

## Case Study 2

### **Case Study 2: Knowledge of combination drugs and target markets leads to commercial success**

**Challenge:** International Company follows previous poor regulatory and strategic development advice and positions its drug-device combination product incorrectly for successful approval and market penetration.

**Background:** A product that delivers a drug using a device, such as a syringe or catheter, is called a combination product in the cases where the device and drug are packaged and labeled together. For example, a syringe by itself is a device, while a vial of drug by itself is a drug. But if the two are needed together under a specific set of instructions, then it is a combination product. This nuance is little-understood and subject to a great deal of controversy. Moreover, until just this year, the rules in the US and EU were at odds with ex-US clients often misguided by local regulatory consultants.

In this case, the client's product was a specific catheter that delivered a drug solution comprised of a vial of off-the-shelf drug powder mixed with a combination of polymers, which yielded a solution at room temperature that gelled at body temperature. The client's product was designed to provide a cure for an organ cancer. The current treatment for such cancer is the surgical removal of the organ. The client based its ROI on the health systems replacement of the cost of surgery and subsequent maintenance therapies.

**Solution:** With its considerable experience with combination drug Camargo was able to correctly recognize the product category and convince the FDA to agree to a combination product. Further, it was able to convince the Agency that it was a suitable candidate for Orphan Drug status, with the attendant fast-track of review. Camargo's knowledge of the commercial marketplace allowed it to identify the correct market. Rather than surgeons, the correct market is urologists.

**Outcome:** The Client was able to focus its drug development efforts on the drug portion of the product. Further, the ROI was better supported enabling the client to go public, gaining money to accelerate the product development of this and other related products. The client embraced the new strategy to the degree that it changed its name from one reflective of the technology to one that articulated its therapeutic impact.