

Applying Design for Manufacturability (DFM) Concept to World's First Intranasal Neurostimulating Device

Case Study



Flex partnered with Allergan to produce TrueTear®, a state-of-the-art technology.

From Pilot to Clinical Build

The program originated with an engagement from Oculeve to work on the disposable portion, pilot and clinical build. As Flex developed a relationship built on trust, Oculeve awarded the durable, then commercial activities to the company. When Allergan acquired Oculeve, the strong partnership with Flex, combined with continued communication, team commitment and sense of urgency enabled a smooth transition that didn't affect the journey to market.

After receiving FDA clearance in April 2017, TrueTear® was introduced to ophthalmologists and is now being produced in Flex's Gushu, China facility.

Meeting Tight Deadlines

Flex was selected based on experience in developing products for FDA submission, and for its detailed proposal that included meeting tight deadlines. Flex's Design and Engineering facility in Dallas delivered on time for the clinical trial, which led to consideration for the durable portion of the product as well as commercial scale-up.

Allergan saw benefits in having the same supplier who could work with the necessary strong sense of urgency and team spirit. It sought a company that specializes in contract manufacturing, which can quickly scale up to mass manufacturing as product awareness and market demand takes off.

COMPANY Allergan

PRODUCT: TrueTear®

SECTOR: Consumer Medical Products

SKETCH-TO-SCALE SOLUTIONS

- Design for Reliability
- Design for Manufacturing
- New Product Introduction



Case Study

Bringing a First-of-Kind in Dry Eye to Market

TrueTear® is an innovative product requiring Flex to manage the unique hydration process essential to maintain the right moisture level. Not only was Flex's expertise in PCBA, assembly and process engineering vital, but the team had to learn how to manage a new manufacturing process.

Flex collaborated with Allergan in various ways to help them bring this first-of-kind product in dry eye to market:

- Designed for manufacturability, then matured the design for scale, developing a repeatable process.
- Worked with Allergan to design the disposable tip, which is key to delivering the electrical pulses.
- Scaled and validated and provided documentation for the FDA filing.
- Developed higher cavitation molds.
- Optimized both the process and design, including closely collaborating to create just the right hydration cycle without losing moisture.
- Designed the fluid dispenser automation.
- Designed the equipment for trays, sleeve.

Results

Ultimately, Flex demonstrated that it could take a new, innovative and complex design and bring it to success within Allergan's necessary timelines.

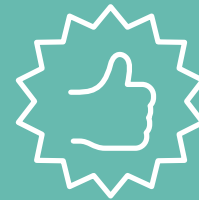
- Program sped to market approval in 18 months followed by immediate production of 60,000 units.
- Flex Gushu is now manufacturing TrueTear® and expected to produce 3 million annually for Allergan.

Flex is the Sketch-to-Scale™ solutions provider that partners with customers to innovate, design, and build intelligent products in a connected world, including the design and commercialization of more than 75 regulated medical devices. With over 200,000 employees and 2,500 engineers across 30 countries, Flex accelerates time to market and optimizes resource allocation for efficient, cost-effective solutions throughout the product life cycle. Our approach is supported by FDA-registered and ISO 13485 compliant facilities and a world-class quality system.

Copyright © 2018, Flex Ltd. All rights reserved.

© 2018 Allergan. All rights reserved.

TrueTear® and its design are trademarks of Oculeve, Inc., an Allergan affiliate. TRU115813 07/18



18
MONTHS
to FDA approval



PROJECTED
3MM
annual volume

"Flex forged a very strong working relationship with the members of our team...With great people who are willing to work together, they made the difference, and stretched to produce this innovative product."

— **Chris Stivers**, Program lead,
Manufacturing

flex®