Ranfac®

RANFAC CERVOS MEDICAL

CASE STUDY

The Background:

Cervos Medical is a joint venture between Ranfac and Endocellutions that specializes in harvesting and processing autologous tissues for the purpose of concentrating and accelerating the healing potential. Endocellutions' partnership with Ranfac has enabled them to penetrate the market and sell tens of thousands of their products over the years. Their devices have been well-received by doctors, who study and use them—so much so that they've even published articles in journals confirming the positive effects on patients. The first product, "Marrow Cellution", was a huge success, with over ten peer reviewed journal articles documenting this; eight of which focus on joint preservation.

The companies' latest project was for the development of a novel Platelet-Rich Plasma (PRP) system, which posed an entirely new design challenge. To ensure that the product performed better than anything else on the market, Ranfac carefully chose each material that interacted with blood, and conducted rigorous testing prior to submitting it for FDA approval.

The Deliverables:

- Drive the development of CERVOS PRP and navigate regulatory clearance through the FDA's Center for Biologics Evaluation and Research.
- Strategize and execute cost-effective production to maintain competitiveness in a price-sensitive market, without compromising product efficacy.
- Design and implement a flexible manufacturing operation to achieve seamless scaling from pilot production to large-scale output of over 100,000 units per year.

The Experience:

The process to make Platelet Rich Plasma (PRP) involves collecting a sample of a patient's blood, transferring it to a processing syringe, and separating the blood into various fractions through centrifugation. The main design challenge was to prevent product failure due to leakage during the centrifugation process, which requires significant g-force to separate the blood within the desired time frame. This presented another design challenge of creating a seal that was strong enough to withstand the force of centrifugation, yet still allowing easy depression of the plunger during

loading of the disposable by a clinician. This facilitated Ranfac's identification of user needs for the device and enabled the structured testing of this aspect. Through the testing process, Ranfac gained a deeper understanding of the chosen materials and made necessary design modifications to meet the stringent testing criteria. This allowed for the successful progression of the production builds.

As the project moved into production, Ranfac's manufacturing engineers leveraged their expertise to effectively integrate robotics and automation into plastic molding and assembly. This innovative approach offers a range of benefits for manufacturing operations, including increased efficiency, precision, and production speed, as well as reduced dependence on manual labor and decreased risk of human error. Furthermore, by enhancing control over the production process, the quality and consistency of the final products are significantly improved. With these advancements in place, Cervos is poised to stay ahead of the competition, meet customer demands, and drive growth for the business.

Andrew McGillicuddy, CEO of Endocellutions, had this to say about the experience: “The capabilities within the Ranfac facility are huge. They provide the engineering, the regulatory, the quality, the manufacturing, and the molding to get a product made. They basically do everything from soup to nuts. It’s rare to find a company that does everything under one roof. Having full source manufacturing capabilities provides a competitive advantage to Ranfac by avoiding any delays and/or miscommunication that cost time and money.”

The Results:

On February 24, 2021, Ranfac received notice from the FDA of its successful 510(k) clearance. This announcement has since led to the rapid growth and recognition of the Cervos Key PRP system among leading institutions across the United States. The system has become known for its capacity to concentrate high platelet doses within a highly customizable platform and its ability to offer this capability at a competitive price point.

> You're going to put a million of these things out on the market and they all have to work every time. You have to do that within a regulatory environment that is onerous. So it's not easy what Ranfac does. And there's not many places in the world that can do what they do, especially in the USA.

ANDREW MCGILLICUDDY
CEO, Endocellutions

Companies that trust us

Ranfac offers the practicality of working with a single source through each stage of product development; from the earliest stages of product conception through regulatory approval and finished good manufacturing.

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