Testing & Compliance
- Sustained Engineering
- Design for Explosive Atmospheres

Customer projects may include complete products, sub-systems or sub-assemblies.

Product Resources is located in Newburyport, MA – about 35 miles north of Boston. All testing and assembly work is done in its 33,000 square foot manufacturing plant.

ISO-certified product manufacturing

Recognizing the importance of quality, Product Resources has earned and maintained the following quality certifications:

- **ISO 9001**-approved for engineering design, development, manufacturing and service – certified by TUV.

- **ISO 13485**-approved for medical device manufacturing and service – certified by TUV.

- **ISO/IEC 80079-34** approved for engineering design, manufacturing and service, audited by TRaC Global, for equipment and instrumentation used in explosive atmospheres.