



# ON-Q\* Pain Relief System Pharmacy Fill Service

Today's healthcare providers are under increasing pressure to do more with fewer resources, all while striving to deliver the highest standards of patient care. For organizations that compound sterile drugs in-house, evolving regulations, heightened quality and safety requirements, and intense regulatory oversight have made compliance more complex than ever.

At the same time, ongoing national drug shortages, particularly with local anesthetics, are creating new challenges. Pharmacists are struggling to secure reliable supply, making it difficult for providers to deliver continuous infusion therapy and consistent pain management to their patients.

Leiters Health is here to help. We are pleased to offer a pharmacy fill service for the AVANOS Medical ON-Q® Pain Relief System pumps, providing a high-quality and reliable outsourcing option. By partnering with us, your pharmacy and clinical staff can focus more time where it matters most, delivering exceptional care to patients.

### **CURRENT OFFERING**

ON-Q* Pain Relief System (Pump/Drug)	Item
ON-Q* CB004; 400ml Select-A-Flow*, 2-14ml/hr, Ropivacaine HCl 0.2% (2 mg/mL), 550mL <sup>†</sup>	K-F9202
ON-Q* CB6004; 600ml Select-A-Flow*, 2-14ml/hr, Ropivacaine HCl 0.2% (2 mg/mL), 750mL <sup>+</sup>	K-F9208
ON-O* CB6007: 600ml Select-A-Flow*, dual, 1-7ml/hr/site, Ropivacaine HCl 0.2% (2 mg/mL), 750mL <sup>†</sup>	K-F9210

### **ADDITIONAL INFORMATION**

- 90 day Beyond Use Date (BUD)1
- Stability testing is completed prior to producing batches.
- Full microbiological and chemistry testing is performed prior to each batch being released.
- A batch specific Certificate of Analysis (CoA), detailing all the testing performed, is provided with every shipment.



## Elevating the standards in 503B pharmaceutical outsourcing.

The world of healthcare is constantly changing. With increasing regulatory pressure, treatment shortages and the need to do more with less, high quality pharmaceutical outsourcing is more important than ever.

Leiters Health, founded in 1926, is an FDA-registered 503B outsourcing provider of hospital and ophthalmic compounded sterile preparations and pharmacy services...

Our team of experts in sterile pharmaceutical manufacturing, repackaging, and compounding provide a sophisticated understanding of what it takes to elevate quality and consistency of supply. We combine our team, our robust processes and our state-of-the-art outsourcing facility to ensure the highest quality products and services.

# THROUGH 3 KEY PILLARS, PEOPLE, PLACE AND PRODUCT, LEITERS HEALTH IS ELEVATING THE STANDARDS IN PHARMACEUTICAL OUTSOURCING.



### **PEOPLE**

- Highly trained multifunctional teams of pharmaceutical experts ensure quality and regulatory compliance for all released product.
- Relevant industry experience with sterile injectable pharmaceutical companies, hospital pharmacies, and academia.
- Our customer experience team of regional based account representatives, account managers and customer service specialists work together to provide you with consistent and reliable service.



### **PLACE**

- FDA-registered and inspected, cGMP compliant 503B outsourcing provider.
- Licensed to ship to all 50 states (+ the District of Columbia).
- State-of-the-art equipment and automation is used throughout our sterile manufacturing process.



### **PRODUCT**

- All sterile preparations are produced under 503B of the FD&C act (503B Guidance), following current Good Manufacturing Practices (cGMP) and meet or exceed USP <797>.
- Full microbiological and chemistry testing is completed prior to each batch being released. This includes sterility, endotoxin, potency, identification, impurities, particulate (subvisible), visual appearance and pH testing.
- A batch specific Certificate of Analysis (CoA), detailing all the testing performed, is provided with every shipment.

### **Quality. Compliance. Consistency.**





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