



Sterile Manufacturing Facility & Process

MPR Designs First-of-a-Kind Combination Device Production Facility and Process

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 start-up pharmaceutical manufacturer was planning the development of a production facility for a new combination drug-device product. The nature of the product and needs of the marketplace required a first-of-a-kind sterile manufacturing process and an aggressive timeline, both key project challenges.

SOLUTION

To decrease the time to market for the product, MPR elected to develop the manufacturing process and the new manufacturing facility simultaneously. In creating the manufacturing process, MPR tested each step individually to develop the necessary techniques. The team then performed end-to-end process studies to optimize critical process parameters. Additionally, each step was analyzed for specific functional requirements. Decisions were made to either adapt available off-the-shelf equipment or design and fabricate custom equipment for every key component of the manufacturing process. As part of transferring the process from testing to production mode, MPR performed commissioning and validation of manufacturing equipment, prepared manufacturing procedures, compiled batch production records and provided technical support through initial production.

MPR also engineered the startup, commissioning and validation of the sterile processing facility. This required detailed planning and coordination of activities with client's engineering, manufacturing and quality assurance departments to achieve the aggressive project timeline. MPR provided on-site troubleshooting of facility and utility systems for HVAC, water, compressed air and steam sterilization.

RESULTS

Creating a new manufacturing process and developing the new facility were completed in 18 months, meeting time-to-market goals. Additionally, the new sterile filling process was successfully implemented, passing rigorous sterility validation testing.

TIMELINE 18 Months

