LUBRIZOL LIFE SCIENCE

Case Study - Secondary Sourcing Strategies to Ensure Supply Chain Security

ABSTRACT

- ChiRhoClin is an established and growing orphan drug company manufacturing vital products for the medical community.
- The collaboration with LLS Health seeks to secure vital supplies of ChiRhoClin's ChiRhoStim® product (Human Secretin for Injection), which aids in the diagnosis of pancreatic cancer and pancreatic exocrine dysfunction, by completing a tech transfer process and implementing a secondary sourcing strategy.
- ChiRhoStim® is a synthetic hormone and requires commercial aseptic manufacturing process includes sterile filtration and lyophilization. In line with ChiRhoClin's growth ambitions, both small batch manufacture and the capability for scaled up production were essential.
- LLS Health supports ChiRhoClin with its state-of-the-art manufacturing facilities. LLS Health is committed to provide a reliable, scalable manufacturing process for ChiRhoStim® and seamlessly achieve FDA approval to meet both current and future demand.

WHO IS CHIRHOCLIN?

Founded in 1991, ChiRhoClin is a growing, family-run pharmaceutical company manufacturing crucial orphan drug products within the medical community, including ChiRhoStim® (Human Secretin for Injection).

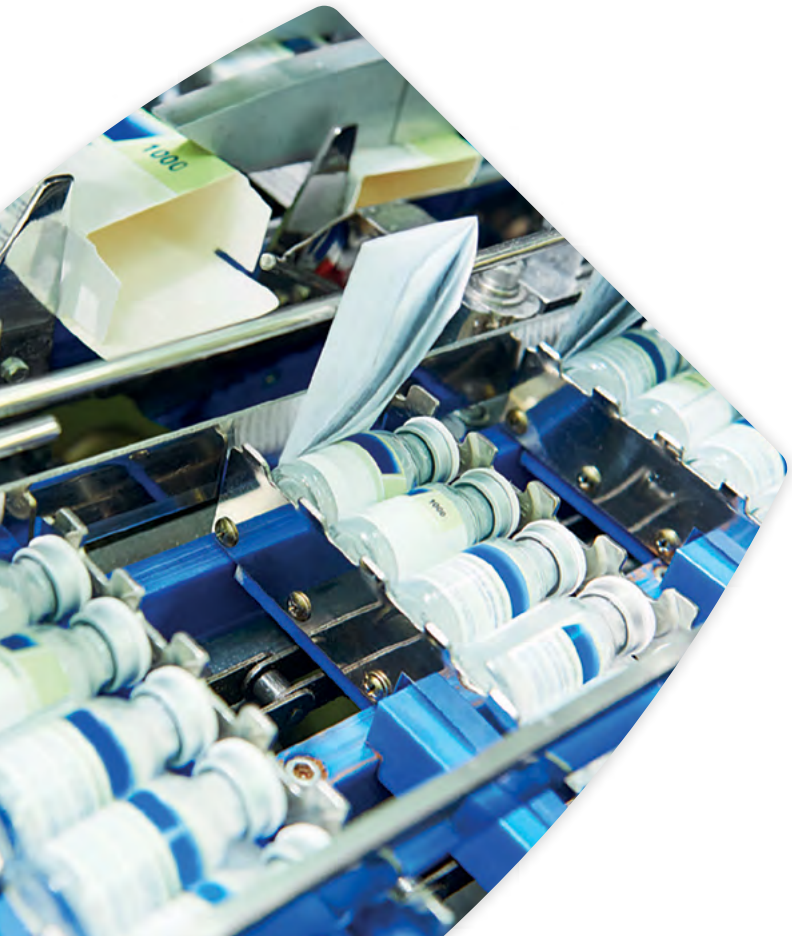
Human secretin, in 1902, became the first hormone ever discovered and was hailed as a significant milestone. The founder of ChiRhoClin, Dr. Edward D. Purich, developed a method of producing and manufacturing secretin synthetically at 99.9% purity. It was on the basis of this innovation, with a view to keeping an essential drug on the market, that ChiRhoClin was formed. Today, the company continues to deliver vital orphan drug products to the patients who need them.

