CASE STUDY

SUMMA HEALTH AND LEITERS COLLABORATE TO REDUCE OPIOID USE

BACKGROUND

For a patient, the statistics paint a grim picture regarding the effects of opioids. Every day, more than 115 people die from opioid overdoses.[1] A one day use of an opioid prescription may pose a six percent risk of long-term opioid use, and dependency can start within three days of initial opioid use.[2]

Opioid addiction invades homes, schools, and communities, leaving devastated lives in its wake.

Summa Health, a nonprofit integrated healthcare delivery system in Northeast Ohio, is more committed than ever to conquer the opioid crisis. To support this commitment, it has set a goal to eliminate opiates from its operating rooms completely.[3]

While Summa Health has already made significant headway on achieving this goal, additional help combating opioid use came from Thomas Mark, M.D. Chair, Department of Anesthesia, with the concept of a compounded multi-drug nerve block using three non-opioid drugs: bupivacaine HCl, dexamethasone sodium phosphate, and epinephrine.[4]

"Summa Health's intent for this combination drug product is to reduce opioid use, improve patient outcomes and satisfaction, minimize complications, and shorten hospital stays," said Dr. Mark.

Initially, Dr. Mark collaborated with his pharmacy colleagues, John Feucht, Vice President of Pharmacy Services, and Glenn Huth R.Ph., Director of Pharmacy Operations, to compound this formulation in-house. However, as demand for the combination product increased, it brought new challenges for the hospital and pharmacy.

Quality assurance, increased regulatory compliance, capital expenditures, drug shortages, and a national scarcity of pharmacy technicians make it difficult for hospitals, surgery centers, and clinics to compound higher volumes of complex combination drugs in-house. Furthermore, the increased expectations of regulatory agencies, accreditation organizations, and consumer groups lead many pharmacists to outsource their drug compounding to a high-quality 503B organization.

Summa Health realized that collaboration was essential for success in reaching its goal to eliminate opiates from its operating rooms. The team at Summa Health understood that

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Vice President of
Pharmacy Services
~ Summa Health

this combination drug product would require heightened regulatory oversight to ensure a robust formulation that delivered the required dosage of each of the three drugs, as well as consistency and quality of supply. Summa Health decided it would need to collaborate with an innovative, forward-thinking partner with superior capabilities to fully develop and manufacture the product under current Good Manufacturing Practices (cGMP) regulations.

This case study details the extensive efforts that Mark, Feucht, and Huth applied to find an FDA-registered 503B outsourcing partner that could efficiently and effectively manufacture and deliver the opioid-free nerve block agent to their health system.

DECISION TO OUTSOURCE

The Summa Health team defined the necessary criteria and conducted comprehensive due diligence that ultimately led them to an innovative, reliable partner. However, the path presented problems. Feedback from prospective 503B partners ranged from a lack of capabilities and confidence to formulate the combination drug product with the requisite quality and testing to vendors not having the operational and production resources to meet demand.

After expanding the outreach, the team's research led them to Leiters — an FDA-registered 503B outsourcing provider of high-quality ready-to-use (RTU) compounded sterile preparations (CSPs). Leiters state-of-the-art facility located in Denver, Colorado follows cGMP and employs a multi-disciplinary team with deep experience in cGMP, sterile pharmaceutical product development, manufacturing, compounding, and repackaging that ensures all products are released under the highest quality and regulatory compliance standards.

"We required a compounding pharmaceutical company that received high grades in quality, compliance, consistency, service, and standardization. This endeavor could not produce variation in the product," said Feucht. "Our decision to choose Leiters ultimately came down to their overall expertise in sterile manufacturing, quality, compliance, and capacity."

Moreover, Leiters demonstrated they could deliver consistent, high-quality pharmacy and sterile compounding services, including extended beyond-use dating and proof of batch-level sterility, potency, and endotoxin testing.

As a pharmacist and Vice President of Business Development at Leiters, Steven D'Amico RPh, understood the challenges facing Summa Health. Leiters spent significant time with the stakeholders at Summa Health to understand their requirements in order to begin the product development process. The Leiters research and development team, involving scientists, microbiologists, pharmacists, and engineers, follows a robust product development process[5] consisting of — but not limited to — the following activities:

- Feasibility testing on varying formulations, components, and processes.
- Initial purity and stability testing for the chosen formulation.
- Full stability studies to assess product formulation, purity, and stability to determine Beyond Use Date (BUD).
- Testing for potency, lack of impurities, pH, clarity, visible and subvisible particles, sterility, endotoxin, container closure integrity, and other needs required for each product formulation.

