



PEAK PERFORMANCE COMPOUNDING SUPPORTS MEDICAL DEVICE OEM WITH DESIGN OF EXPERIMENT FOR NEW PRODUCT DEVELOPMENT

A Customer Success Story

The development of new and improved medical devices is key to enhancing patient outcomes and improving the quality of care worldwide. Peak Performance Compounding, LLC proudly supports leading medical OEMs in the early stages of the product life cycle with comprehensive development services, including formulation studies, material sampling, processing trials and scale-up. Together, we work with our broad range of internal support services, along with partnering processors, to bridge the gap between development and commercialization; reducing time to market and overall material costs.

The following case study examines an actual Design of Experiment (DOE) between Peak Performance Compounding and a leading medical device manufacturer.

Customer Profile: The customer for this DOE was a large medical device OEM.

Material Needs: The customer required a highly filled tungsten compound for device visibility under x-ray technology.

- High level of radiopacity
- Maximum dispersion of tungsten filler
 - Loading level to be determined from formulation and extrusion studies
 - Smooth surface finish required; free from agglomerates

Market Application: The application in question was a narrow, thin-wall, radiopaque catheter.

Material Challenges: This OEM needed support in the formulation and processing of their tungsten filled catheter compound. They were unable to meet the desired loading level and degree of radiopacity without compromising the quality of the blend and surface finish of the catheter tube. Their production yields were low and material costs were high.



The Peak Solution: Peak has extensive experience in processing highly filled compounds, specifically high specific gravity tungsten blends. Utilizing a custom formulation, proper equipment and set-up, along with down-stream modifications, we were able to satisfy the customer's unique device requirements and reduce production scrap / material costs.

- Developed a Design of Experiment (DOE), mapping out the relationship between high specific gravity tungsten compounds and radiopacity
- Provided various formulations and samples
- Customized underwater pelletizing process to produce spherical pellets for ease of processing and enhanced filler dispersion
- Utilized a continuous blade sharpening procedure
- Implemented customized feeder technology and screw design

The Outcome: Peak proudly met our customer's unique material needs and provided them with the following material and business-related benefits:

- A custom formulation that provided the desired device radiopacity, surface finish and performance
- Success in scale up from lab DOE to production quantities
- Provided high-quality spherical pellets, consistent in size and shape
 - Free from agglomerates, bumps and nibs
 - No strings or tails
- Ability to run at a highly efficient production rate with high yields and low scrap
- Successfully met customer's cost target and timeline for device qualification and commercialization
- Enabled OEM to manufacture and market a cost-effective, high-quality radiopaque catheter

For more information on this case study or to discuss how Peak Performance Compounding, LLC can assist with your unique material needs, please email info@peak-pci.com