THE PRODUCT: CHIRHOSTIM®

The most sensitive and specific product for diagnosing early pancreatic disease and chronic pancreatitis, ChiRhoStim®, plays a key role in the diagnosis of pancreatic cancer and pancreatic exocrine dysfunction. The product is approved for pancreatic function testing, facilitating cannulation during endoscopic retrograde cholangiopancreatography (ERCP), and gastrinoma testing. In addition, secretions of the pancreatic fluid after secretin stimulation – facilitated by ChiRhoStim® – can turn static images into dynamic ones throughout multiple imaging modalities such as magnetic resonance cholangiopancreatography (MRCP), computed tomography (CT), and endoscopic ultrasound (EUS).

In light of its relative importance in the gastrointestinal and radiological community, a stable secondary manufacturing source for ChiRhoStim® ensures a robust, uninterrupted supply.

ChiRhoClin's goal was to increase production in line with demand and it was imperative to develop a tailored approach with a collaborative partner.



THE CHALLENGE: SECURING SUPPLY

A number of challenges and needs were considered when developing a secondary sourcing strategy and selecting a CDMO partner.

First, we assessed the current climate for establishing a US-based manufacturing source of critical pharmaceuticals – an important step to combat supply chain issues. In the case of ChiRhoStim® and previous difficulties with securing supply, quality was of the essence in the choice of manufacturing partner and the tech transfer process in order to ensure that patients continue to receive essential supplies of the product.

Additionally, although a diagnostic agent, ChiRhoStim® is manufactured and filled like any other drug product. However, as a biologic, its manufacture is more complex, and the product is sterile filtered and lyophilized in an aseptic manufacturing process.

Finally, in light of ChiRhoClin's ambitions to grow, it was necessary to partner with a CDMO with the capability for small batch sizes while also possessing the expertise for scaled-up production.

These unique circumstances led to ChiRhoClin seeking a partner who could work together as a team to devise a tailored approach and ultimately help secure patients' access to its high-quality offerings.

THE SOLUTION: LLS HEALTH'S ROLE AS A COMMERCIAL MANUFACTURING PARTNER

LLS Health is partnering with ChiRhoClin, leveraging its commercial manufacturing capabilities to provide a reliable, scalable manufacturing process for ChiRhoStim® that will enable the product to meet both current and future demand. With an FDA preapproval inspection completed for a topical ophthalmic therapeutic and specialization in sterilized products, LLS Health is well positioned to provide the support needed to handle the tech transfer process smoothly, while its ability to handle small batch sizes makes its team highly suited to the task.

Additionally, in the case of older drug products, and especially more complex formulations, it may be beneficial during tech transfer to have a CDMO that is well versed in state-of-the-art development. This can confer the ability to strengthen the CMC package of the drug product during tech transfer to ensure it is up to date in terms of FDA expectations and is a service LLS Health is able to offer, as required. By working synergistically to meet the needs of ChiRhoClin's orphan drug product, we are able to support development as needed and ensure factors are taken into account with a view to achieving FDA approval more seamlessly.

In addition, supported by Berkshire Hathaway, LLS Health has a comprehensive development and analytical department. With 20+ years of experience in the development of sterile and non-sterile drug products for clinical trials, the combination of experience and expertise is ideal for tech transfers and driving projects from clinical to commercial manufacturing.

LOOKING TO THE FUTURE

The collaboration between ChiRhoClin and LLS Health seeks to secure the supply of an essential medicine, facilitate its tech transfer journey and achieve FDA approval of the manufacturing process within the next few years.

With small patient populations sometimes in danger of being overlooked, a concerted effort to maintain supplies of crucial drugs is vital. Furthermore, as the patient populations in need of orphan drug products such as ChiRhoStim® have no alternative, expedited production is essential both from a humanitarian standpoint to prevent misdiagnosis, and from a commercial perspective to ensure a consistent supply in line with demand.

Would you like to learn how LLS Health can streamline your commercial manufacturing journey? **Get in touch to find out more.**

To find out more information about ChiRhoStim® (Human Secretin for injection), pancreatic disease, and theranostics products, please visit us at **www.ChiRhoClin.com**

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