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KEY BENEFITS OF OUTSOURCING TO LEITERS

Leiters, founded in 1926, has a long history of evolving and innovating to meet the latest regulatory requirements and market needs. They produce all of their sterile preparations under Section 503B of the FD&C Act (503B Guidance), cGMP, and USP <797>. Their facility consistently upholds all standards based on the audits conducted by the FDA, States of California and Florida Boards of Pharmacy, multiple health systems, group purchasing organizations, and other independent accreditation organizations.

Partnering with Leiters provides the following benefits to partners:

- Decreasing the compounding burden on pharmacists and pharmacy technicians, allowing them to focus on essential pharmacy tasks and their patients.
- Providing a consistent and reliable supply of high-quality RTU pre-packaged and labeled CSP's.
- Inherent safety factors by using repeatable validated cGMP aseptic processes.
- Supporting your facility during drug shortages.
- Extended Beyond Use Dates (BUD) to enable better inventory management and reduce waste.
- Documented quality reporting.

Quality Assurance and Laboratory Testing

Every product produced at Leiters goes through rigorous quality assurance processes, and all testing is completed by independent laboratories.

- Prior to commercialization, each new product completes a development process including independent laboratory confirmation of identity, potency, and sterility.
- Independent laboratory testing of chemical and microbiological characteristics, including identification, bioburden, and endotoxin of all incoming active and inactive ingredients.
- Use of aseptic processes and sterile filtration during production to enhance Sterility Assurance Level (SAL).
- Stability testing is performed before producing batches.
- BUDs are established based on product-specific stability testing of both chemical and microbiological characteristics.
- Microbiological and chemistry testing (including sterility, endotoxin, potency, identification, impurities, particulate-sub visible, visual appearance, and pH testing) is completed before any product release.

In addition, Leiters provides a Certificate of Analysis (CoA) with every shipment, detailing all the requisite testing.

Leiters uses state-of-the-art equipment and automation throughout their sterile manufacturing process including — but not limited to — vertical laminar flow hoods, bio-decontamination system, negative-pressure isolators, laboratory fume hoods, biosafety cabinets, automated syringe filling and inspection, and automated labeling machines.

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RESULTS

Summa Health and Leiters have collaborated for over two years on this compounded nerve block agent. Leiters has consistently provided Summa with a high-quality compounded formulation in a RTU pre-filled syringe that has allowed Summa to provide their patients with an opioid-free drug.

By outsourcing the compounding of this drug to Leiters, Summa Health has realized many positive improvement in their pharmacy operations. They entail:

- Improved shelf life. Leiters service offers a 90-day shelf life, a substantial increase over previous in-house nine-day shelf life.
- Procurement of the RTU syringes, removed a vast compounding burden from the pharmacy technicians enabling enhanced patient care and safety by providing medicines in a dose that is ready to administer.
- Streamlined and improved the previous time-consuming effort of compounding in house.
- Consistent and reliable delivery.
- Decreases the potential for medication error by providing a pre-printed and labeled RTU syringe.

CONCLUSION

The partnership between Summa Health and Leiters exemplifies a successful collaboration between the surgical department, hospital pharmacy, and a 503B outsourcing facility.

D'Amico summarizes the relationship with Summa Health as, "A great collaboration across the continuum of care. Together, we are improving patient care and pharmacy operations. While this project began as a formulation for one health system, we see this as a broader opportunity for many physicians and health systems."

"Summa Health and Leiters are well on the way to eliminate opiates from the operating room," said Dr. Mark. "Their services have been critical to our success."

References:
[1] https://www.summahealth.org/flourish/entries/2018/11/eliminating-the-need-for-opioids-in-surgical-procedures
[2] https://leiters.com/on-q-pain-relief-system-fill-service/
[3] https://www.cleveland19.com/2019/02/21/summa-health-working-eliminate-opioids-all-surgeries/
[4] A provisional patent for the combination product was filed by Leiters on April 14, 2021
[5] Contact Leiters for additional information about our new product development process

Leiters Health
QUALITY COMPOUNDING FOR LIFE™