



Drug Delivery Device Manufacturing Facility

MPR Designs Manufacturing Facility for Implantable Drug Delivery Device

Practice Areas



Medical Devices



Diagnostics



Laboratory Instruments



Analytical Instruments



Biotechnology



Pharmaceuticals

Product Types



Durables



Disposables



Packaging

Service Areas



Research and Development



Voice of the Customer



Conceptualization



Proof-of-Concept



Detailed Engineering



Industrial Design



Design for Manufacturing



Supply Chain



Regulatory



Intellectual Property



Scale-Up



Fundraising



Device Certification

CHALLENGE

A specialty pharmaceutical company sought to develop a first-of-a-kind drug delivery device, and design and rapidly construct a manufacturing facility for the combination product. However, the traditional facility build-out approach using process engineering, architect, builder, and validation firms creates schedule risk due to the various organizational interfaces. To manage this risk and complete the project on a very aggressive timeline, the company engaged MPR to provide the overall leadership, project management, and owner's engineering services.

SOLUTION

MPR started by developing a unique, product-specific delivery technology, based on product formulation and delivery requirements. The firm oversaw laboratory experiments to determine important physical properties of drug components, optimization of formulation, filling methodologies and other key delivery considerations. MPR then led rapid construction of a Current Good Manufacturing Practices (cGMP)-compliant facility for the product. The firm eliminated organizational inefficiencies typically encountered in traditional construction projects by integrating architecture and engineering services, construction and facility validation under MPR's leadership. In addition to the construction program, the MPR assignment included start-up, commissioning and validation of the facility's equipment, as well as operator training and technical support.

RESULTS

MPR developed the manufacturing process and \$50 million, 90,000 square foot manufacturing facility in 14 months, enabling ramp-up to full-scale manufacturing within a six-month product launch timeframe. The manufacturing facility passed the FDA's pre-market inspection process in one day with no 483 findings, a rarely achieved milestone.

TIMELINE 14 Months





Implantable Drug Delivery Device

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CHALLENGE

A specialty pharmaceutical company had developed an implantable pain management device to consistently provide accurate, small-dosage deliveries of medication to patients with chronic diseases. The company's goal was to create a process to efficiently and effectively manufacture this unique miniature drug delivery system. However, traditional manufacturing processes and commercial off-the-shelf (COTS) equipment alone were not appropriate for producing this highly precise, miniaturized and implantable device.

SOLUTION

MPR's first step was to divide this major assignment into a series of smaller technical tasks, such as determining how to accurately fill individual delivery devices with the drug, preserving sterility throughout the manufacturing and filling process, and maintaining extremely high quality control over medication fill levels during the process. These individual solutions were integrated into an overall best practices and technologies manufacturing process, then applied to a rapid prototype for validation. During this process, MPR also created process documentation and training. While developing a drug product under stringent FDA requirements involves rigorous validation testing, many manufacturers use a complex and inefficient testing approach. However, the multi-disciplined MPR team conducted both engineering and validation testing almost concurrently, achieving higher development efficiencies and reducing product time-to-market.

RESULTS

MPR's ability to appropriately balance customized and COTS equipment in a comprehensive production methodology enabled creation of a completely validated, aseptic manufacturing process that was ready to support clinical trials in a record eight months.

TIMELINE 8 Months





Drug Delivery System

MPR Develops Innovative Drug Delivery Implant for Treatment of Chronic Pain

Practice Areas

-  Medical Devices
-  Diagnostics
-  Laboratory Instruments
-  Analytical Instruments
-  Biotechnology
-  Pharmaceuticals

Product Types

-  Durables
-  Disposables
-  Packaging

Service Areas

-  Research and Development
-  Voice of the Customer
-  Conceptualization
-  Proof-of-Concept
-  Detailed Engineering
-  Industrial Design
-  Design for Manufacturing
-  Supply Chain
-  Regulatory
-  Intellectual Property
-  Scale-Up
-  Fundraising
-  Device Certification

CHALLENGE

A specialty pharmaceutical company engaged MPR to assist them with the development of a unique drug delivery system intended for the treatment of chronic pain. The product is a small implantable delivery device that distributes minute amounts of a pain-relieving narcotic, providing continuous relief for several months at a time. The key technical challenge with the device was regulation of the dosage, as too little would render the product ineffective while too much would be lethal.

SOLUTION

MPR worked with the client's development group to solve significant design challenges that were affecting drug delivery performance. First principles techniques were applied to analyze the method of action used to dispense the drug. This led to insights into the physical processes involved, including capillary action, diffusion and osmosis, that allowed us to optimize the design of the system. High precision, miniature components were designed with passive safety features that could adequately control drug flow within required limits. A computer-controlled filling, assembly, and inspection process was also developed by MPR to ensure critical aspects of the system were controlled during the manufacturing process.

RESULTS

MPR developed innovative design solutions that enabled this first-of-a-kind product to meet its performance requirements. MPR was also instrumental in the design and implementation of the manufacturing process at a contract manufacturer's facility. In less than 9 months, MPR helped the client progress from the concept stage to successful production of over 1,000 units for clinical trials.

TIMELINE 9 Months

