

A STUDY IN SUCCESS

RR Donnelley Case Study

RR Donnelley Global Turnkey Solutions provides cleanroom kitting and assembly solution for medical device manufacturer.

Background

r4 Vascular is a start-up medical device company that elected to focus on research and development, marketing and customer service while outsourcing manufacturing activities. The company's products include medical kits used for interventional procedures by cardiologists, radiologists and nephrologists.

Challenge

r4 Vascular wanted a relatively fast ramp-up of six months, which required an FDA-registered facility—ISO Class 8, Federal Standard 209, which mandated the maximum number of particles of 0.5 micrometers or more in diameter acceptable in a cubic foot of air be 100,000.

Specific challenges for r4 Vascular included providing:

- Sourcing and procurement of product components
- Quality assurance program management that addressed regulatory compliance issues, including maintaining a Device History Record (DHR) and Device Master Record (DMR)
- Order entry system development for accepting orders directly from the sales force or hospitals and providing the pick, pack and fulfillment services required to deliver finished goods
- EtO sterilization sub-contractor and associated testing laboratories management
- Process and software validation
- Warehousing and inventory management
- Marketing collateral, product literature and promotional premiums, production and fulfillment management

Solution

The RR Donnelley Global Turnkey Solutions team provided the supply chain expertise and engineering solutions to accomplish the quick ramp-up for a client with no existing infrastructure. Our centrally located, FDA-registered, ISO 13485-accredited and cGMP-trained facility, which included a 5,000-sq.-ft. cleanroom, provided the specialized space required by the customer. We developed the IT solutions required to manage the complexities of the supply chain and integrated our ERP system with that of our clients to deliver a seamless link between the two companies.

RR Donnelley's solution enables r4 Vascular to scale volume upward and it supports their changing global kitting and fulfillment needs as business grows.

Key aspects of the solution included:

Project management

- Oversaw multiple product launches
- Designed packaging and label requirement setup as well as lot-level track and traceability
- Identified and managed EtO sterilization vendor
- Managed validations necessary for regulatory body approvals
- Developed comprehensive inbound materials management, warehousing and quality assurance programs

Kitting and assembly

- Assembled complex product kits that included managing specification and SKU variables

Procurement

- Centralized function to bring greater economies of scale by leveraging both RR Donnelley Global Turnkey Solutions and customer-approved vendors

Fulfillment and distribution

- Developed sales order processes and system setup and management for distributing products directly to hospitals

RR DONNELLEY

Benefits

Although implementation is still in the early stages, r4 Vascular is already experiencing a number of important benefits. "RR Donnelley Global Turnkey Solutions' supply base management service eliminated significant headaches for us," said Mark Kraus, Vice President of Operations at start-up medical device maker r4 Vascular, Inc. "Because of RR Donnelley Global Turnkey Solutions, we did not have to expend time and money normally directed at supply chain development and human resources, thus allowing us to fully utilize our capital resources on the completion of product development as well as sales and marketing."

RR Donnelley Global Turnkey Solutions also provides the regulatory compliance management required of medical device companies, relieving the company of a time-consuming yet important function.

Results

By utilizing the existing world-class systems and facilities of RR Donnelley Global Turnkey Solutions, the customer was able to avoid significant capital investment and gain cash flow advantages. More specifically, outsourcing provided these financial advantages:

- Lower direct and indirect labor costs
- Fewer administrative requirements
- Enabling of asset avoidance
- Ability to scale upward domestically or internationally without investing in facilities, systems and related personnel



RR Donnelley Global Turnkey Solutions Plover, Wisconsin facility

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